UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **September 30, 2015**

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road, Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 847-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No _____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	X	Accelerated filer	_____
Non-accelerated filer	_____ (Do not check if a smaller reporting company)	Smaller reporting company	_____

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes _____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of October 16, 2015:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,913,776
Common Stock, $.001 par value	102,151,256

REGENERON PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In thousands, except share data)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 654,587	$ 648,719
Marketable securities	241,055	251,761
Accounts receivable - trade, net	1,088,207	739,379
Accounts receivable from Sanofi	199,117	111,510
Accounts receivable from Bayer HealthCare	151,991	125,483
Inventories	190,668	128,861
Deferred tax assets	60,521	46,179
Prepaid expenses and other current assets	89,494	79,046
Total current assets	2,675,640	2,130,938
Marketable securities	681,326	460,154
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	1,475,123	974,309
Deferred tax assets	346,243	269,237
Other assets	4,583	3,034
Total assets	$ 5,182,915	$ 3,837,672
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 577,428	$ 483,489
Deferred revenue from Sanofi, current portion	100,908	15,927
Deferred revenue - other, current portion	54,148	58,098
Other current liabilities	2,506	97,146
Total current liabilities	734,990	654,660
Deferred revenue from Sanofi	599,339	62,819
Deferred revenue - other	78,942	72,430
Facility lease obligations	364,144	310,938
Convertible senior notes	30,723	146,773
Other long-term liabilities	77,910	39,801
Total liabilities	1,886,048	1,287,421
Stockholders' equity:		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,914,776 in 2015 and 1,973,368 in 2014	2	2
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 105,572,737 in 2015 and 102,475,154 in 2014	106	102
Additional paid-in capital	2,880,109	2,450,782
Retained earnings	697,706	216,644
Accumulated other comprehensive income	7,721	52,251
Treasury stock, at cost; 3,437,000 shares in 2015 and 2,017,732 in 2014	(288,777)	(169,530)
Total stockholders' equity	3,296,867	2,550,251
Total liabilities and stockholders' equity	$ 5,182,915	$ 3,837,672

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Statements of Operations				
Revenues:				
Net product sales	$ 737,562	$ 448,844	$ 1,939,954	$ 1,229,244
Sanofi collaboration revenue	224,735	132,925	593,201	406,028
Bayer HealthCare collaboration revenue	157,596	135,853	415,679	358,460
Technology licensing and other revenue	17,529	8,166	56,817	23,496
	1,137,422	725,788	3,005,651	2,017,228
Expenses:				
Research and development	425,924	337,728	1,159,367	919,608
Selling, general, and administrative	209,993	144,003	543,572	343,960
Cost of goods sold	67,199	33,655	170,624	91,073
Cost of collaboration and contract manufacturing	41,884	21,938	111,254	54,471
	745,000	537,324	1,984,817	1,409,112
Income from operations	392,422	188,464	1,020,834	608,116
Other income (expense):				
Investment and other income	2,603	2,591	4,533	5,205
Interest expense	(1,715)	(9,232)	(10,632)	(31,022)
Loss on extinguishment of debt	(21)	—	(16,927)	(10,787)
	867	(6,641)	(23,026)	(36,604)
Income before income taxes	393,289	181,823	997,808	571,512
Income tax expense	(182,891)	(98,448)	(516,746)	(323,481)
Net income	$ 210,398	$ 83,375	$ 481,062	$ 248,031
Net income per share - basic	$ 2.04	$ 0.83	$ 4.68	$ 2.47
Net income per share - diluted	$ 1.82	$ 0.73	$ 4.18	$ 2.19
Weighted average shares outstanding - basic	103,348	100,796	102,825	100,325
Weighted average shares outstanding - diluted	115,944	117,423	115,144	113,203
Statements of Comprehensive Income				
Net income	$ 210,398	$ 83,375	$ 481,062	$ 248,031
Other comprehensive (loss) income:				
Unrealized (loss) gain on marketable securities, net of tax	(11,432)	22,632	(44,530)	28,083
Comprehensive income	$ 198,966	$ 106,007	$ 436,532	$ 276,114

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities:		
Net income	$ 481,062	$ 248,031
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	51,999	38,551
Non-cash compensation expense	300,657	208,732
Loss on extinguishment of debt	16,927	10,787
Other non-cash charges and expenses, net	33,197	28,473
Deferred taxes	(65,975)	(34,161)
Changes in assets and liabilities:		
(Increase) decrease in Sanofi, Bayer HealthCare, and trade accounts receivable	(462,943)	53,642
Increase in inventories	(81,459)	(50,917)
Increase in prepaid expenses and other assets	(13,223)	(28,850)
Increase in deferred revenue	624,063	3,466
Increase in accounts payable, accrued expenses, and other liabilities	164,652	76,506
Total adjustments	567,895	306,229
Net cash provided by operating activities	1,048,957	554,260
Cash flows from investing activities:		
Purchases of marketable securities	(550,142)	(478,436)
Sales or maturities of marketable securities	265,995	216,478
Capital expenditures	(500,154)	(215,464)
Net cash used in investing activities	(784,301)	(477,422)
Cash flows from financing activities:		
Proceeds (payments) in connection with facility and capital lease obligations	26,405	(810)
Repayments of convertible senior notes	(146,007)	(61,125)
Payments in connection with reduction of outstanding warrants	(523,487)	(143,041)
Proceeds from issuance of Common Stock	150,423	80,804
Payments in connection with Common Stock tendered for employee tax obligations	(71,673)	(175,866)
Excess tax benefit from stock-based compensation	305,551	334,146
Net cash (used in) provided by financing activities	(258,788)	34,108
Net increase in cash and cash equivalents	5,868	110,946
Cash and cash equivalents at beginning of period	648,719	535,608
Cash and cash equivalents at end of period	$ 654,587	$ 646,554

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2014 Condensed Consolidated Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

The previously issued (i) Consolidated Balance Sheet as of December 31, 2014 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and (ii) Condensed Consolidated Statement of Operations and Comprehensive Income for the three and nine months ended September 30, 2014 and Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2014 contained in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, have each been revised in this Quarterly Report on Form 10-Q to reflect a correction in the Company's accounting for certain stock option awards. See Note 4.

In addition, the previously issued Consolidated Balance Sheet as of December 31, 2014 in this Quarterly Report on Form 10-Q was previously revised to reflect a correction related to the accounting for costs incurred in connection with commercial bulk drug product manufactured by the Company, but not billed, under the Company's collaboration agreements with Sanofi and Bayer HealthCare, and the related tax impacts. The correcting adjustments resulted in a reduction to both accounts receivable and deferred revenue by $41.0 million, and reduced both income tax assets, net and additional paid-in capital by $14.2 million. The previously issued Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2014 was also revised in this Quarterly Report on Form 10-Q to reflect a $9.4 million increase in cash flows from operating activities and a corresponding reduction in cash flows from financing activities related to the tax impact of these adjustments. These adjustments had no impact on the Company's previously issued Consolidated Statements of Operations and Comprehensive Income in any reporting period. The Company determined that the error is not material to any previously-issued financial statements.

Certain reclassifications have been made to prior period amounts to conform with the current period's presentation.

2. Product Sales

EYLEA® net product sales in the United States totaled $734.4 million and $445.0 million for the three months ended September 30, 2015 and 2014, respectively, and $1,930.0 million and $1,218.8 million for the nine months ended September 30, 2015 and 2014, respectively. In addition, ARCALYST® net product sales totaled $3.2 million and $3.8 million for the three months ended September 30, 2015 and 2014, respectively, and $9.9 million and $10.4 million for the nine months ended September 30, 2015 and 2014, respectively.

The Company recorded 65% and 72% for the three months ended September 30, 2015 and 2014, respectively, and 67% and 75% for the nine months ended September 30, 2015 and 2014, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the nine months ended September 30, 2015 and 2014.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2014	$ 3,083	$ 21,166	$ 532	$ 24,781
Provision related to current period sales	41,290	88,049	6,024	135,363
Credits/payments	(38,011)	(71,007)	(6,052)	(115,070)
Balance as of September 30, 2015	$ 6,362	$ 38,208	$ 504	$ 45,074
Balance as of December 31, 2013	$ 4,400	$ 19,663	$ 538	$ 24,601
Provision related to current period sales	23,265	53,689	1,202	78,156
Credits/payments	(23,873)	(54,878)	(1,211)	(79,962)
Balance as of September 30, 2014	$ 3,792	$ 18,474	$ 529	$ 22,795

Under the provisions of the Patient Protection and Affordable Care Act ("PPACA") and the Health Care and Education Reconciliation Act of 2010, a non-tax deductible annual fee (the "Branded Prescription Drug Fee") is imposed on pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. In July 2014, the Internal Revenue Service ("IRS") issued final regulations that provide guidance on the Branded Prescription Drug Fee. The final regulations differ in some respects from the temporary regulations previously issued by the IRS in 2011, including that a company is liable for the fee based on its branded prescription drug sales in the current year, instead of the liability only being applicable upon the first qualifying branded prescription drug sale of the following fee year under the temporary regulations. As a result of the issuance of these final IRS regulations, the Company began recording an estimate of the fee in the same period in which its qualifying branded prescription drug sales occur. Therefore, in the third quarter of 2014, an incremental charge was recorded to (i) recognize a liability for the estimated fee payable based on 2014 sales through the first nine months of 2014, and (ii) expense the remaining prepaid asset recorded under the previous accounting for the estimated fee payable based on 2013 sales. The impact of the incremental charge in the third quarter of 2014 was $40.6 million, which was included in selling, general, and administrative expenses.

3. Collaboration Agreements

a. Sanofi

Sanofi collaboration revenue, as detailed below, consisted primarily of reimbursement for research and development and commercialization expenses that the Company incurred, partly offset by sharing of losses in connection with commercialization of antibodies, under the companies' Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and License and Collaboration Agreement (each as amended), collectively referred to as the "Antibody Collaboration". In addition, in July 2015, the Company and Sanofi entered into a collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration").

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three Months Ended September 30,	
Sanofi Collaboration Revenue	**2015**	**2014**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 205,114	$ 140,497
Reimbursement of Regeneron commercialization-related expenses	53,341	1,688
Regeneron's share of losses in connection with commercialization of antibodies	(74,865)	(12,830)
Other	2,561	2,561
Total Antibody	186,151	131,916
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	18,584	—
Other	20,000	—
Total Immuno-oncology	38,584	—
ZALTRAP®:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	(1,008)
Reimbursement of Regeneron research and development expenses	—	1,261
Other	—	756
Total ZALTRAP	—	1,009
	$ 224,735	$ 132,925

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

	Nine Months Ended September 30,	
Sanofi Collaboration Revenue	**2015**	**2014**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 585,450	$ 405,212
Reimbursement of Regeneron commercialization-related expenses	89,145	7,062
Regeneron's share of losses in connection with commercialization of antibodies	(143,583)	(17,125)
Other	7,683	7,683
Total Antibody	538,695	402,832
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	18,584	—
Other	20,000	—
Total Immuno-oncology	38,584	—
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	(4,912)
Reimbursement of Regeneron research and development expenses	686	3,691
Other	15,236	4,417
Total ZALTRAP	15,922	3,196
	$ 593,201	$ 406,028

Antibodies

Under the Company's November 2007 Antibody Collaboration with Sanofi, as amended, agreed upon worldwide research and development expenses incurred by both companies during the term of the agreement are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. During the three months ended September 30, 2015 and 2014, the Company recognized as additional research and development expense $25.1 million and $28.4 million, respectively, and during the nine months ended September 30, 2015 and 2014, the Company recognized as additional research and development expense $72.6 million and $81.3 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent® and sarilumab. In July 2014, in connection with the Company's Antibody Collaboration with Sanofi, the Company purchased a U.S. Food and Drug Administration ("FDA") priority review voucher from a third party for $67.5 million. The Company and Sanofi equally shared the priority review voucher's purchase price, and the Company's share of the cost, or $33.8 million, was recorded as a research and development expense during the third quarter of 2014. The Company subsequently transferred the voucher to Sanofi, which used the priority review voucher in connection with the Biologics License Application submission to the FDA for Praluent.

Effective in the second and fourth quarters of 2014, the Company and Sanofi began sharing pre-launch commercialization expenses related to Praluent and sarilumab, respectively, in accordance with the companies' License and Collaboration Agreement. In July 2015, the FDA approved Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein ("LDL") cholesterol. In the third quarter of 2015, the Company also recorded its share of the Antibody Collaboration's losses in connection with commercialization of Praluent within Sanofi collaboration revenue.

In May 2013, the Company acquired from Sanofi full exclusive rights to antibodies targeting the platelet derived growth factor (PDGF) family of receptors and ligands in ophthalmology. With respect to PDGF antibodies, the Company made two $5.0 million development milestone payments to Sanofi in the first quarter of 2014 and a $10.0 million development milestone payment to

Sanofi in the second quarter of 2015, each of which was recorded as research and development expense. The Company is also obligated to pay up to $20.0 million in additional potential development milestones as well as royalties on any future sales of PDGF antibodies.

In July 2015, in connection with the Company's new immuno-oncology collaboration with Sanofi, as described below, the Company's Antibody Discovery Agreement and License and Collaboration Agreement with Sanofi were each amended. In connection with these amendments, Sanofi's funding of the Company's antibody discovery activities under the existing Antibody Collaboration have been reduced from up to $160.0 million to up to $145.0 million in 2015, and from up to $160.0 million to up to $130.0 million in both 2016 and 2017, or an aggregate reduction of $75.0 million over this three-year period. In addition, the Company's discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and develop fully human monoclonal antibodies against these targets will be funded by Sanofi under the terms of the companies' new immuno-oncology collaboration.

Immuno-Oncology

The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement ("IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement"). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable upfront payment to the Company. Pursuant to the IO Discovery Agreement, the Company will spend up to $1,090.0 million ("IO Discovery Budget") to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse the Company for up to $825.0 million ("IO Discovery Funding") of these costs, subject to certain annual limits, which consists of (i) $750.0 million in new funding and (ii) $75.0 million of funding that would have otherwise been available to Regeneron under the existing Antibody Discovery Agreement, as described above. The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs. Pursuant to the IO Discovery Agreement, the Company will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of Investigational New Drug ("IND") Applications, and clinical development through proof-of-concept. The Company will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from Regeneron's share of future profits, if any, from commercialized products to the extent they are sufficient for this purpose. However, the Company is not required to apply more than 10% of its share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, the Company will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable upfront payment to the Company. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with the Company through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between the Company and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and the Company will reimburse half of the total development costs for all such candidates from its share of future profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, Sanofi and the Company will share equally, on an ongoing basis, the development costs for the drug candidates for which the Company is the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products. Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop the Company's antibody product candidate targeting the receptor known as Programmed Cell Death protein 1, or PD-1 ("REGN2810"). The parties will

share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. The Company will have principal control over the development of REGN2810 and will lead commercialization activities in the United States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. The Company will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

With respect to each product candidate that enters development under the IO License and Collaboration Agreement, Sanofi or the Company may, by giving twelve months' notice, opt-out of further development and/or commercialization of the product, in which event the other party will retain exclusive rights to continue the development and/or commercialization of such product.

At the inception of the IO Collaboration, the Company's significant deliverables consisted of (i) license to certain rights and intellectual property, (ii) providing research and development services, and (iii) manufacturing clinical supplies. The Company concluded that the license did not have standalone value, primarily due to the fact that such rights were not sold separately by the Company, nor could Sanofi receive any benefit from the license without the fulfillment of other ongoing obligations by the Company, including the clinical supply arrangement. Therefore, the deliverables were considered a single unit of accounting. Consequently, the $640.0 million in aggregate upfront payments was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

ZALTRAP

In September 2003, the Company entered into a collaboration agreement ("ZALTRAP Collaboration Agreement") with Aventis Pharmaceuticals Inc. (predecessor to Sanofi U.S.) to jointly develop and commercialize ZALTRAP. Under the terms of the ZALTRAP Collaboration Agreement, as amended, Regeneron and Sanofi shared co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan, and the Company was entitled to receive a percentage of sales of ZALTRAP in Japan. Sanofi commenced sales of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with 5-fluorouracil, leucovorin, irinotecan ("FOLFIRI"), for patients with metastatic colorectal cancer ("mCRC") that is resistant to or has progressed following an oxaliplatin-containing regimen, in the United States in the third quarter of 2012 and in certain European and other countries in the first quarter of 2013.

In February 2015, the Company and Sanofi entered into an amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"), with an effective date of July 1, 2014. Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. The Company will also be paid for all quantities of ZALTRAP manufactured by it, pursuant to a supply agreement, through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities, or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement. Unless terminated earlier in accordance with its provisions, the Amended ZALTRAP Agreement will continue to be in effect until such time as neither Sanofi nor its affiliates or sublicensees is developing or commercializing ZALTRAP.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015, the Company recognized $14.9 million of collaboration revenue, which was previously recorded as deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since the risk of inventory loss no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as the Company had no further performance obligations. In addition, during the three and nine months ended September 30, 2015, the Company recorded $9.0 million and $32.0 million, respectively, in technology licensing and other revenue, primarily related to (i) revenues earned from Sanofi based on a percentage of net sales of ZALTRAP and (ii) revenues earned from Sanofi for manufacturing ZALTRAP commercial supplies.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

b. Bayer HealthCare

The Company and Bayer HealthCare globally collaborate on the development and commercialization of EYLEA outside of the United States. In addition, in January 2014, the Company entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta).

The collaboration revenue the Company earned from Bayer HealthCare is detailed below:

	Three Months Ended September 30,	
Bayer HealthCare Collaboration Revenue	**2015**	**2014**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 130,510	$ 85,351
Sales milestones	—	30,000
Cost-sharing of Regeneron EYLEA development expenses	1,827	4,394
Other	21,155	12,745
Total EYLEA	153,492	132,490
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	1,508	518
Other	2,596	2,845
Total PDGFR-beta	4,104	3,363
	$ 157,596	$ 135,853

	Nine Months Ended September 30,	
Bayer HealthCare Collaboration Revenue	**2015**	**2014**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 326,567	$ 213,291
Sales milestones	15,000	75,000
Cost-sharing of Regeneron EYLEA development expenses	6,948	26,235
Other	50,685	34,490
Total EYLEA	399,200	349,016
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	8,688	1,657
Other	7,791	7,787
Total PDGFR-beta	16,479	9,444
	$ 415,679	$ 358,460

EYLEA outside the United States

In the first quarter of 2015, the Company earned a $15.0 million sales milestone from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period. During the nine months ended September 30, 2014, the Company earned five $15.0 million sales milestones (two of which were recorded in the third quarter of 2014) from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million, $600 million, $700 million, $800 million, and $900 million, respectively, over a twelve-month period.

In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following branch retinal vein occlusion ("BRVO"). In connection with this decision, Bayer HealthCare reimbursed Regeneron $15.7 million for a defined share of the EYLEA global development costs that the Company had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014 and is included with "Cost-sharing of Regeneron EYLEA development expenses" in the table above. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO are also shared (for countries other than Japan). The Company is entitled to receive a tiered percentage of EYLEA net sales in Japan.

PDGFR-beta antibody outside the United States

In January 2014, the Company entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to the Company in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. The $25.5 million upfront payment was initially recorded as deferred revenue, and will be recognized as revenue over the related performance period. Bayer HealthCare is also obligated to reimburse the Company for 50% of development milestone payments to Sanofi related to the Company's acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to the Company in the first quarter of 2014 (both of which, for the purpose of revenue recognition, were not considered substantive) and a $5.0 million development milestone payment to the Company in the second quarter of 2015 (which was recognized as a substantive milestone).

c. Mitsubishi Tanabe Pharma

In September 2015, the Company and Mitsubishi Tanabe Pharma Corporation ("MTPC") entered into a collaboration agreement (the "MTPC Collaboration Agreement") providing MTPC with development and commercial rights to fasinumab, the Company's nerve growth factor antibody in late-stage clinical development, in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the "MTPC Territories"). In connection with the MTPC Collaboration Agreement, MTPC made a $10.0 million non-refundable upfront payment, and the Company is entitled to receive up to an aggregate of $65.0 million in development milestones achieved by the Company and $150.0 million in other contingent payments, primarily related to development milestones achieved by MTPC.

Under the MTPC Collaboration Agreement, the Company is obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, the Company will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and is eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million. Unless terminated earlier in accordance with its provisions, the MTPC Collaboration Agreement will continue to be in effect until such time as MTPC has ceased developing or commercializing fasinumab in the MTPC Territories.

At the inception of the MTPC Collaboration Agreement, the Company's significant deliverables consisted of (i) exclusive rights to develop and commercialize fasinumab in the MTPC Territories, and (ii) manufacturing clinical and commercial supplies. The Company concluded that the license did not have standalone value, as such right was not sold separately by the Company, nor could MTPC receive any benefit from the license without the manufacturing services to be rendered by the Company. Therefore, the deliverables were considered a single unit of accounting. Consequently, the $10.0 million upfront payment was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

(Unless otherwise noted, dollars in thousands, except per share data)

4. Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's applicable Long-Term Incentive Plan based on the grant-date fair value of those awards. The Company recognized stock-based compensation expense of $102.6 million and $68.1 million for the three months ended September 30, 2015 and 2014, respectively, and $300.7 million and $208.7 million for the nine months ended September 30, 2015 and 2014, respectively.

Revisions of Previously-Issued Financial Statements

During the first quarter of 2015, the Company determined that for certain stock option awards granted to an employee in prior periods, the incorrect requisite service period was utilized in determining the period over which the related compensation expense should have been recorded. Such awards were made as part of the Company's annual employee option grants in December of each applicable year. As a result, compensation expense for the three months and years ended December 31, 2014 and 2013 was understated, and compensation expense for the three months ended March 31, 2014 and 2013, June 30, 2014 and 2013, and September 30, 2014 and 2013 was overstated. These revisions consisted entirely of non-cash adjustments, and therefore had no impact on the Company's previously reported total cash flows from operating activities and total cash flows in its Statements of Cash Flows. The Company evaluated the impact of these items on prior periods, assessing materiality quantitatively and qualitatively, and concluded that the errors were not considered to be material to any previously-issued quarterly or annual financial statements. However, the Company concluded that it would revise the applicable prior period amounts in this filing to reflect the impact of these corrections because the cumulative amount of such corrections is expected to be material to the year ending December 31, 2015. The Company's prior-period financial statements will reflect these revisions for the applicable periods presented in future filings.

The table below presents the impact of these revisions, including the related tax effect, on the Company's previously-filed financial statements.

	December 31, 2014		
	As Previously Reported	Adjustments	As Revised
Balance Sheet Data:			
Deferred tax assets (noncurrent)	$ 266,869	$ 22,152	$ 289,021
Total assets	3,871,827	22,152	3,893,979
Additional paid-in capital	2,404,118	60,890	2,465,008
Retained earnings	255,382	(38,738)	216,644
Total stockholders' equity	2,542,325	22,152	2,564,477
Total liabilities and stockholders' equity	3,871,827	22,152	3,893,979

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three Months Ended September 30, 2014			Nine Months Ended September 30, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Consolidated Statement of Operations Data:						
Selling, general, and administrative	$ 149,748	$ (5,745)	$ 144,003	$ 361,012	$ (17,052)	$ 343,960
Total operating expenses	543,069	(5,745)	537,324	1,426,164	(17,052)	1,409,112
Income from operations	182,719	5,745	188,464	591,064	17,052	608,116
Income before income taxes	176,078	5,745	181,823	554,460	17,052	571,512
Income tax expense	96,358	2,090	98,448	316,562	6,919	323,481
Net income	79,720	3,655	83,375	237,898	10,133	248,031
Net income per share - basic	$ 0.79	$ 0.04	$ 0.83	$ 2.37	$ 0.10	$ 2.47
Net income per share - diluted	$ 0.70	$ 0.03	$ 0.73	$ 2.10	$ 0.09	$ 2.19

	Nine Months Ended September 30, 2014		
	As Previously Reported	Adjustments	As Revised
Consolidated Statement of Cash Flows Data:			
Cash flows from operating activities			
Net income	$ 237,898	$ 10,133	$ 248,031
Non-cash compensation expense	225,784	(17,052)	208,732
Deferred taxes	(50,466)	6,919	(43,547)

The table below presents the impact of these revisions, including the related tax effects, on previously filed year-end Consolidated Statements of Operations for the three months and year ended December 31, 2014.

	Three Months Ended December 31, 2014			Year Ended December 31, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Consolidated Statement of Operations Data:						
Selling, general, and administrative	$ 143,743	$ 31,564	$ 175,307	$ 504,755	$ 14,512	$ 519,267
Total operating expenses	554,962	31,564	586,526	1,981,126	14,512	1,995,638
Income from operations	247,367	(31,564)	215,803	838,431	(14,512)	823,919
Income before income taxes	221,287	(31,564)	189,723	775,747	(14,512)	761,235
Income tax expense	111,111	(11,483)	99,628	427,673	(4,564)	423,109
Net income	110,176	(20,081)	90,095	348,074	(9,948)	338,126
Net income per share - basic	$ 1.09	$ (0.20)	$ 0.89	$ 3.46	$ (0.10)	$ 3.36
Net income per share - diluted	$ 0.96	$ (0.18)	$ 0.78	$ 3.07	$ (0.09)	$ 2.98

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

5. Net Income Per Share

The Company's basic net income per share amounts have been computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. The calculations of basic and diluted net income per share are as follows:

	Three Months Ended September 30,	
	2015	**2014**
Net income - basic	$ 210,398	$ 83,375
Effective of dilutive securities:		
Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs	145	2,803
Net income - diluted	$ 210,543	$ 86,178
(Shares in thousands)		
Weighted average shares - basic	103,348	100,796
Effect of dilutive securities:		
Stock options	9,632	9,377
Restricted stock	481	430
Convertible senior notes	308	4,033
Warrants	2,175	2,787
Dilutive potential shares	12,596	16,627
Weighted average shares - diluted	115,944	117,423
Net income per share - basic	$ 2.04	$ 0.83
Net income per share - diluted	$ 1.82	$ 0.73

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

	Nine Months Ended September 30,	
	2015	**2014**
Net income - basic and diluted	$ 481,062	$ 248,031
(Shares in thousands)		
Weighted average shares - basic	102,825	100,325
Effect of dilutive securities:		
Stock options	9,449	9,515
Restricted stock	475	413
Warrants	2,395	2,950
Dilutive potential shares	12,319	12,878
Weighted average shares - diluted	115,144	113,203
Net income per share - basic	$ 4.68	$ 2.47
Net income per share - diluted	$ 4.18	$ 2.19

Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive include the following:

	Three Months Ended September 30,	
(Shares in thousands)	**2015**	**2014**
Stock options	594	1,277

	Nine Months Ended September 30,	
(Shares in thousands)	**2015**	**2014**
Stock options	3,388	3,741
Convertible senior notes	1,253	4,483

(Unless otherwise noted, dollars in thousands, except per share data)

6. Marketable Securities

Marketable securities as of September 30, 2015 and December 31, 2014 consist of both debt securities issued by investment grade institutions as well as equity securities. The Company also held restricted marketable securities as of December 31, 2014, consisting of the Company's investment in Avalanche Biotechnologies, Inc. common shares, which were subject to customary transfer restrictions until January 2015 under a lock-up agreement with the underwriters of Avalanche's initial public offering.

The following tables summarize the Company's investments in marketable securities:

	Amortized	Unrealized		Fair
As of September 30, 2015	**Cost Basis**	**Gains**	**Losses**	**Value**
Unrestricted				
Corporate bonds	$ 812,137	$ 805	$ (988)	$ 811,954
U.S. government and government agency obligations	54,963	155	(3)	55,115
Municipal bonds	27,741	27	(3)	27,765
Equity securities	17,005	10,635	(93)	27,547
	$ 911,846	$ 11,622	$ (1,087)	$ 922,381
As of December 31, 2014				
Unrestricted				
Corporate bonds	$ 548,832	$ 136	$ (1,462)	$ 547,506
U.S. government and government agency obligations	28,596	3	(46)	28,553
Municipal bonds	37,044	37	(43)	37,038
Equity securities	2,005	5,374	—	7,379
	616,477	5,550	(1,551)	620,476
Restricted				
Equity securities	15,000	76,439	—	91,439
	$ 631,477	$ 81,989	$ (1,551)	$ 711,915

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of September 30, 2015 mature at various dates through August 2020. The fair values of debt security investments by contractual maturity consist of the following:

	September 30, 2015	December 31, 2014
Maturities within one year	$ 241,055	$ 251,761
Maturities after one year through five years	653,779	360,208
Maturities after five years through ten years	—	1,128
	$ 894,834	$ 613,097

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position.

	Less than 12 Months		12 Months or Greater		Total	
As of September 30, 2015	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 373,513	$ (960)	$ 27,779	$ (28)	$ 401,292	$ (988)
U.S. government and government agency obligations	2,809	(2)	2,504	(1)	5,313	(3)
Municipal bonds	4,658	(3)	—	—	4,658	(3)
Equity securities	14,907	(93)	—	—	14,907	(93)
	$ 395,887	$ (1,058)	$ 30,283	$ (29)	$ 426,170	$ (1,087)
As of December 31, 2014						
Corporate bonds	$ 390,613	$ (1,462)	—	—	$ 390,613	$ (1,462)
U.S. government and government agency obligations	25,549	(46)	—	—	25,549	(46)
Municipal bonds	10,779	(43)	—	—	10,779	(43)
	$ 426,941	$ (1,551)	—	—	$ 426,941	$ (1,551)

For the three and nine months ended September 30, 2015 and 2014, total realized gains and losses on sales of marketable securities were not material.

Changes in the Company's accumulated other comprehensive income (loss) for the three and nine months ended September 30, 2015 and 2014 related to unrealized gains and losses on available-for-sale marketable securities. For the three and nine months ended September 30, 2015 and 2014, amounts reclassified from accumulated other comprehensive income (loss) into investment income in the Company's Statements of Operations were related to realized gains and losses on sales of marketable securities.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(Unless otherwise noted, dollars in thousands, except per share data)

7. Fair Value Measurements

The Company's assets that are measured at fair value on a recurring basis consist of the following:

		Fair Value Measurements at Reporting Date Using	
As of September 30, 2015	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$ 811,954	—	$ 811,954
U.S. government and government agency obligations	55,115	—	55,115
Municipal bonds	27,765	—	27,765
Equity securities	27,547	$ 27,547	—
	$ 922,381	$ 27,547	$ 894,834
As of December 31, 2014			
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$ 547,506	—	$ 547,506
U.S. government and government agency obligations	28,553	—	28,553
Municipal bonds	37,038	—	37,038
Equity securities	7,379	$ 7,379	—
	620,476	7,379	613,097
Restricted			
Equity securities	91,439	—	91,439
	$ 711,915	$ 7,379	$ 704,536

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three and nine months ended September 30, 2015 and 2014.

There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and nine months ended September 30, 2015 and 2014. During the nine months ended September 30, 2015, transfers of marketable securities from Level 2 to Level 1 were $91.4 million in connection with the lapse of the transfer restrictions on the Company's investment in Avalanche common shares in January 2015. The Company's policy for recognition of transfers between levels of the fair value hierarchy is to recognize any transfer at the beginning of the fiscal quarter in which the determination to transfer was made. There were no other transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2015, and there were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2014.

(Unless otherwise noted, dollars in thousands, except per share data)

As of September 30, 2015 and December 31, 2014, the Company had $33.1 million and $169.4 million, respectively, in aggregate principal amount of 1.875% convertible senior notes (the "Notes") that will mature on October 1, 2016 unless earlier converted or repurchased. As described in Note 10, an additional portion of the Notes was surrendered for conversion during the first nine months of 2015. The fair value of the outstanding Notes was estimated to be $175.2 million and $819.8 million as of September 30, 2015 and December 31, 2014, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

Additionally, as described in Note 10, pursuant to a November 2014 amendment agreement with a warrant holder, a portion of the Company's warrants were classified as a liability and measured at fair value as of December 31, 2014. The fair value of this liability was estimated to be $87.5 million as of December 31, 2014, and was determined based on Level 2 inputs, such as market and observable sources. During the first quarter of 2015, upon expiration of the November 2014 amendment agreement, the remaining warrants were re-measured at fair value and reclassified back to additional paid-in capital.

8. Inventories

Inventories consist of the following:

	September 30, 2015	December 31, 2014
Raw materials	$ 34,983	$ 10,923
Work-in-process	110,616	73,519
Finished goods	12,513	10,768
Deferred costs	32,556	33,651
	$ 190,668	$ 128,861

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. For the three months ended September 30, 2015 and 2014, cost of goods sold included inventory write-downs and reserves totaling $1.8 million and $1.6 million, respectively. For the nine months ended September 30, 2015 and 2014, cost of goods sold included inventory write-downs and reserves totaling $9.9 million and $3.5 million, respectively.

9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2015	December 31, 2014
Accounts payable	$ 106,917	$ 99,508
Accrued payroll and related costs	120,933	92,778
Accrued clinical trial expense	62,569	41,555
Accrued sales-related charges, deductions, and royalties	160,941	133,085
Other accrued expenses and liabilities	126,068	116,563
	$ 577,428	$ 483,489

10. Debt

a. Convertible Debt

In the first nine months of 2015, the Company settled conversion obligations for $146.0 million principal amount of the Company's Notes that was previously surrendered for conversion. In accordance with the terms of the Notes, the Company elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted Notes, and shares of the Company's Common Stock in respect of any amounts due in excess thereof. Consequently, in the first nine months of 2015, the Company paid $146.0 million in cash and issued 1,419,287 shares of Common Stock. In addition, in the first nine months of 2015, the Company allocated $705.9 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholders' equity, and recognized a $16.9 million loss on the debt extinguishment. As of September 30, 2015, an aggregate principal amount of $33.1 million of the original $400.0 million aggregate principal amount of Notes remained outstanding.

In connection with the initial offering of the Notes in October 2011, the Company entered into convertible note hedge and warrant transactions with multiple counterparties, which were recorded to additional paid-in capital. As a result of the Note conversions described above, in the first nine months of 2015, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 1,419,268 shares of Common Stock, which was approximately equal to the number of shares the Company was required to issue to settle the non-cash portion of the related Note conversions. The Company recorded the cost of the shares received, or $119.2 million, as Treasury Stock during the first nine months of 2015.

In addition to the Note conversions described above, the Company received notifications in the third and fourth quarters of 2015 that an additional $20.5 million aggregate principal amount of the Notes were surrendered for conversion, and settlement is anticipated during the fourth quarter of 2015. The Company has elected to settle the related conversion obligations through a combination of cash and shares (total payment will be based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the Notes). In connection with these Note conversions, the Company exercised a proportionate amount of its convertible note hedges, for which the Company expects to receive shares of Common Stock equivalent to the number of shares the Company will be required to issue to settle the non-cash portion of the related Note conversions.

In the first nine months of 2014, the Company settled conversion obligations for $61.1 million principal amount of the Notes surrendered for conversion. Upon settlement of the Notes, which occurred during the second quarter of 2014, the Company paid $61.1 million in cash and issued 521,876 shares of Common Stock. In addition, during the second quarter of 2014, the Company allocated $156.7 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholders' equity, and recognized a $10.8 million loss on the debt extinguishment. In connection with the Note conversions in the first nine months of 2014, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 521,876 shares of Common Stock, which was equivalent to the number of shares the Company was required to issue to settle the non-cash portion of the related Note conversions. The Company recorded the cost of the shares received, or $43.8 million, as Treasury Stock during the first nine months of 2014.

In November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 493,229. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder had closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $397.75 per share, during the period starting on November 26, 2014 and ending no later than February 12, 2015. The Company was obligated to settle any payments due under the amendment agreement in February 2015. Given that the amendment agreement contained a conditional obligation that required settlement in cash, and the Company's obligation was indexed to the Company's share price, the Company reclassified the estimated fair value of the 493,229 warrants from additional paid-in capital to a liability in November 2014, with such liability subsequently measured at fair value with changes in fair value recognized in earnings. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2014, the Company recorded a $59.8 million accrued liability as of December 31, 2014 in connection with the warrant holder reducing the number of warrants it held. During the first quarter of 2015, the warrant holder closed out additional portions of its hedge position, and, as a result, in February 2015 the Company paid a total of $124.0 million to reduce the number of warrants held by such warrant holder by 416,480. Upon expiration of the November 2014 amended agreement, in the first quarter of 2015, the remaining warrants were re-measured at fair value, and $23.3 million was reclassified back to additional paid-in capital, consistent with the original classification of the warrants

under the 2011 issuance. Total losses related to changes in fair value of the warrants during the first quarter of 2015 were not material.

In addition to the warrant transaction described above, during the first nine months of 2015, the Company entered into agreements to reduce the number of warrants held by warrant holders. Pursuant to the agreements, the Company paid an aggregate amount of $399.5 million to the warrant holders during 2015 to reduce the number of shares of Common Stock issuable upon exercise of the warrant by 898,547 in the aggregate. As of September 30, 2015, an aggregate of 2,225,068 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

During the first nine months of 2014, the Company also entered into agreements to reduce the number of warrants held by warrant holders. Pursuant to the agreements, the Company paid an aggregate amount of $143.0 million to the warrant holders during 2014 to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants by 727,516 in the aggregate.

b. Credit Facility

In March 2015, the Company entered into an agreement with a syndicate of lenders (the "Credit Agreement") which provides for a $750.0 million senior unsecured five-year revolving credit facility (the "Credit Facility"). The Credit Agreement includes an option for the Company to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for the Company to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty.

Any loans under the Credit Facility have a variable interest rate based on either the London Interbank Offered Rate ("LIBOR") or an alternate base rate, plus an applicable margin that varies with the Company's debt rating and total leverage ratio. The Company had no borrowings outstanding under the Credit Facility as of September 30, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. The Company was in compliance with all covenants of the Credit Facility as of September 30, 2015.

11. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded an income tax provision in its Statement of Operations of $182.9 million and $98.4 million for the three months ended September 30, 2015 and 2014, respectively, and $516.7 million and $323.5 million for the nine months ended September 30, 2015 and 2014, respectively. The Company's effective tax rate was 46.5% and 54.1% for the three months ended September 30, 2015 and 2014, respectively, and 51.8% and 56.6% for the nine months ended September 30, 2015 and 2014, respectively. The Company's effective tax rate for the three and nine months ended September 30, 2015 was negatively impacted, compared to the U.S. federal statutory rate, by (i) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, (ii) the non-deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

The Company's effective tax rate for the three and nine months ended September 30, 2014 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, the incremental charge related to the non-tax deductible Branded Prescription Drug Fee (see Note 2), and expiration at the end of 2013 of the federal tax credit for increased research activities. In addition, the Company's effective tax rate for the nine months ended September 30, 2014 was negatively impacted by New York State tax legislation enacted in the first quarter of 2014. This tax legislation reduced the New York State income tax rate to zero percent for "qualified manufacturers," including Regeneron, effective in 2014; however, it also resulted in the Company reducing its related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in the Company's effective tax rate by 2.2% for the nine months ended September 30, 2014.

The Company also recorded an income tax benefit in its Statement of Comprehensive Income of $6.5 million and $25.4 million for the three and nine months ended September 30, 2015, respectively, in connection with unrealized losses on available-for-sale marketable securities. The Company recorded an income tax provision in its Statement of Comprehensive Income of $13.5 million and $14.9 million for the three and nine months ended September 30, 2014, respectively, in connection with the Company's unrealized gains on available-for-sale marketable securities.

12. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable and accrued expenses as of September 30, 2015 and December 31, 2014 were $84.7 million and $56.2 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses as of September 30, 2014 and December 31, 2013 were $38.6 million and $16.1 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses as of September 30, 2015 and December 31, 2014 was $0.3 million and $7.5 million, respectively, for the Company's conversion settlement obligation related to the Company's Notes which were surrendered for conversion but not settled as of the end of the respective period. No such amounts were payable as of September 30, 2014 and December 31, 2013.

Included in accounts payable and accrued expenses as of December 31, 2014 was $59.8 million related to the Company's payment obligation for a reduction in the number of warrants based on a warrant holder closing out a portion of its hedge position. Additionally, included within other current liabilities as of December 31, 2014 was $87.5 million in connection with the estimated fair value of the remaining warrant liability. See Note 10. There were no such liabilities recorded in connection with warrants as of September 30, 2015, September 30, 2014, and December 31, 2013.

The Company recognized a facility lease obligation of $27.0 million and $92.6 million during the nine months ended September 30, 2015 and 2014, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

13. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

Proceedings Relating to '287 Patent and '018 Patent

The Company is a party to patent infringement litigation involving its European Patent No. 1,360,287 and, with respect to certain defendants, also European Patent No. 2,264,163 (collectively, as applicable, the "'287 Patent"), as well as its U.S. Patent No. 8,502,018 (the "'018 Patent"). Each of these patents concerns genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (the "'287 Patent Infringement Litigation" and "'018 Patent Infringement Litigation," respectively), the Company claims infringement of several claims of the '287 Patent and the '018 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent and the '018 Patent (as applicable). At this time, the Company is not able to predict the outcome of, or an estimate of gain, if any, related to, these proceedings.

Proceedings Relating to Praluent (alirocumab) Injection

On October 17, 2014 and October 28, 2014, Amgen Inc. filed complaints against Regeneron, Sanofi, Aventisub LLC (subsequently removed and replaced with Sanofi-Aventis U.S. LLC), and Aventis Pharmaceuticals, Inc. in the United States District Court for the District of Delaware seeking an injunction to prohibit Regeneron and the other defendants from manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) Praluent, which Regeneron is jointly developing with Sanofi. On November 11, 2014 and November 17, 2014 Amgen filed complaints against Regeneron, Sanofi, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc. in the same court seeking the same relief. Amgen asserts U.S. Patent Nos. 8,563,698, 8,829,165, and 8,859,741 in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 in the second complaint, U.S. Patent No. 8,883,983 in the third complaint, and U.S. Patent No. 8,889,834 in the fourth complaint. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. On December 15, 2014, all of the four proceedings were consolidated into a single case. On September 15, 2015, Amgen filed a motion for leave to file a supplemental and second amended complaint. The complaint alleges, among other things, willful infringement of the asserted patents, which would entitle Amgen to treble damages if the court finds willful infringement. The Company and Sanofi have opposed the motion, and the parties are awaiting the court's decision on the motion. The trial is currently set to begin on March 7, 2016, and a permanent injunction hearing (which would be held if the court finds infringement by the Company and Sanofi) is currently scheduled to begin on March 23, 2016. This matter has not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to estimate a range of possible loss, if any.

Proceedings Relating to Patents Owned by Genentech and City of Hope

On July 27, 2015, the Company and Sanofi-Aventis U.S. LLC filed a complaint in the United States District Court for the Central District of California (Los Angeles division) seeking a declaratory judgment of invalidity, as well as non-infringement by the manufacture, use, sale, offer of sale, or importation of Praluent (alirocumab), of U.S. Patent No. 7,923,221 (the "'221 Patent") jointly owned by Genentech, Inc. ("Genentech") and City of Hope relating to the production of recombinant antibodies in host cells. On the same day, the Company and Sanofi-Aventis U.S. LLC initiated an inter partes review in the United States Patent and Trademark Office seeking a declaration of invalidity of U.S. Patent No. 6,331,415 jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by the Company and Sanofi and counterclaimed, alleging that the Company and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016. At this time, the Company is not able to predict the outcome of these proceedings.

14. Recently Issued Accounting Standards

In May 2014, the FASB issued a new standard related to revenue recognition, *Revenue from Contracts with Customers*, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. In July 2015, the FASB decided to delay the effective date of the new standard by one year; as a result, the new standard will be effective for annual and interim reporting periods beginning after December 15, 2017. Early adoption will be permitted, but no earlier than 2017 for calendar year-end entities. The standard allows for two transition methods - retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. The Company has not yet determined its method of transition and is evaluating the impact that this guidance will have on the Company's financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned, including without limitation sarilumab, dupilumab, fasinumab, and REGN2222; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA® (aflibercept) Injection and Praluent), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our sales or other financial projections or guidance, including without limitation capital expenditures and income tax obligations, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

Overview

Regeneron Pharmaceuticals, Inc. is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. We commercialize medicines for eye diseases, high low-density lipoprotein (LDL) cholesterol, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis (RA), asthma, atopic dermatitis, pain, and infectious diseases.

Our total revenues were $1,137.4 million in the third quarter and $3,005.7 million in the first nine months of 2015, compared to $725.8 million in the third quarter and $2,017.2 million in the first nine months of 2014. Our net income was $210.4 million, or $1.82 per diluted share, in the third quarter and $481.1 million, or $4.18 per diluted share, in first nine months of 2015, compared to net income of $83.4 million, or $0.73 per diluted share, in the third quarter and $248.0 million, or $2.19 per diluted share, in the first nine months of 2014. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have three marketed products:

- **EYLEA (aflibercept) Injection**, known in the scientific literature as VEGF Trap-Eye, is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD), diabetic macular edema (DME), macular edema following central retinal vein occlusion (CRVO), and macular edema following retinal vein occlusion (RVO), which includes macular edema following branch retinal vein occlusion (BRVO). EYLEA is also available in Japan and the EU for the treatment of myopic choroidal neovascularization (mCNV) and in the United States for the treatment of diabetic retinopathy in patients with DME. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO and BRVO, DME, and mCNV pending in other countries. We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States.

- **Praluent (alirocumab) Injection**, which is available in the United States for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol. In September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (heterozygous familial hypercholesterolemia (HeFH) and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent.

- **ARCALYST® (rilonacept) Injection for Subcutaneous Use**, which is available in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children 12 years and older.

In the first quarter of 2015, we and Sanofi entered into an amended and restated ZALTRAP® agreement (Amended ZALTRAP Agreement). Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays us a percentage of aggregate net sales of ZALTRAP during each calendar year of between 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. Refer to "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP" below for further details of the Amended ZALTRAP Agreement. ZALTRAP is currently available in the United States, EU, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

We have 14 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 13 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our *VelocImmune®* technology.

Trap-based Clinical Programs

EYLEA

In Phase 3 clinical development for the treatment of Neovascular Glaucoma (NVG) (in Japan) in collaboration with Bayer HealthCare. As described below, aflibercept is also being studied in combination with (i) an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), and (ii) an antibody to angiopoietin-2 (Ang2).

Antibody-based Clinical Programs in Collaboration with Sanofi

Praluent

Antibody to PCSK9. In Phase 3 clinical development for LDL cholesterol reduction and for the prevention of cardiovascular events. In the third quarter of 2015, the U.S. Food and Drug Administration (FDA) approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In the third quarter of 2015, the European Commission granted marketing authorization for Praluent for the treatment of LDL cholesterol in certain adult patients with hypercholesterolemia. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

Sarilumab (REGN88)

Antibody to the interleukin-6 receptor (IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).

Dupilumab (REGN668)

Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis in adults (Phase 3), atopic dermatitis in children (Phase 2), asthma (Phase 3), nasal polyps in patients who also have chronic sinusitis (NPwCS) (Phase 2), and eosinophilic esophagitis (EoE) (Phase 2).

REGN2222

Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. Phase 3 clinical study in RSV initiated in the second quarter of 2015. In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015, and will be entitled to receive royalties on any future sales of the product candidate.

REGN2810

Antibody to programmed cell death protein 1 (PD-1). Phase 1 clinical study in advanced malignancies initiated in the first quarter of 2015.

Antibody-based Clinical Program in Collaboration with Bayer HealthCare

REGN2176-3

Combination product comprised of an antibody to PDGFR-beta co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 2 clinical study for the treatment of wet AMD initiated in the second quarter of 2015.

Antibody-based Clinical Program in Collaboration with Mitsubishi Tanabe Pharma

Fasinumab (REGN475)*

Antibody to Nerve Growth Factor (NGF). Phase 2b/3 study in pain due to osteoarthritis initiated in the second quarter of 2015; currently on partial clinical hold by the FDA limiting duration of trials in osteoarthritis to 16 weeks.

Antibody-based Clinical Programs Developing Independently

Evinacumab (REGN1500)*

Antibody to Angptl-3. Phase 2 clinical study for the treatment of dyslipidemia in homozygous familial hypercholesterolemia initiated in the first quarter of 2015. Partial clinical hold that excluded women of childbearing potential was lifted by the FDA in the third quarter of 2015.

REGN1033*

Antibody to myostatin (GDF8). In Phase 2 clinical development in skeletal muscle disorders. In the second quarter of 2015, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN1033.

REGN1908-1909*

Antibody to Feld1 in Phase 1/Phase 2 clinical development against allergic disease.

REGN1193*

Antibody to glucagon receptor (GCGR). In Phase 1 clinical development.

REGN1979

Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia.

REGN910-3**

Combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology. In Phase 1 clinical development for the treatment of wet AMD and DME.

* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on future sales of the product candidate.

** We acquired from Sanofi full exclusive rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, which were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive a potential development milestone and royalties on any future sales of the product candidate.

REGN1400, an antibody to ErbB3, and REGN1154, an antibody against an undisclosed target, both of which were previously in Phase 1 studies, are no longer in clinical development.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to combine that foundation with our clinical development, manufacturing, and commercial capabilities. We are executing our long-term objective to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*® technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

In 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC performs sequencing and genotyping to generate de-identified genomic data. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC is undertaking both large population-based efforts as well as family- and founder-based approaches. RGC leverages laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 70,000 unique samples per year.

Marketed Products

EYLEA (aflibercept) Injection

We commenced sales of EYLEA in the United States for the treatment of wet AMD in the fourth quarter of 2011, macular edema following CRVO in the third quarter of 2012, DME in the third quarter of 2014, and macular edema following RVO in the fourth quarter of 2014. In addition, in March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME. Outside the United States, Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012, macular edema secondary to CRVO in the fourth quarter of 2013, visual impairment due to DME in the third quarter of 2014, and mCNV in Japan in the fourth quarter of 2014. In February and June 2015, the European Commission and the Japanese Ministry of Health, Labour and Welfare (MHLW), respectively, approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. In October 2015, the European Commission granted marketing authorization for EYLEA for the treatment of visual impairment due to mCNV. In the fourth quarter of 2014, Bayer HealthCare submitted a regulatory application in China for EYLEA for the treatment of wet AMD. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO and BRVO, DME, and mCNV pending in other countries.

We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Bayer HealthCare markets, and records revenue from sales of EYLEA outside the United States, where, for countries other than Japan, the companies share equally the profits and losses from sales of EYLEA. In Japan, we are entitled to receive a percentage of the sales of EYLEA. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from such sales.

Net product sales of EYLEA in the United States were $734.4 million in the third quarter and $1,930.0 million in the first nine months of 2015, compared to $445.0 million in the third quarter and $1,218.8 million in the first nine months of 2014. Bayer HealthCare records revenue from sales of EYLEA outside the United States, which were $371.1 million in the third quarter and $1,000.7 million in the first nine months of 2015, compared to $277.0 million in the third quarter and $741.9 million in the first nine months of 2014.

Praluent (alirocumab) Injection

In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In addition, in September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent. Under our collaboration agreement, Sanofi will record product sales and cost of sales for commercialized products, and Regeneron has the right to co-promote such products. We have exercised our option to co-promote Praluent in the United States. We and Sanofi will equally share profits and losses from sales within the United States.

Net product sales of Praluent in the United States were $4.0 million the third quarter of 2015.

ARCALYST (rilonacept) Injection for Subcutaneous Use

ARCALYST is available in the United States for the treatment of CAPS in adults and children 12 years and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. Net product sales of ARCALYST were $3.2 million in the third quarter and $9.9 million in the first nine months of 2015, compared to $3.8 million in the third quarter and $10.4 million in the first nine months of 2014.

Trap-based Clinical Programs

EYLEA - Ophthalmologic Diseases

Overview

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet AMD, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results. CRVO is caused by obstruction of the central retinal vein that leads to a back-up of blood and fluid in the retina. Release of VEGF contributes to increased vascular permeability in the eye and macular edema. In BRVO, a blockage occurs in the blood vessels branching from the main vein draining the retina, resulting in the release of VEGF and consequent retinal edema. For centrally involved DME, VEGF-mediated leakage of fluid from blood vessels in the eye results in interference with vision. Wet AMD, diabetic retinopathy (which includes DME), and RVO are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by neovascular proliferation and/or retinal edema.

EYLEA is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors. EYLEA is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Neovascular Glaucoma

NVG is a secondary glaucoma triggered by the formation of new blood vessels (neovascularization) on the iris and the anterior chamber angle. Neovascularization restricts aqueous outflow and consequently elevates intraocular pressure (IOP). NVG is a serious condition that may lead to permanent loss of vision, a persistently painful eye, and, especially in the advanced stages, is unlikely to respond to treatment. NVG is caused by eye diseases leading to retinal ischemia, mainly CRVO, proliferative diabetic retinopathy (PDR), and ocular ischemic syndrome (OIS).

NVG meets the criteria for an orphan indication in Japan where the estimated number of NVG patients is 30,000 to 40,000. In the second quarter of 2015, Bayer HealthCare initiated a Phase 3 study in Japan to assess the efficacy and safety of intravitreal administration of aflibercept in comparison to sham treatment on the change in IOP in patients with NVG.

Late-Stage Antibody-based Clinical Programs

Praluent for LDL cholesterol reduction

Overview

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol (LDL-C) through inhibition of HMG-CoA, an enzyme regulating the early and rate-limiting step in cholesterol biosynthesis that ultimately results in an increase in LDL receptors to increase the uptake of plasma LDL lipoproteins. Similar to statins, PCSK9 impacts the number of available LDL receptors and therefore plays a key role in modulating LDL-C levels in the body. PCSK9 is a secreted protein that binds to and induces the destruction of the LDL receptor, thereby interfering with cellular uptake and increasing circulating levels of LDL cholesterol. In a landmark study published in *The New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL-C, but also a significant reduction in the risk of coronary heart disease (CHD). We used our *VelocImmune* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called Praluent, that is intended to lower LDL cholesterol.

Clinical Programs

Phase 3 ODYSSEY Program. We and Sanofi initiated the global Phase 3 ODYSSEY program for Praluent in 2012. The ODYSSEY program consists of more than 23,500 patients, and includes clinical trials evaluating the effect of Praluent, dosed every two weeks, on lowering LDL cholesterol. In addition, the potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing 18,000-patient ODYSSEY OUTCOMES trial. LDL cholesterol reduction is the primary efficacy endpoint for initial regulatory filings. Additionally, the ODYSSEY program includes two trials of Praluent dosed every four weeks, ODYSSEY CHOICE I and ODYSSEY CHOICE II. Patients in the ODYSSEY CHOICE I trial received Praluent 300 mg (most in combination with statins) every four weeks and patients in the CHOICE II trial received Praluent 150 mg monotherapy and in combination with non-statin lipid lowering therapy every four weeks.

In 2013, we and Sanofi reported data from the ODYSSEY MONO trial, which evaluated the efficacy and safety of Praluent monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. In 2014, we and Sanofi reported detailed positive results from nine additional Phase 3 ODYSSEY studies. All ten studies (ODYSSEY MONO, LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II, and ALTERNATIVE) met their primary efficacy endpoint of a greater percent reduction from baseline in LDL-C at 24 weeks compared to placebo or active comparator. Based on the positive results of these studies, a Biologics License Application (BLA) for U.S. regulatory approval of Praluent was submitted, and accepted by the FDA in January 2015. An FDA rare pediatric disease priority review voucher was utilized in connection with this BLA submission, as a result of which the submission was accepted by the FDA for priority review. In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated stain therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In addition, in September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

In January 2015, we and Sanofi announced that the ODYSSEY CHOICE I and ODYSSEY CHOICE II studies met their primary efficacy endpoints. The trials compared the reduction from baseline in LDL-C at 24 weeks with Praluent versus placebo in patients with hypercholesterolemia. In these trials dosing every four weeks, the mean percent reduction in LDL-C from baseline was consistent with that seen in previous Phase 3 trials evaluating Praluent in every other week dosing. The most common adverse events (AEs) in the trials (occurring in at least 5% of Praluent-treated patients) were injection site reactions, headache, upper respiratory tract infection, arthralgia, nausea, sinusitis, pain in extremity, and fatigue. Injection site reactions occurred more frequently in the Praluent groups compared to placebo.

In July 2015, we and Sanofi announced that the Phase 3 ODYSSEY JAPAN trial met its primary endpoint. At week 24, patients in the Praluent group experienced an average 64% greater reduction from baseline in their LDL-C when added to current standard of care including statins, compared to standard of care alone ($p<0.0001$). Patients were started on the lower dose of 75 mg, with the option to adjust their dose to 150 mg if they had not achieved their LDL-C goal (as defined by the Japan Atherosclerosis Society (JAS) guidelines) at week 8. At week 24, 97% of patients in the Praluent group reached their LDL-C treatment goal, compared to 10% for placebo ($p<0.0001$). Ninety-nine percent of patients who received Praluent at week 8 remained on the initial 75 mg dose, while 1% of patients had their dose adjusted to receive 150 mg every two weeks, also as a single 1 milliliter (mL) injection. The most common adverse events (occurring in at least 5% of patients in the Praluent group) were nasopharyngitis, injection site reaction, and back pain. Results were presented at the Annual Scientific Meeting of the JAS in Sendai, Japan.

ODYSSEY JAPAN evaluated Praluent (n =144) compared to placebo (n =72), both on top of standard care, in Japanese patients with hypercholesterolemia, with either HeFH or at high CV risk, and who could not reach their LDL-C treatment goal as defined by the JAS guidelines despite lipid-lowering treatments that included statins. The mean LDL-C value at baseline was 141.2 mg/dL. Patients were initially randomized to receive either Praluent 75 mg every two weeks administered as a single 1 mL injection, or placebo. Patients in both groups received statins, with or without other lipid-lowering therapies.

Sarilumab (REGN88; IL-6R Antibody) for inflammatory diseases

Overview

IL-6 is a key cytokine involved in the pathogenesis of RA, causing inflammation and joint destruction. Sarilumab is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune* technology.

Rheumatoid Arthritis

Phase 3 Studies. In 2013, we and Sanofi announced that in the 52 week SARIL-RA-MOBILITY Phase 3 clinical trial in adult patients with active RA who were inadequate responders to methotrexate (MTX) therapy, sarilumab treatment in combination with MTX improved disease signs and symptoms as well as physical function, and inhibited progression of joint damage. Additional data from the trial were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2015. A summary of primary endpoints and most common AEs for this trial, as well as additional Phase 3 trials, is as follows:

Completed Efficacy and Safety Studies					
		Primary efficacy endpoints			
Study	**Patient group**	**ACR[a] 20/50/70**	**HAQ-DI[b]**	**mTSS[c]**	**Safety findings**
MOBILITY *(n=1,197)* *150mg + MTX (n=400)*	Moderate to severe RA with inadequate response to MTX	58/37/20 (p<0.0001 vs. placebo)	-0.53	0.90	Infections, neutropenia, injection site reactions, and increased transaminases
200mg + MTX (n=398)		66/46/25 (p<0.0001 vs. placebo)	-0.55	0.25	
Placebo + MTX (n=399)		33/17/7	-0.29	2.78	
TARGET *(n=546)* *150mg + DMARD[d] (n=181)*	Moderate to severe active RA with inadequate response to, or intolerant of, one or more tumor necrosis factor-alpha (TNF-alpha) inhibitors	56/37[e]/20[f]	-0.50	NA	Infections, neutropenia, injection site reactions, and hypertriglyceridemia
200mg + DMARD (n=181)		61/41[e]/16[f]	-0.49		
Placebo + DMARD (n=184)		34/18/7	-0.29		

NA = not applicable

a. ACR = American College of Rheumatology score

b. HAQ-DI = the Health Assessment Question-Disability Index

c. mTSS = van der Heijde modified total Sharp score

d. DMARD = non-biologic disease modifying anti-rheumatic drugs

e. p<0.0001 vs. placebo

f. p<0.025 vs. placebo

Completed Safety Studies			
Study	**Patient group**	**Primary endpoint**	**Study met primary endpoint?**
ASCERTAIN *(n=202)*	Moderate to severe active RA with inadequate response to, or intolerant of, one or more TNF-alpha inhibitors	Assess safety of two subcutaneous doses of sarilumab and tocilizumab in combination with DMARDs	Yes
EASY *(n=217)*	Completed patients from MOBILITY, TARGET, or ASCERTAIN trials	Product technical failures	Yes

Detailed results from the SARIL-RA-TARGET, SARIL-RA-EASY, and SARIL-RA-ASCERTAIN trials will be presented at the upcoming annual meeting of the American College of Rheumatology and other medical congresses.

We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-ONE, SARIL-RA-MONARCH, and SARIL-RA-KAKEHASI (in Japan). In addition, the SARIL-RA-HARUKA long-term safety trial was initiated in Japan in the first quarter of 2015. In the second quarter of 2015, an open-label, randomized, parallel group, single-dose Phase 1 study to assess the safety of IL-6 receptor blockade with sarilumab or tocilizumab monotherapy in Japanese patients with RA was also initiated. The broad SARIL-RA clinical development program is focused on adult populations with moderate-to-severe RA who are inadequate responders to either MTX or tumor necrosis factor alpha inhibitor therapy. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, or SARIL-RA-ONE are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab.

Non-infectious Uveitis

Phase 2 SARIL-NIU-SATURN Study. SARIL-NIU-SATURN was a small Phase 2, randomized double-masked, placebo-controlled study (n=58) conducted to assess the effect of sarilumab on non-infectious uveitis of the posterior ocular segment. The primary endpoint of the study was the proportion of patients with a 2-step decrease in vitreous haze (based on a 9-point grading scale) or a steroid dose of less than 10 mg/day at week 16. Results of this study at the pre-specified primary endpoint, week 16, showed that compared with placebo patients, a greater proportion of patients randomized to sarilumab met the primary endpoint; however, this was not statistically significant. Approximately 70% of patients enrolled in the study had a baseline vitreous haze score of less than 2 as judged by the reading center, limiting our ability to interpret the vitreous haze component of the primary endpoint for these patients. Other indications of a positive effect of treatment with sarilumab compared to placebo included decreased average vitreous haze score, reduced macular edema and improved best-corrected visual acuity in patients presenting with more severe baseline ocular inflammation, and associated with improvement of leakage on fluorescein angiography. Overall, safety observations were consistent with the findings in studies of other indications with sarilumab. The study is ongoing and will continue through week 52, when we will discuss next steps with our collaborator Sanofi.

Dupilumab (REGN668; IL-4R Antibody) for allergic and inflammatory conditions

Overview

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies atopic (allergic) dermatitis, asthma, chronic sinusitis with nasal polyposis, and eosinophilic esophagitis. Dupilumab is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to bind to IL-4R alpha subunit and block signaling from both IL-4 and IL-13.

Atopic Dermatitis

Phase 2b Trial. In July 2014, we and Sanofi announced positive results from a Phase 2b dose-ranging study of dupilumab in adult patients with moderate-to-severe atopic dermatitis. All doses of dupilumab met the primary endpoint of a greater improvement in Eczema Severe Score Index (EASI) scores from baseline compared to placebo. In the Phase 2b trial, all five subcutaneous doses of dupilumab showed a dose-dependent improvement in the primary endpoint, the mean percent change in EASI score from baseline to week 16. The improvements in EASI score ranged from a high of 74% for patients in the highest dose group, who received 300 mg weekly, to a low of 45% in patients who received the lowest dose of 100 mg monthly, compared to 18% for patients in the placebo group ($p<0.0001$ for all doses). The most common AE in the Phase 2b study was nasopharyngitis, which was balanced across dupilumab treatment groups (18.5% to 23%) compared to placebo (21%). Injection site reactions were more frequent in the dupilumab group (5% to 9.5%) compared to placebo (3%), as was headache (12% to 15%) compared to placebo (8%).

Dupilumab-treated patients showed highly statistically significant and dose-dependent improvements in additional key efficacy measures compared to placebo after 16 weeks of treatment:

- 12% to 33% of dupilumab-treated patients achieved clearing or near-clearing of skin lesions, as measured by an Investigator's Global Assessment (IGA) score of 0 or 1, compared to 2% with placebo ($p=0.02$ to $p<0.0001$).
- Dupilumab-treated patients experienced a 16.5% to 47% mean reduction in itching, as measured by the pruritus numerical-rating scale (NRS) score, compared to an increase of 5% in the placebo group ($p=0.0005$ to $p<0.0001$).

This Phase 2b double-blind, placebo-controlled, 16-week, dose-ranging study randomized 380 patients with moderate-to-severe atopic dermatitis, who could not be adequately controlled with topical medication or for whom topical treatment was not advisable. Patients were randomized to receive one of five doses of dupilumab (300 mg weekly, 300 mg every other week, 300 mg monthly, 200 mg every other week, 100 mg monthly) or placebo. Patients in the study had approximately 50% of their skin affected by

atopic dermatitis at baseline. In the year preceding enrollment in the study, approximately 35% of patients received an oral corticosteroid and approximately 20% received a systemic non-steroid immunosuppressant for atopic dermatitis. Approximately 60% of patients had another allergic condition, including approximately 40% of patients who had a history of asthma.

Phase 3 Study. In the fourth quarter of 2014, four Phase 3 trials in atopic dermatitis, LIBERTY AD CHRONOS, LIBERTY AD SOLO 1, LIBERTY AD SOLO 2, and LIBERTY AD Open label Extension, were initiated. Enrollment has been completed in the LIBERTY AD CHRONOS, LIBERTY AD SOLO 1 and LIBERTY AD SOLO 2 pivotal trials. LIBERTY AD CHRONOS is a randomized, double-blind, placebo-controlled, multi-national study with the primary objective of demonstrating the efficacy of dupilumab in adults with moderate-to-severe atopic dermatitis when administered concomitantly with topical corticosteroids through 16 weeks. Secondary objectives of the LIBERTY AD CHRONOS trial will evaluate the long-term safety and efficacy of dupilumab up to 52 weeks. The LIBERTY AD Phase 3 clinical program will consist of patients with moderate-to-severe atopic dermatitis at sites worldwide.

In November 2014, the FDA granted Breakthrough Therapy designation to dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis who are not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate. This designation is based on positive results from Phase 1 and 2 clinical trials, and the determination that atopic dermatitis is a serious disease and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies.

Phase 2 Trial in Adolescents and Children. In March 2015, a Phase 2 pharmacokinetic and safety study in adolescents and children (6-17 years of age) with moderate-to-severe atopic dermatitis was initiated and is fully enrolled.

Asthma

Phase 2b Study. In May 2015, we and Sanofi presented positive results from an interim analysis of a pivotal Phase 2b study of dupilumab in adult patients with moderate-to-severe asthma, who are uncontrolled despite treatment with inhaled corticosteroids and long-acting beta agonists (ICS/LABA), at the American Thoracic Society 2015 International Conference. As previously reported in 2014, the study met its primary endpoint of improving lung function in asthma patients with high blood eosinophil counts ((HEos), greater than or equal to 300 eosinophilic cells/microliter). New data presented on secondary endpoints at the American Thoracic Society 2015 International Conference included positive results in study patients with low blood eosinophil counts ((LEos), less than 300 eosinophilic cells/microliter), who are thought to be less likely to suffer from "allergic" asthma and thus less likely to respond to Type 2 helper T-cell (TH2) targeted therapies. Based on discussions with the FDA, this Phase 2b study may be considered one of two pivotal efficacy studies required for a potential dupilumab BLA in asthma.

The results presented in May 2015 focused on LEos asthma patients. In this population, patients treated every other week with either 200 mg or 300 mg doses of dupilumab showed a greater than 8% improvement in forced expiratory volume over one second ((FEV1), a standard measure of lung function) at week 12 ($p<0.001$), in comparison to placebo, both in combination with ICS/LABA. Additionally, the 200 mg and 300 mg every other week doses of dupilumab in combination with ICS/LABA showed 68% and 62% reductions, respectively, in adjusted annualized rate of severe exacerbations in the LEos population ($p<0.01$ and $p<0.05$), in comparison to placebo in combination with ICS/LABA. These results are consistent with previously reported positive results in HEos asthma patients and the overall patient population, in which the two every other week doses (200 mg and 300 mg) of dupilumab in combination with ICS/LABA demonstrated a statistically significant 12% to 15% improvement in FEV1 over placebo at week 12 and a 64% to 75% improvement in annualized rate of severe exacerbations over placebo. Dupilumab also significantly reduced mean fractional exhaled nitric oxide (FeNO) across both every other week doses tested (200 mg and 300 mg) and the three patient populations (overall, LEos and HEos), in a roughly dose-dependent manner. FeNO is recommended by the American Thoracic Society clinical practice guidelines to assess airway inflammation, since higher-than-normal levels of nitric oxide may be released when a patient has a chronic airway disease, such as asthma.

The most common AE was injection site reaction, which was more frequent in the dupilumab dose groups (13% to 25%) compared to placebo (12%). Other common AEs in the study included upper respiratory tract infection (10% to 13% dupilumab; 13% placebo), headache (5% to 10% dupilumab; 8% placebo), nasopharyngitis (3% to 10% dupilumab; 6% placebo) and bronchitis (5% to 8% dupilumab; 8% placebo). The incidence of infections was balanced across treatment groups (42% to 45% dupilumab; 46% placebo), as was the incidence of serious AEs (3% to 7% dupilumab; 5% placebo).

These results were based on a pre-specified interim analysis, which occurred when all patients had reached week 12 of the 24-week treatment period; the average treatment duration at the time of the analysis was 21.4 weeks. The primary endpoint of the study was improvement from baseline in FEV1 at week 12 in the HEos group. Final analyses on exacerbations and safety will be conducted after 24 weeks of treatment and a 16-week follow-up period.

Phase 3 Study. A Phase 3 trial, LIBERTY ASTHMA QUEST, in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015. LIBERTY ASTHMA QUEST is expected to serve as the second required pivotal efficacy study, since, based on discussions with the FDA, the Phase 2b study will also be considered a pivotal efficacy study. The global, placebo-

controlled Phase 3 study is expected to enroll more than 1,600 patients with uncontrolled persistent asthma and will evaluate two doses of dupilumab, 200 mg and 300 mg, subcutaneously administered every other week.

Nasal Polyposis

Phase 2 Trial. In 2013, a Phase 2 trial in NPwCS was initiated. In September 2014, we and Sanofi announced positive results from the Phase 2 proof-of-concept study of dupilumab in patients with moderate-to-severe NPwCS who did not respond to intranasal corticosteroids. The randomized, double-blind, placebo-controlled study enrolled 60 adult patients with moderate-to-severe NPwCS. Patients in the study received 300 mg of dupilumab or placebo administered once per week subcutaneously for 16 weeks, following an initial loading dose of 600 mg. All patients in the study also received a standard-of-care nasal corticosteroid spray. Patients were eligible for the study if they continued to have severe NPwCS despite standard treatment for at least one month. Fifty percent of patients in the study had received prior surgery for their condition. Asthma was also present in 58 percent of NPwCS patients in the study. The conditions are often co-morbid and symptoms/exacerbations are frequently interdependent.

In the study, dupilumab resulted in a statistically-significant improvement in the size of nasal polyps, as measured by endoscopic Nasal Polyp Score (NPS), the primary endpoint of the study. Statistically significant improvements in all secondary efficacy endpoints were also observed, including objective measures of sinusitis by CT scan, nasal air flow, and patient-reported symptoms (sense of smell, congestion, postnasal drip, runny nose and sleep disturbance). In a pre-specified exploratory analysis, dupilumab-treated patients who also had asthma demonstrated significant improvements in asthma control. The safety profile was consistent with previous studies. The most common AEs with dupilumab were injection site reactions, nasopharyngitis, oropharyngeal pain, epistaxis, headache, and dizziness.

Eosinophilic Esophagitis

Phase 2 Trial. A Phase 2 trial of dupilumab in eosinophilic esophagitis was initiated in the first quarter of 2015. EoE is a chronic allergic inflammatory disease that is considered a major cause of gastrointestinal illness. Eosinophils are a type of white blood cell that, due to allergens, can accumulate in the esophagus, causing inflammation and tissue injuries that create difficulty swallowing. People with eosinophilic esophagitis may also have allergies, asthma, atopic dermatitis, or chronic respiratory disease.

REGN2222 (RSV-F Antibody) for RSV

Overview

Respiratory Syncytial Virus, or RSV, is a virus that infects the lungs and breathing passages. It is the most common cause of bronchiolitis (inflammation of the small airways) and is the second most common cause of death, globally, in the first year of life. RSV results in a significant healthcare burden, as it is the leading cause of infant hospitalizations in the United States. In addition to hospitalizations, RSV frequently results in emergency department, urgent care, and physicians' office visits. It is estimated that about half of all children will have an RSV infection by their first birthday. REGN2222 is a fully human monoclonal antibody to the RSV-F protein. REGN2222 was generated using our *VelocImmune* technology.

Clinical Program

Based on clinical results from a Phase 1 study, and following discussions with the FDA, REGN2222 entered into a Phase 3 pivotal clinical study (NURSERY Pre-Term) in the third quarter of 2015. NURSERY Pre-Term is a two part study, and Part A is currently enrolling patients in the Southern hemisphere. Part A is an open-label pharmacokeninetic study, which is designed to enable dose selection for Part B; Part B is expected to commence later this year in the Northern Hemisphere.

Fasinumab (REGN475; NGF Antibody) for pain due to osteoarthritis

Overview

Persistent osteoarthritic pain represents a growing unmet medical need. Pain is a frequent reason for physician visits, a common reason for taking prescription medications, and a major cause of work disability and impaired quality of life. Targeting NGF is a potential advance in pain management. NGF expression is elevated in many acute and chronic painful conditions and NGF blockade has demonstrated efficacy in various animal models of pain. Fasinumab is a fully human monoclonal antibody to NGF, generated using our *VelocImmune* technology.

Clinical Program

A Phase 2b/3 clinical study in patients with pain due to osteoarthritis was initiated in the second quarter of 2015. Fasinumab is currently on partial clinical hold by the FDA, limiting duration of trials in osteoarthritis to 16 weeks.

Research Programs

Our preclinical research programs include the areas of oncology/immuno-oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain and neurobiology, cardiovascular diseases, and infectious diseases.

In September 2015, we and the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) entered into an agreement to develop, test, and manufacture a monoclonal antibody therapy for the treatment of Ebola virus infection. HHS will provide initial funding of approximately $17.0 million to support our preclinical development and antibody manufacturing. HHS also has the option to provide for up to an additional $32.2 million for a Phase 1 study in healthy volunteers, and further manufacturing and development studies.

Research and Development Technologies

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate EYLEA, ZALTRAP, and ARCALYST. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region," resulting in high affinity product candidates. *VelociSuite* is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite. *VelociSuite* consists of *VelocImmune*, *VelociGene*, *VelociMouse*®, and *VelociMab*. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse* technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

We have utilized our *VelociSuite* technologies to develop a class of potential drug candidates, known as bi-specific antibodies. In the area of immunotherapies in oncology, we are exploring the use of bi-specific antibodies that target tumor antigens and the CD3 receptor on T-cells to harness the oncolytic properties of T-cells. Our first such bi-specific antibody, which entered into clinical development in 2014, targets CD20 and CD3.

Regeneron Genetics Center. In 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC. RGC leverages de-identified clinical and molecular data from human volunteers for medically relevant associations in a blinded fashion designed to preserve patients' privacy. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC is undertaking both large population-based efforts as well as family- and founder-based approaches. RGC utilizes laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 70,000 unique samples per year.

Central to the work of RGC is a collaboration with the Geisinger Health System of Pennsylvania. During the initial five-year collaboration term, Geisinger plans to collect samples from more than 100,000 consented patient volunteers, while RGC will perform sequencing and genotyping to generate de-identified genomic data. RGC has expanded on its foundational population-based collaboration with Geisinger with a number of other institutions, including Columbia University Medical Center, the Clinic for Special Children, Baylor College of Medicine, and SickKids in Toronto.

Collaboration Agreements

Collaborations with Sanofi

Antibodies. Since November 2007, we and Sanofi have been parties to a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement (Antibody Discovery Agreement) and a License and Collaboration Agreement (each as amended), collectively referred to as the Antibody Collaboration. Pursuant to the collaboration, Sanofi was responsible for funding up to $160.0 million per year of our antibody discovery activities over the period from 2010-2014, and, as amended in connection with the companies' July 2015 immuno-oncology collaboration as described below, is funding up to $145.0 million in 2015, and up to $130.0 million in each of 2016 and 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Our discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and develop fully human monoclonal antibodies against these targets will now be funded by Sanofi under the terms of the companies' new immuno-oncology collaboration. We lead the design and conduct of research activities under the Antibody Discovery Agreement, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified through discovery research under the Antibody Discovery Agreement, Sanofi has the option to license rights to the candidate under the License and Collaboration Agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with Sanofi generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs.

Under our collaboration agreement, Sanofi will record product sales and cost of sales for commercialized products, and Regeneron has the right to co-promote such products. We have exercised our option to co-promote Praluent in the United States. We have not exercised our option to co-promote Praluent outside the United States; however, we retain the right to do so at a future date subject to the terms of the collaboration agreement. We and Sanofi will equally share profits and losses from sales within the United States. We and Sanofi will share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and will share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Immuno-Oncology. In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable upfront payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million (IO Discovery Budget) to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits, which consists of (i) $750.0 million in new funding and (ii) $75.0 million of funding that would have otherwise been available to Regeneron under the existing Antibody Discovery

Agreement, as described above. The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs. Pursuant to the IO Discovery Agreement, we will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of IND Applications, and clinical development through proof-of-concept. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable upfront payment to us. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with us through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between us and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and we will reimburse half of the total development costs for all such candidates from our share of future profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for the drug candidates for which we are the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (REGN2810). The parties will share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. We will have principal control over the development of REGN2810 and will lead commercialization activities in the United States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. We will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

With respect to each product candidate that enters development under the IO License and Collaboration Agreement, we or Sanofi may, by giving twelve months' notice, opt-out of further development and/or commercialization of the product, in which event the other party will retain exclusive rights to continue the development and/or commercialization of such product.

ZALTRAP. Since September 2003, we and Sanofi have been parties to a global collaboration (ZALTRAP Collaboration Agreement) for the development and commercialization of ZALTRAP. In February 2015, we and Sanofi entered into an Amended ZALTRAP Agreement. Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays us a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. We will also be paid for all quantities of ZALTRAP manufactured by us pursuant to a supply agreement through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation (which was approximately $461 million at December 31, 2014) to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement.

Collaborations with Bayer HealthCare

EYLEA outside the United States. Since October 2006, we and Bayer HealthCare have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEA through an integrated global plan. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales.

Since inception of the agreement, we have earned $110.0 million of development milestone payments and $165.0 million of sales milestone payments from Bayer HealthCare. During the first quarter of 2015, we earned the final potential milestone payment under our Bayer HealthCare collaboration agreement in connection with EYLEA outside the United States.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits (including payments to us based on sales in Japan). The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. As a result, we expect that a portion of our share of EYLEA profits outside the United States will be used to reimburse Bayer HealthCare for this repayment obligation.

Within the United States, we retain exclusive commercialization rights to EYLEA and are entitled to all profits from any such sales.

PDGFR-beta antibody outside the United States. In January 2014, we entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, is being developed under the agreement. Under the agreement, we will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to license and collaborate on further development and commercialization outside the United States.

In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to us in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to us in the 2014, and an additional $5.0 million development milestone payment to us in the second quarter of 2015. Further, in connection with our initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, we are eligible to receive up to $10.0 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

If Bayer HealthCare exercises its right to opt-in to the collaboration, they will obtain exclusive commercialization rights to the product outside the United States, continue to pay for 25% of global development costs and 50% of development costs exclusively for the territory outside the United States, pay a $20.0 million opt-in payment to us, pay a $20.0 million development milestone to us upon receipt of the first marketing approval in the EU or Japan, share profits and losses from sales outside the United States equally with us, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales. If Bayer HealthCare does not opt-in to the collaboration, we will have exclusive rights to develop and commercialize PDGFR-beta antibodies (except as a combination product with EYLEA) for use outside the United States.

We also have the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If we opt-out of the collaboration and Bayer HealthCare exercises its right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination product with EYLEA) outside of the United States, be responsible for all development costs outside of the United States, be responsible for all royalty and milestone payments to a third party, and will retain all of the profits from sales of the PDGFR-beta antibody outside of the United States.

Collaboration with Mitsubishi Tanabe Pharma

Fasinumab Asia. In September 2015, we entered into a collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) providing MTPC with development and commercial rights to fasinumab in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the MTPC Territories). In connection with

the agreement, MTPC made a $10.0 million non-refundable upfront payment, and we are entitled to receive up to an aggregate of $215.0 million in development milestone and other contingent payments.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as MTPC has ceased developing or commercializing fasinumab in the MTPC Territories.

General

Developing and commercializing new medicines entails significant risk and expense. Before significant revenues from the commercialization of our antibody candidates or new indications for our marketed products can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our continued success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, will expand and require additional resources. We also expect to incur substantial costs related to the commercialization of Praluent and preparation for potential commercialization of our late-stage antibody product candidates, approximately half of which we expect to be reimbursed by Sanofi under the companies' collaboration agreement. Our operating results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, and the continuation of our collaborations, in particular with Sanofi and Bayer HealthCare, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2015 to date were, and plans for the next twelve months are, as follows:

Trap-based Clinical Program:

2015 Events to Date	2015-2016 Plans (next 12 months)
EYLEA	
Ÿ Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with wet AMD, macular edema secondary to CRVO, and DME, and continued to pursue regulatory applications for marketing approval in additional countries	Ÿ Bayer HealthCare to file for additional ex-US regulatory approvals for various indications
Ÿ European Commission and Japanese MHLW approved EYLEA for the treatment of macular edema secondary to BRVO	Ÿ Regulatory agency decisions on applications outside the United States for various indications
Ÿ FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME	Ÿ We and Bayer HealthCare to report 3-year data from Phase 3 DME trials
Ÿ Initiated Phase 3 trial for NVG in Japan	
Ÿ European Commission approved EYLEA for the treatment of mCNV	

Antibody-based Clinical Programs:

	2015 Events to Date	2015-2016 Plans (next 12 months)
Praluent (PCSK9 Antibody)	Ÿ BLA accepted for priority review in the United States Ÿ Regulatory application accepted for review by the EMA Ÿ Reported positive results from ODYSSEY CHOICE I and CHOICE II trials Ÿ ODYSSEY LONG TERM 18-month trial results published in *The New England Journal of Medicine* Ÿ Reported positive results from ODYSSEY Japan trial Ÿ FDA approved Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol Ÿ European Commission granted marketing authorization for Praluent for the treatment of LDL cholesterol in certain adult patients with hypercholesterolemia	Ÿ Complete patient enrollment of Phase 3 ODYSSEY OUTCOMES trial Ÿ Report additional results from Phase 3 ODYSSEY trials Ÿ File for additional regulatory approvals outside the United States Ÿ Regulatory agency decisions on applications outside the United States
Sarilumab (IL-6R Antibody)	Ÿ Initiated and completed patient enrollment in Phase 3 MONARCH study (head-to-head monotherapy study against adalimumab) Ÿ Initiated several studies in Japan Ÿ Reported positive results from SARIL-RA-TARGET, SARIL-RA-EASY, and SARIL-RA-ASCERTAIN trials Ÿ Completed patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis and reported top-line results Ÿ BLA submitted in the United States	Ÿ Continue patient enrollment in Phase 3 SARIL-RA program Ÿ Report results from additional Phase 3 trials Ÿ Regulatory agency decision on application for U.S. approval
Dupilumab (IL-4R Antibody)	Ÿ Initiated Phase 2 study in EoE Ÿ Initiated and completed enrollment for Phase 2 study in atopic dermatitis in adolescents and children Ÿ Initiated Phase 3 study in asthma Ÿ Presented positive pivotal Phase 2b data in asthma at the American Thoracic Society 2015 International Conference Ÿ Completed patient enrollment in Phase 3 atopic dermatitis pivotal trials	Ÿ Continue patient enrollment in various Phase 2 and Phase 3 studies Ÿ Complete patient enrollment in Phase 2 EoE and Phase 3 asthma studies
REGN2222 (RSV-F Antibody)	Ÿ Completed Phase 1 study Ÿ Initiated Part A of Phase 3 NURSERY Pre-Term study	Ÿ Continue patient enrollment in Part A of Phase 3 NURSERY Pre-Term study Ÿ Initiate Part B of Phase 3 NURSERY Pre-Term study
Fasinumab (NGF Antibody)	Ÿ Initiated sixteen-week Phase 2b/3 study in osteoarthritis Ÿ On partial clinical hold by the FDA	Ÿ Complete patient enrollment in Phase 2b/3 study Ÿ Initiate full development program pending removal of partial clinical hold

Antibody-based Clinical Programs (continued):

	2015 Events to Date	2015-2016 Plans (next 12 months)
Evinacumab (Angptl-3 Antibody)	Ÿ Initiated Phase 2 study Ÿ Partial clinical hold lifted by the FDA	Ÿ Complete patient enrollment in Phase 1 and Phase 2 studies
REGN1033 (GDF8 Antibody)	Ÿ Phase 2 proof-of-concept study in elderly men and women with sarcopenia met its primary endpoint, while secondary, functional endpoints were mixed. Ÿ Sanofi elected not to continue co-development	Ÿ Determine future development plan
REGN1908-1909 (Feld1 Antibody)	Ÿ Completed patient enrollment in Phase 2 study	
REGN2176-3 (PDGFR-beta Antibody co-formulated with aflibercept)	Ÿ Received Fast Track designation from the FDA for the treatment of patients with wet AMD Ÿ Initiated Phase 2 study	Ÿ Continue patient enrollment in Phase 2 study
REGN1193 (GCGR Antibody)	Ÿ Continued patient enrollment in Phase 1 study	Ÿ Complete patient enrollment in Phase 1 study
REGN1979 (CD20 and CD3 Antibody)	Ÿ Continued patient enrollment in Phase 1 study	Ÿ Complete patient enrollment in Phase 1 study
REGN910-3 (Ang2 Antibody co-formulated with aflibercept)	Ÿ Completed patient enrollment in Phase 1 study	
REGN2810 (PD-1 Antibody)	Ÿ Initiated Phase 1 study	Ÿ Continue patient enrollment in Phase 1 study

Corporate Information

We were incorporated in the State of New York in 1988 and publicly listed in 1991. Our principal executive offices are located at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number at that address is (914) 847-7000.

We make available free of charge on or through our Internet website (*http://www.regeneron.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

Investors and other interested parties should note that we use our media and investor relations website (*http://newsroom.regeneron.com*) and our social media channels to publish important information about Regeneron, including information that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our media and investor relations website and the social media channels listed on our media and investor relations website, in addition to our SEC filings, press releases, conference calls, and webcasts.

Results of Operations

The results of operations discussion below reflects certain revisions to previously-issued financial statements. See Note 4 of the Notes to Condensed Consolidated Financial Statements for a description of such revisions.

Three Months Ended September 30, 2015 and 2014

Net Income

Net income for the three months ended September 30, 2015 and 2014 consists of the following:

(In millions)	2015	2014
Revenues	$ 1,137.4	$ 725.8
Operating expenses	(745.0)	(537.3)
Other income (expense)	0.9	(6.6)
Income before income taxes	393.3	181.9
Income tax expense	(182.9)	(98.5)
Net income	$ 210.4	$ 83.4

Revenues

Revenues for the three months ended September 30, 2015 and 2014 consist of the following:

(In millions)	2015	2014
Net product sales	$ 737.6	$ 448.8
Collaboration revenue:		
Sanofi	224.7	132.9
Bayer HealthCare	157.6	135.9
Total collaboration revenue	382.3	268.8
Technology licensing and other revenue	17.5	8.2
Total revenues	$ 1,137.4	$ 725.8

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. We received marketing approval from the FDA for EYLEA for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in July 2014, macular edema following BRVO in October 2014, and diabetic retinopathy in patients with DME in March 2015. For the three months ended September 30, 2015, EYLEA net product sales increased to $734.4 million from $445.0 million for the three months ended September 30, 2014 due to higher sales volume. For the three months ended September 30, 2015 and 2014, we also recognized ARCALYST net product sales of $3.2 million and $3.8 million, respectively.

For the three months ended September 30, 2015 and 2014, we recorded 65% and 72%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of June 30, 2015	$ 5.5	$ 39.5	$ 0.5	$ 45.5
Provision related to current period sales	15.8	33.3	2.6	51.7
Credits/payments	(14.9)	(34.6)	(2.6)	(52.1)
Balance as of September 30, 2015	$ 6.4	$ 38.2	$ 0.5	$ 45.1
Balance as of June 30, 2014	$ 4.1	$ 20.4	$ 0.5	$ 25.0
Provision related to current period sales	8.5	17.5	0.4	26.4
Credits/payments	(8.8)	(19.4)	(0.4)	(28.6)
Balance as of September 30, 2014	$ 3.8	$ 18.5	$ 0.5	$ 22.8

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, primarily consisted of reimbursement for research and development and commercialization expenses that we incurred, partly offset by sharing of losses in connection with commercialization of antibodies, under the companies' Antibody Collaboration.

Sanofi Collaboration Revenue	Three Months Ended September 30,	
(In millions)	**2015**	**2014**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 205.1	$ 140.5
Reimbursement of Regeneron commercialization-related expenses	53.3	1.7
Regeneron's share of losses in connection with commercialization of antibodies	(74.9)	(12.8)
Other	2.6	2.5
Total Antibody	186.1	131.9
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	18.6	—
Other	20.0	—
Total Immuno-oncology	38.6	—
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	(1.0)
Reimbursement of Regeneron research and development expenses	—	1.3
Other	—	0.7
Total ZALTRAP	—	1.0
Total Sanofi collaboration revenue	$ 224.7	$ 132.9

In the third quarter of 2015, Sanofi's reimbursement of our antibody research and development expenses consisted of $42.5 million under our Antibody Discovery Agreement and $162.6 million under our License and Collaboration Agreement, compared to $47.9 million and $92.6 million, respectively, in the third quarter of 2014. The higher reimbursement of research and development costs in the third quarter of 2015, compared to the same period in 2014, was primarily due to increased development activities for dupilumab.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with commercialization of Praluent and sarilumab. Effective in the second and fourth quarters of 2014, we and Sanofi

began sharing pre-launch commercial expenses related to Praluent and sarilumab, respectively, in accordance with the companies' License and Collaboration Agreement. Consequently, we began recording our share of losses in connection with commercialization of Praluent and sarilumab. Sanofi provides us with an estimate of our share of the profit or loss from commercialization of antibodies for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

Following the FDA approval in July 2015, sales of Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol, commenced in the United States. Praluent net product sales, which are recorded by Sanofi, were $4.0 million in the third quarter of 2015. We and Sanofi incurred higher commercialization expenses for Praluent primarily in connection with launching the product in the United States.

Other Sanofi antibody revenue includes recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of September 30, 2015, $64.9 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (as described above under "Collaboration Agreements - Collaboration with Sanofi - *Immuno-Oncology*"). In the third quarter of 2015, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $12.8 million under our IO Discovery Agreement and $5.8 million under our IO License and Collaboration Agreement.

Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in the third quarter of 2015 in connection with the execution of the IO Collaboration agreements. As of September 30, 2015, $620.0 million of the up-front payments was deferred and will be recognized ratably as revenue in future periods.

In September 2003, we and Sanofi entered into a ZALTRAP Collaboration Agreement to jointly develop and commercialize ZALTRAP. Under the terms of ZALTRAP Collaboration Agreement, we and Sanofi shared profits and losses on sales of ZALTRAP outside of Japan, and we were entitled to receive a percentage of sales of ZALTRAP in Japan. Our share of the loss in connection with the commercialization of ZALTRAP in the third quarter of 2014 represents our share of the costs of launching and commercializing ZALTRAP, partly offset by net product sales. As described above under "Collaboration Agreements - Collaborations with Sanofi - *ZALTRAP*" and below in the "*Nine Months Ended September 30, 2015 and 2014*" section, in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, primarily consisted of recognition of our share of profits in connection with commercialization of EYLEA outside the United States.

Bayer HealthCare Collaboration Revenue	**Three Months Ended September 30,**	
(In millions)	**2015**	**2014**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 130.5	$ 85.4
Sales milestones	—	30.0
Cost-sharing of Regeneron EYLEA development expenses	1.8	4.4
Other	21.2	12.7
Total EYLEA	153.5	132.5
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	1.5	0.5
Other	2.6	2.9
Total PDGFR-beta antibody	4.1	3.4
Total Bayer HealthCare collaboration revenue	$ 157.6	$ 135.9

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, visual impairment due to DME in the third quarter of 2014, mCNV (in Japan) in the fourth quarter of 2014, and macular edema following BRVO in the second quarter of 2015. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below.

Regeneron's Net Profit from EYLEA Sales Outside the United States	**Three Months Ended September 30,**	
(In millions)	**2015**	**2014**
Net product sales outside the United States	$ 371.1	$ 277.0
Regeneron's share of collaboration profit from sales outside the United States	$ 144.2	$ 99.8
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(13.7)	(14.4)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 130.5	$ 85.4

Bayer HealthCare records revenue from sales of EYLEA outside the United States. Bayer HealthCare provides us with an estimate of our share of the profit or loss, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. In the third quarter of 2015 and 2014, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare.

In the third quarter of 2014, we earned two $15.0 million sales milestone payment from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $800 million and $900 million, respectively, over a twelve-month period.

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, principally related to Bayer HealthCare's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States and reimbursements for producing EYLEA commercial supplies for Bayer HealthCare. In addition, other EYLEA revenue includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of September 30, 2015, $11.8 million of the EYLEA up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Collaboration Agreements - Collaborations with Bayer HealthCare - *PDGFR-beta antibody outside the United States*." Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front payment and non-substantive milestones received in the first quarter of 2014. As of September 30, 2015, $12.1 million of the PDGFR-beta up-front and 2014 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Technology Licensing and Other Revenue

In connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the third quarter of both 2015 and 2014, we recognized $5.9 million of revenue related to this agreement. As of September 30, 2015, $63.3 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

In connection with the February 2015 Amended ZALTRAP Agreement with Sanofi, we recorded $9.0 million of revenue in the third quarter of 2015 primarily related to manufacturing ZALTRAP commercial supplies for Sanofi and the percentage of net sales of ZALTRAP Sanofi is obligated to pay us.

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris (canakinumab). In the third quarter of 2015 and 2014, technology licensing and other revenue included $2.6 million and $1.9 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $745.0 million in the third quarter of 2015 from $537.3 million in the third quarter of 2014. Our average headcount in the third quarter of 2015 increased to 3,966 from 2,714 in the same period in 2014, principally in connection with expanding our research and development and commercialization activities.

Operating expenses in the third quarter of 2015 and 2014 included a total of $102.6 million and $68.1 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in the third quarter of 2015 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2014 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $425.9 million in the third quarter of 2015 from $337.7 million in the same period of 2014. The following table summarizes the major categories of our research and development expenses:

Research and Development Expenses	**Three Months Ended September 30,**		**Increase**
(In millions)	**2015**	**2014**	**(Decrease)**
Payroll and benefits [1]	$ 129.2	$ 99.2	$ 30.0
Clinical trial expenses	81.2	46.7	34.5
Clinical manufacturing costs [2]	121.0	72.0	49.0
Research and other development costs	33.4	58.1	(24.7)
Occupancy and other operating costs	33.5	29.1	4.4
Cost-sharing of Bayer HealthCare and Sanofi development expenses [3]	27.6	32.6	(5.0)
Total research and development expenses	$ 425.9	$ 337.7	$ 88.2

[1] Includes Non-cash Compensation Expense of $52.8 million for the three months ended September 30, 2015 and $39.0 million for the three months ended September 30, 2014.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Also includes Non-cash Compensation Expense of $10.8 million for the three months ended September 30, 2015 and $7.1 million for the three months ended September 30, 2014.

[3] Under our collaborations with Bayer HealthCare and Sanofi, in periods when Bayer HealthCare or Sanofi incurs certain development expenses, we also recognize, as additional research and development expense, the portion of our collaborators' development expenses that we are obligated to reimburse. Our collaborators provide us with estimated development expenses for the most recent fiscal quarter. Bayer HealthCare and Sanofi's estimates are reconciled to their actual expenses for such quarter in the subsequent fiscal quarter, and our portion of our collaborators' development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to additional costs for clinical studies of dupilumab and fasinumab, partly offset by lower REGN1033- and EYLEA-related costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of dupilumab and sarilumab. Research and other development costs decreased primarily due to our 50% share ($33.8 million) of the cost of purchasing a FDA priority review voucher in the third quarter of 2014 for use with the Praluent BLA filing, partly offset by higher expenditures in connection with our expanded research activities.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaborations with Bayer HealthCare and Sanofi, the portion of Bayer HealthCare and Sanofi's respective development expenses which they incur and we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**Three Months Ended September 30,**		**Increase**
(In millions)	**2015**	**2014**	**(Decrease)**
Praluent	$ 64.0	$ 105.1	$ (41.1)
Dupilumab	101.5	36.2	65.3
Sarilumab	29.2	21.7	7.5
EYLEA	15.6	27.8	(12.2)
Other antibody candidates in clinical development	67.7	65.4	2.3
Other research programs and unallocated costs	147.9	81.5	66.4
Total research and development expenses	$ 425.9	$ 337.7	$ 88.2

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3b and 4 studies. Phase 3b studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $210.0 million in the third quarter of 2015 from $144.0 million in the third quarter of 2014 primarily due to higher headcount and related costs, higher Non-cash Compensation Expense principally for the reason described under "*Expenses*" above and higher commercialization expenses related to Praluent, partly offset by lower costs associated with the Branded Prescription Drug Fee as described below. Selling, general, and administrative expenses included $36.5 million and $21.2 million of Non-cash Compensation Expense in the third quarter of 2015 and 2014, respectively.

Selling, general, and administrative expenses in the third quarter of 2014 included a $40.6 million incremental charge related to the Branded Prescription Drug Fee, which is a non-tax deductible annual fee (the Branded Prescription Drug Fee) imposed on

pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. In July 2014, the Internal Revenue Service (IRS) issued final regulations that provide guidance on the Branded Prescription Drug Fee. The final regulations differ in some respects from the temporary regulations previously issued by the IRS in 2011, including that a company is liable for the fee based on its branded prescription drug sales in the current year, instead of the liability only being applicable upon the first qualifying branded prescription drug sale of the following fee year under the temporary regulations. As a result of the issuance of these final IRS regulations, we began recording an estimate of the fee in the same period in which our qualifying branded prescription drug sales occur. Therefore, in the third quarter of 2014, an incremental charge was recorded to (i) recognize a liability for the estimated fee payable based on 2014 sales through the first nine months of 2014, and (ii) expense the remaining prepaid asset recorded under the previous accounting for the estimated fee payable based on 2013 sales.

Cost of Goods Sold

Cost of goods sold was $67.2 million in the third quarter of 2015 and $33.7 million in the third quarter of 2014. Cost of goods sold primarily consists of royalties, as well as costs in connection with producing U.S. EYLEA commercial supplies and various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility. Cost of goods sold increased principally due to the increase in U.S. EYLEA net product sales.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer HealthCare, increased to $41.9 million in the third quarter of 2015 from $21.9 million in the third quarter of 2014. This increase was primarily due to royalties payable to Genentech in connection with higher sales of EYLEA outside the United States, as well as the recognition of costs associated with commercial supplies of EYLEA manufactured for Bayer HealthCare.

Other Income and Expense

Total other income (net of other expenses) was $0.9 million in the third quarter of 2015 and total other expenses (net of other income) was $6.6 million in the third quarter of 2014. Interest expense in the third quarter of 2015 decreased compared to the third quarter of 2014 primarily due to conversions of a substantial principal amount of our 1.875% convertible senior notes (the Notes) since the third quarter of 2014.

Income Taxes

In the third quarter of 2015 and 2014, we recorded income tax expense of $182.9 million and $98.4 million, respectively. The effective tax rate was 46.5% and 54.1% for the third quarter of 2015 and 2014, respectively. The third quarter 2015 effective tax rate was negatively impacted, compared to the U.S. federal statutory rate, by (i) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, (ii) the non-tax deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

The effective tax rate for the third quarter of 2014 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the incremental charge related to the non-tax deductible Branded Prescription Drug Fee (as described above), and expiration at the end of 2013 of the federal tax credit for increased research activities.

Nine Months Ended September 30, 2015 and 2014

Net Income

Net income for the nine months ended September 30, 2015 and 2014 consists of the following:

(In millions)	2015	2014
Revenues	$ 3,005.7	$ 2,017.2
Operating expenses	(1,984.9)	(1,409.1)
Other income (expense)	(23.0)	(36.6)
Income before income taxes	997.8	571.5
Income tax expense	(516.7)	(323.5)
Net income	$ 481.1	$ 248.0

Revenues

Revenues for the nine months ended September 30, 2015 and 2014 consist of the following:

(In millions)	2015	2014
Net product sales	$ 1,940.0	$ 1,229.2
Collaboration revenue:		
Sanofi	593.2	406.0
Bayer HealthCare	415.7	358.5
Total collaboration revenue	1,008.9	764.5
Technology licensing and other revenue	56.8	23.5
Total revenues	$ 3,005.7	$ 2,017.2

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. For the nine months ended September 30, 2015, EYLEA net product sales increased to $1,930.0 million from $1,218.8 million for the nine months ended September 30, 2014 due to higher sales volume. For the nine months ended September 30, 2015 and 2014, we also recognized ARCALYST net product sales of $9.9 million and $10.4 million, respectively.

For the nine months ended September 30, 2015 and 2014, we recorded 67% and 75%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2014	$ 3.1	$ 21.2	$ 0.5	$ 24.8
Provision related to current period sales	41.3	88.0	6.0	135.3
Credits/payments	(38.0)	(71.0)	(6.0)	(115.0)
Balance as of September 30, 2015	$ 6.4	$ 38.2	$ 0.5	$ 45.1
Balance as of December 31, 2013	$ 4.4	$ 19.7	$ 0.5	$ 24.6
Provision related to current period sales	23.3	53.7	1.2	78.2
Credits/payments	(23.9)	(54.9)	(1.2)	(80.0)
Balance as of September 30, 2014	$ 3.8	$ 18.5	$ 0.5	$ 22.8

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, primarily consisted of reimbursement for research and development and commercialization expenses that we incurred, partly offset by sharing of losses in connection with commercialization of antibodies, under the companies' Antibody Collaboration.

Sanofi Collaboration Revenue	**Nine Months Ended September 30,**	
(In millions)	**2015**	**2014**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 585.5	$ 405.2
Reimbursement of Regeneron commercialization-related expenses	89.1	7.0
Regeneron's share of losses in connection with commercialization of antibodies	(143.6)	(17.1)
Other	7.7	7.7
Total Antibody	538.7	402.8
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	18.6	—
Other	20.0	—
Total Immuno-oncology	38.6	—
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	(4.9)
Reimbursement of Regeneron research and development expenses	0.7	3.7
Other	15.2	4.4
Total ZALTRAP	15.9	3.2
Total Sanofi collaboration revenue	$ 593.2	$ 406.0

In the first nine months of 2015, Sanofi's reimbursement of our antibody research and development expenses consisted of $145.0 million under our Antibody Discovery Agreement and $440.5 million under our License and Collaboration Agreement, compared to $131.0 million and $274.2 million, respectively, in the first nine months of 2014. The higher reimbursement of research and development costs in the first nine months of 2015, compared to the same period in 2014, was primarily due to increased research and pre-clinical activities under our Antibody Discovery Agreement and increased development activities for dupilumab, REGN2222, and Praluent.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with commercialization of Praluent and sarilumab. Effective in the second and fourth quarters of 2014, we and Sanofi began sharing pre-launch commercial expenses related to Praluent and sarilumab, respectively, in accordance with the companies' License and Collaboration Agreement (and, accordingly, we began recording our share of losses in connection with commercialization of Praluent and sarilumab). Sanofi provides us with an estimate of our share of the profit or loss from commercialization of antibodies for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

Following the FDA approval in July 2015, sales of Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol, commenced in the United States. Praluent net product sales, which are recorded by Sanofi, were $4.0 million in the third quarter of 2015. We and Sanofi incurred higher commercialization expenses for Praluent in the first nine months of 2015 primarily in connection with preparing for and launching the product in the United States.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (as described above under "Collaboration Agreements - Collaboration with Sanofi - *Immuno-Oncology*"). In the third quarter of 2015, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $12.8 million under our IO Discovery Agreement and $5.8 million under our IO License and Collaboration Agreement.

Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in the third quarter of 2015 in connection with the execution of the IO Collaboration agreements.

In September 2003, we and Sanofi entered into a ZALTRAP Collaboration Agreement to jointly develop and commercialize ZALTRAP. Under the terms of ZALTRAP Collaboration Agreement, we and Sanofi shared profits and losses on sales of ZALTRAP outside of Japan, and we were entitled to receive a percentage of sales of ZALTRAP in Japan. Our share of the loss in connection with the commercialization of ZALTRAP in the first nine months of 2014 represents our share of the costs of commercializing ZALTRAP, partly offset by net product sales.

As described above under "Collaboration Agreements - Collaborations with Sanofi - *ZALTRAP*," in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement. As a result, in the first quarter of 2015 we recognized $14.9 million of previously deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since our risk of inventory loss under the collaboration no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as we had no further performance obligations.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, primarily consisted of recognition of our share of profits in connection with commercialization of EYLEA outside the United States and sales milestones achieved.

Bayer HealthCare Collaboration Revenue	**Nine Months Ended September 30,**	
(In millions)	**2015**	**2014**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 326.6	$ 213.3
Sales milestones	15.0	75.0
Cost-sharing of Regeneron EYLEA development expenses	6.9	26.2
Other	50.7	34.5
Total EYLEA	399.2	349.0
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	8.7	1.7
Other	7.8	7.8
Total PDGFR-beta antibody	16.5	9.5
Total Bayer HealthCare collaboration revenue	$ 415.7	$ 358.5

Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below.

Regeneron's Net Profit from EYLEA Sales Outside the United States	Nine Months Ended September 30,	
(In millions)	**2015**	**2014**
Net product sales outside the United States	$ 1,000.7	$ 741.9
Regeneron's share of collaboration profit from sales outside the United States	$ 368.1	$ 256.8
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(41.5)	(43.5)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 326.6	$ 213.3

Bayer HealthCare records revenue from sales of EYLEA outside the United States. Bayer HealthCare provides us with an estimate of our share of the profit or loss, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. In the first nine months of 2015 and 2014, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare.

In the first nine months of 2015, we earned a $15.0 million sales milestone payment from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period. In the first nine months of 2014, we earned five $15.0 million sales milestone payments from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million, $600 million, $700 million, $800 million, and $900 million, respectively, over a twelve-month period.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in the first nine months of 2015 compared to the same period in 2014. In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare reimbursed us $15.7 million for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014. In addition, all future agreed-upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any future profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO are also shared (for countries other than Japan). We are entitled to receive a tiered percentage of EYLEA net sales in Japan.

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, principally related to Bayer HealthCare's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States and reimbursements for producing EYLEA commercial supplies for Bayer HealthCare. In addition, other EYLEA revenue includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Collaboration Agreements - Collaborations with Bayer HealthCare - *PDGFR-beta antibody outside the United States.*" Bayer HealthCare is also obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer HealthCare made a $5.0 million development milestone payment to us in the second quarter of 2015, which was recognized as revenue in the second quarter and included in "Cost-sharing of REGN2176-3 development expenses" in the table above.

Technology Licensing and Other Revenue

In connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the first nine months of both 2015 and 2014, we recognized $17.7 million of revenue related to this agreement.

In connection with the February 2015 Amended ZALTRAP Agreement with Sanofi, we recorded $32.0 million of revenue in the first nine months of 2015 primarily related to manufacturing ZALTRAP commercial supplies for Sanofi and a percentage of net sales of ZALTRAP from July 1, 2014 (the effective date of the Amended ZALTRAP Agreement) through September 30, 2015.

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris. In the first nine months of 2015 and 2014, technology licensing and other revenue included $7.0 million and $5.4 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $1,984.8 million in the first nine months of 2015 from $1,409.1 million in the first nine months of 2014. Our average headcount in the first nine months of 2015 increased to 3,535 from 2,551 in the same period in 2014, principally in connection with expanding our research and development and commercialization activities.

Operating expenses in the first nine months of 2015 and 2014 included a total of $300.7 million and $208.7 million, respectively, of Non-cash Compensation Expense. The increase in total Non-cash Compensation Expense in the first nine months of 2015 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2014 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $1,159.4 million in the first nine months of 2015 from $919.6 million in the same period of 2014. The following table summarizes the major categories of our research and development expenses:

Research and Development Expenses	**Nine Months Ended September 30,**		**Increase**
(In millions)	**2015**	**2014**	**(Decrease)**
Payroll and benefits [1]	$ 365.9	$ 288.6	$ 77.3
Clinical trial expenses	212.2	147.5	64.7
Clinical manufacturing costs [2]	306.0	191.5	114.5
Research and other development costs	98.6	110.4	(11.8)
Occupancy and other operating costs	97.6	85.6	12.0
Cost-sharing of Bayer HealthCare and Sanofi development expenses [3]	79.1	96.0	(16.9)
Total research and development expenses	$ 1,159.4	$ 919.6	$ 239.8

[1] Includes Non-cash Compensation Expense of $154.2 million for the nine months ended September 30, 2015 and $113.9 million for the nine months ended September 30, 2014.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Also includes Non-cash Compensation Expense of $28.9 million for the nine months ended September 30, 2015 and $19.3 million for the nine months ended September 30, 2014.

[3] Under our collaborations with Bayer HealthCare and Sanofi, in periods when Bayer HealthCare or Sanofi incurs certain development expenses, we also recognize, as additional research and development expense, the portion of our collaborators' development expenses that we are obligated to reimburse. Our collaborators provide us with estimated development expenses for the most recent fiscal quarter. Bayer HealthCare and Sanofi's estimates are reconciled to their actual expenses for such quarter in the subsequent fiscal quarter, and our portion of our collaborators' development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased primarily due to additional costs for clinical studies of dupilumab and fasinumab, partly offset by lower Praluent-, EYLEA-, and REGN1033-related costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of dupilumab, Praluent, sarilumab, and, to a lesser extent, several other antibody product candidates.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaborations with Bayer HealthCare and Sanofi, the portion of Bayer HealthCare and Sanofi's respective development expenses which they incur and we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**Nine Months Ended September 30,**		**Increase**
(In millions)	**2015**	**2014**	**(Decrease)**
Praluent	$ 195.2	$ 222.5	$ (27.3)
Dupilumab	269.2	118.7	150.5
Sarilumab	67.4	65.4	2.0
EYLEA	52.4	89.0	(36.6)
Other antibody candidates in clinical development	191.4	149.1	42.3
Other research programs and unallocated costs	383.8	274.9	108.9
Total research and development expenses	$ 1,159.4	$ 919.6	$ 239.8

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2015 and 2014, and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $543.6 million in the first nine months of 2015 from $344.0 million in the first nine months of 2014 primarily due to higher headcount and related costs, higher Non-cash Compensation Expense principally for the reason described under "*Expenses*" above, and higher commercialization-related expenses related to Praluent. Selling, general, and administrative expenses included $110.8 million and $73.6 million of Non-cash Compensation Expense in the first nine months of 2015 and 2014, respectively.

Cost of Goods Sold

Cost of goods sold was $170.6 million in the first nine months of 2015 and $91.1 million in the first nine months of 2014. Cost of goods sold primarily consists of royalties, as well as costs in connection with producing U.S. EYLEA commercial supplies and various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility. Cost of goods sold increased principally due to the increase in U.S. EYLEA net product sales. In addition, in the first nine months of 2015 and 2014, cost of goods sold included inventory write-downs and reserves totaling $9.9 million and $3.5 million, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer HealthCare, increased to $111.3 million in the first nine months of 2015 from $54.5 million in the first nine months of 2014. This increase was primarily due to the recognition of costs associated with commercial supplies of ZALTRAP, as well as royalties payable to Genentech in connection with higher sales of EYLEA outside the United States and the recognition of costs associated with commercial supplies of EYLEA manufactured for Bayer HealthCare. Under our collaboration arrangements, when the product is sold by our collaborators to third-party customers, our risk of inventory loss no longer exists, and we therefore recognize our related manufacturing costs for the sold product as cost of collaboration manufacturing. However, as described above, in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi. As a result, in the first quarter of 2015 we recognized as expense $20.2 million of previously inventoried costs for ZALTRAP commercial supplies that were shipped to Sanofi because our risk of inventory loss no longer exists under the Amended ZALTRAP Agreement.

Other Income and Expense

Total other expenses (net of other income) decreased to $23.0 million in the first nine months of 2015 from $36.6 million in the first nine months of 2014. Interest expense in the first nine months of 2015 decreased compared to the first nine months of 2014 primarily due to conversions of a substantial principal amount of our Notes since the third quarter of 2014. In addition, in the first nine months of 2015 and 2014, we recognized a $16.9 million and a $10.8 million loss, respectively, in connection with Notes which were surrendered for conversion during the respective periods.

Income Taxes

In the first nine months of 2015 and 2014, we recorded income tax expense of $516.7 million and $323.5 million, respectively. The effective tax rate was 51.8% for the first nine months of 2015 and 56.6% for the first nine months of 2014. The effective tax rate for the first nine months of 2015 was negatively impacted, compared to the U.S. federal statutory rate, by (i) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, (ii) the non-tax deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

The effective tax rate for the first nine months of 2014 was negatively impacted, compared to the U.S. federal statutory rate, by (i) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, (ii) expiration at the end of 2013 of the federal tax credit for increased research activities, (iii) the incremental charge related to the non-tax deductible Branded Prescription Drug Fee (as described above), and (iv) New York State tax legislation enacted in the first quarter of 2014. This tax legislation reduced the New York State income tax rate to zero percent for "qualified manufacturers," including Regeneron, effective in 2014; however, it also resulted in the reduction of our related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in our effective tax rate by 2.2% for the first nine months of 2014.

Liquidity and Capital Resources

The sources and uses of cash discussion below reflects certain revisions to previously-issued financial statements. See Notes 1 and 4 of the Notes to Condensed Consolidated Financial Statements for a description of such revisions.

Sources and Uses of Cash for the Nine Months Ended September 30, 2015 and 2014

As of September 30, 2015, we had $1,577.0 million in cash, cash equivalents, and marketable securities compared with $1,360.6 million as of December 31, 2014. Additionally, as of September 30, 2015, we had borrowing availability of $750.0 million under a revolving credit facility that was entered into during the first quarter of 2015 (see further description under "*Credit Facility*" below).

Cash Provided by Operating Activities

Net cash provided by operating activities was $1,049.0 million in the first nine months of 2015. Our net income of $481.1 million in the first nine months of 2015 included Non-cash Compensation Expense of $300.7 million and depreciation and amortization of $52.0 million. In addition, deferred tax assets as of September 30, 2015 increased by $66.0 million, compared to December 31, 2014, primarily due to an increase in Non-cash Compensation Expense, partly offset by an increase in deferred tax liabilities associated with earnings of foreign subsidiaries.

As of September 30, 2015, Sanofi, Bayer HealthCare, and trade accounts receivable increased by $462.9 million, compared to December 31, 2014, primarily due to higher U.S. EYLEA sales and higher amounts due from Sanofi in connection with the companies' Antibody Collaboration. Inventories as of September 30, 2015 increased by $81.5 million, compared to December 31, 2014, primarily due to increased production of EYLEA commercial supplies as well as capitalization of Praluent inventory. Deferred revenue increased by $624.1 million as of September 30, 2015, compared to December 31, 2014, primarily due to $640.0 million of upfront payments received from Sanofi in connection with the companies' IO Collaboration. Accounts payable, accrued expenses, and other liabilities increased by $164.7 million as of September 30, 2015, compared to December 31, 2014, primarily due to (i) higher accruals for sales-related charges and deductions, and royalties related to EYLEA, (ii) higher expenditures in connection with our expanding research and development activities, (iii) higher payroll and payroll-related costs, and (iv) higher tax-related liabilities.

Net cash provided by operating activities was $554.3 million in the first nine months of 2014. Our net income of $248.0 million in the first nine months of 2014 included Non-cash Compensation Expense of $208.7 million and depreciation and amortization of $38.6 million. In addition, deferred tax assets as of September 30, 2014 increased by $34.2 million, compared to end-of-year 2013, primarily due to an increase in Non-cash Compensation Expense and a credit for alternative minimum tax paid, partly offset by the reduction of our deferred tax assets related to the New York State tax legislation enacted in the first quarter of 2014, which reduced our New York State income tax rate to zero percent effective in 2014.

As of September 30, 2014, Sanofi, Bayer HealthCare, and trade accounts receivable decreased by $53.6 million, compared to December 31, 2013, primarily due to lower trade accounts receivable resulting from shortened payment terms to certain of our U.S. EYLEA customers effective January 2014, partly offset by higher amounts receivable from Bayer HealthCare in connection with the commercialization of EYLEA outside the United States. Inventories increased by $50.9 million, compared to December 31, 2013, primarily in connection with increased production of EYLEA commercial supplies. Accounts payable, accrued expenses, and other liabilities increased by $76.5 million at September 30, 2014, compared to December 31, 2013, primarily due to higher accruals for sales-related charges, including the impact of the Branded Prescription Drug Fee incremental charge as described above, and higher accruals related to various clinical studies and capital expenditures.

Cash Used in Investing Activities

Net cash used in investing activities was $784.3 million and $477.4 million in the first nine months of 2015 and 2014, respectively. In the first nine months of 2015 and 2014, purchases of marketable securities exceeded sales or maturities by $284.1 million and $262.0 million, respectively. Capital expenditures were $500.2 million and $215.5 million in the first nine month of 2015 and 2014, respectively. Capital expenditures in the first nine months of 2015 primarily included costs in connection with renovations of our Limerick, Ireland manufacturing facility, tenant improvement and associated costs related to two new buildings at our leased Tarrytown, New York facilities, and expansion of our Rensselaer, New York manufacturing facilities. In addition, in April 2015, we acquired an approximate 100-acre parcel of undeveloped land adjacent to our current Tarrytown, New York location for an aggregate purchase price of $73.0 million. We intend to develop this property to accommodate and support our growth, primarily in connection with expanding our existing research and development and office space. Capital expenditures in the first nine months of 2014 primarily included costs in connection with expanding our Rensselaer, New York manufacturing facilities, tenant improvement and associated costs related to our leased facilities in Tarrytown, New York, and the acquisition and renovations of our Limerick, Ireland manufacturing facility.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $258.8 million in the first nine months of 2015 and net cash provided by financing activities was $34.1 million in the first nine months of 2014. In the first nine months of 2015, proceeds in connection with facility and capital leases obligations primarily relates to reimbursements of $27.4 million we received from our landlord for tenant improvement costs in connection with our leased facilities in Tarrytown, New York. In the first nine months of 2015 and 2014, $146.0 million and $61.1 million principal amount of our Notes, respectively, that was previously surrendered for conversion was settled. In accordance with the terms of the Notes, we elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted Notes, and shares of our Common Stock in respect of any amounts due in excess thereof. Also during the first nine months of 2015 and 2014, we paid an aggregate amount of $523.5 million and $143.0 million, respectively, to warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants. Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $150.4 million in the first nine months of 2015, compared to $80.8 million in the first nine months of 2014. In addition, payments for employee tax obligations in connection with stock option exercises and vesting of restricted stock were $71.7 million in the first nine months of 2015 compared to $175.9 million in the first nine months of 2014. Cash flows from financing activities also increased by $305.6 million and $334.1 million in the first nine months of 2015 and 2014, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations.

Credit Facility

In March 2015, we entered into an agreement with a syndicate of lenders (the Credit Agreement) which provides for a $750.0 million senior unsecured five-year revolving credit facility (the Credit Facility). The Credit Agreement includes an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty. We had no borrowings outstanding under the Credit Facility as of September 30, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Credit Facility as of September 30, 2015.

Immuno-Oncology Collaboration with Sanofi

As described above under "Collaboration Agreements - Collaborations with Sanofi," in July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology. The IO Collaboration is governed by an IO Discovery Agreement and an IO License and Collaboration Agreement. In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable upfront payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse us for up to $825.0 million of these costs, subject to certain annual limits (including an annual limit of $55.0 million in 2015), to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Pursuant to the IO Discovery Agreement, we will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of IND Applications, and clinical development through proof-of-concept. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable upfront payment to us. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with us through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between us and Sanofi on a candidate-by-candidate basis. Sanofi will fund

drug candidate development costs up front for the candidates for which it is the principal controlling party and we will reimburse half of the total development costs for all such candidates from our share of future profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for the drug candidates for which we are the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (REGN2810). The parties will share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. We will have principal control over the development of REGN2810 and will lead commercialization activities in the Unites States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. We will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

Fasinumab Collaboration with Mitsubishi Tanabe Pharma

As described above under "Collaboration Agreements - Collaborations with Mitsubishi Tanabe Pharma," in September 2015, we and MTPC entered into a collaboration agreement providing MTPC with development and commercial rights to fasinumab in Japan and certain other countries in Asia. In connection with the agreement, MTPC made a $10.0 million non-refundable upfront payment, and we are entitled to receive up to an aggregate of $65.0 million in development milestones achieved by us and $150.0 million in other contingent payments, primarily related to development milestones achieved by MTPC.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

Tarrytown, New York Lease

In April 2013, we entered into a new lease agreement for approximately 297,000 square feet of additional new laboratory and office space to be constructed in two new buildings (the Buildings), which was completed in the third quarter of 2015, at our current Tarrytown, New York location. The term of the lease, which commenced during the second half of 2014, is approximately 15 years and contains three renewal options to extend the term of the lease by five years each. The lease provides for (i) monthly payments over its term, which will commence in the fourth quarter of 2015 and will be based on the landlord's costs of construction and tenant allowances, and (ii) additional charges for utilities, taxes, and operating expenses. Based upon various factors, including our involvement in the Buildings' construction and our responsibility for directly paying for a substantial portion of tenant improvements, we are deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of Financial Accounting Standards Board (FASB) authoritative guidance. Consequently, in addition to capitalizing the tenant improvements, we capitalize the landlord's costs of constructing these new facilities, offset by a corresponding facility lease obligation. In addition, we recognize, as additional facility lease obligation, reimbursements from our landlord for tenant improvement costs that we incurred since, under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation. We will allocate a portion of our future lease payments to the Buildings and the land on which the Buildings were constructed. The land element of the lease is treated for accounting purposes as an operating lease. As of September 30, 2015 and December 31, 2014, the Buildings' facility lease obligation balance was $207.1 million and $152.8 million, respectively.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $500.2 million in the first nine months of 2015 and $215.5 million in the first nine months of 2014 (as described under "*Cash Used in Investing Activities*" above). We expect to incur capital expenditures of approximately $125 million to $175 million in the fourth quarter of 2015 primarily in connection with renovating our new Limerick, Ireland facility, tenant improvements primarily related to the Buildings at our leased Tarrytown, New York facilities, and expanding and renovating a portion of our manufacturing facilities at our Rensselaer, New York facility.

Funding Requirements

We expect continued increases in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), capital expenditures, costs related to the preparation for potential commercialization of our late-stage antibody product candidates, and commercialization of EYLEA and Praluent. We believe that our existing capital resources, borrowing availability under our revolving credit facility, funds generated by anticipated EYLEA net product sales, and, as described above under "Collaboration Agreements," funding for reimbursement of research and development costs that we are entitled to receive under our collaboration agreements with Sanofi and Bayer HealthCare, will enable us to meet our projected operating needs for the foreseeable future.

Under our Antibody Collaboration with Sanofi and our collaboration with Bayer HealthCare for EYLEA outside the United States, we and our collaborator share profits and losses in connection with commercialization of drug products. Profits or losses under each collaboration are measured by calculating net sales less cost of goods sold and shared commercialization and other expenses. If the applicable collaboration is profitable, we have contingent contractual obligations to reimburse Sanofi and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses funded by Sanofi and Bayer HealthCare. These reimbursements would be deducted each quarter, in accordance with a formula, from our share of the collaboration profits (and, for our EYLEA collaboration with Bayer HealthCare, our percentage on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. In particular, as of December 31, 2014, our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately $262 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration was approximately $1,308 million. Therefore, we expect that, for the foreseeable future, a portion of our share of profits from sales of EYLEA outside the United States and a portion of our share of profits, if any, from sales of Praluent will be used to reimburse our collaborator for this obligation.

We enter into research collaboration and licensing agreements that may require us to pay amounts upon the achievement of various development and commercial milestones, which, in the aggregate, could be significant. For example, in May 2013, we acquired from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications; consequently, we are obligated to pay up to $20.0 million in potential additional development milestones as well as royalties on any future sales of PDGF antibodies. Additionally, if required by the agreement, we may be required to make royalty payments calculated based on a percentage of net product sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring and for which the specific timing cannot be predicted.

The amount we need to fund operations will depend on various factors, including revenues from net product sales, the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations (in particular those with Sanofi and Bayer HealthCare). Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above.

In addition to our anticipated commercialization costs for EYLEA and Praluent, our commercialization costs over the next few years will depend on, among other things, whether or not our antibody product candidates in later stage clinical development receive regulatory approval, the market potential for product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on sales of certain commercial products. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay additional royalties or share the profits from such sales pursuant to our license or collaboration agreements. In addition, under the provisions of the PPACA and the Health Care and Education Reconciliation Act of 2010, the Branded Prescription Drug Fee is imposed on pharmaceutical manufacturers that sell branded

prescription drugs to specified government programs. This fee is allocated to companies, including Regeneron, based on their market share of total branded prescription drug sales into these government programs.

As described above, in the first nine months of 2015 and 2014, we made cash payments of $71.7 million and $175.9 million, respectively, for employee tax obligations in connection with stock option exercises and vesting of restricted stock. Future cash requirements for such payments will depend on various factors, including the level of stock option grants and exercises and the sales prices of our Common Stock, and may continue to be substantial.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will be substantial.

In the third and fourth quarters of 2015, we received notifications that an additional $20.5 million aggregate principal amount of our Notes were surrendered for conversion, and settlement is anticipated during the fourth quarter of 2015. We elected to settle these conversion obligations through a combination of cash and shares (total payment will be based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the Notes). In connection with these Note conversions, we exercised a proportionate amount of our Note hedges, for which we expect to receive shares of Common Stock approximately equal to the number of shares we will be required to issue to settle the non-cash portion of the related Note conversions. In future periods, other holders of these debt securities may surrender their Notes for conversion.

We may also from time to time seek to repurchase or retire our outstanding Notes, or other outstanding securities, through cash purchases or exchanges for other securities, in open market purchases, privately negotiated transactions, or otherwise.

Due primarily to the amounts of our tax credit carry-forwards available for tax purposes, which totaled approximately $146 million as of December 31, 2014, and potential excess tax benefits in connection with stock option exercises, we expect our cash income tax payments for 2015 to be significantly less than the income tax expense recorded in our financial statements in 2015, which is based on an effective tax rate. However, we expect our cash income tax payments in 2015 to be substantially higher than such payments in 2014.

Future Impact of Recently Issued Accounting Standards

In May 2014, the FASB issued a new standard related to revenue recognition, *Revenue from Contracts with Customers*, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. In July 2015, the FASB decided to delay the effective date of the new standard by one year; as a result, the new standard will be effective for interim and annual reporting periods beginning after December 15, 2017. Early adoption will be permitted, but no earlier than 2017 for calendar year-end entities. The standard allows for two transition methods - retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. We have not yet determined our method of transition and are evaluating the impact that this guidance will have on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures Around Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (filed February 12, 2015). There have been no material changes to our market risks or to our management of such risks as of September 30, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business, including those described in our Annual Report on Form 10-K for the year ended December 31, 2014 (filed February 12, 2015), our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015 (filed May 7, 2015), our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015 (filed August 4, 2015), and those described below. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. For a description of risks relating to these and other legal proceedings we face, see Part II, Item 1A. "Risk Factors," including the discussion under the headings entitled "Risks Related to Intellectual Property and Market Exclusivity," "Regulatory and Litigation Risks," and "Risks Related to Our Common Stock."

Proceedings Relating to '287 Patent and '018 Patent

As previously reported, we are parties to patent infringement litigation involving our European Patent No. 1,360,287 (the '287 Patent) and our U.S. Patent No. 8,502,018 (the '018 Patent), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse.

On October 19, 2015, following the grant of our European Patent No. 2,264,163 (the '163 Patent) by the European Patent Office, we added an infringement claim based on the '163 Patent to our '287 Patent infringement litigation against Kymab Ltd and Novo Nordisk A/S in the English High Court of Justice, Chancery Division, Patents Court, in London (previously consolidated into a single case). Both Kymab and Novo Nordisk counterclaimed alleging invalidity of the '163 Patent. A trial to adjudicate the claims of infringement and invalidity of the '287 Patent and the '163 Patent is currently set to begin in the week of November 16, 2015.

On November 2, 2015, the United States District Court for the Southern District of New York issued an opinion and order in our '018 Patent infringement litigation against Merus B.V. finding that the '018 Patent was procured by inequitable conduct, thus rendering it unenforceable. We plan to appeal the court's order.

Proceedings Relating to Praluent (alirocumab) Injection

As previously reported, we are currently a party to a patent infringement action initiated by Amgen Inc. against us and Sanofi relating to Praluent, which we are jointly developing and commercializing with Sanofi. On September 15, 2015, Amgen filed a motion for leave to file a supplemental and second amended complaint. The complaint alleges, among other things, willful infringement of the asserted patents, which would entitle Amgen to treble damages if the court finds willful infringement. We and Sanofi have opposed the motion, and the parties are awaiting the court's decision on the motion. The trial is currently set to begin on March 7, 2016, and a permanent injunction hearing (which would be held if the court finds infringement by us and Sanofi) is currently scheduled to begin on March 23, 2016.

Proceedings Relating to Patents Owned by Genentech and City of Hope

As previously reported, we and Sanofi-Aventis U.S. LLC are parties to litigation concerning U.S. Patent No. 7,923,221 (the '221 Patent), which is jointly owned by Genentech, Inc. and City of Hope and relates to the production of recombinant antibodies in host cells. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by us and Sanofi and counterclaimed, alleging that we and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Commercialization of EYLEA

We are substantially dependent on the success of EYLEA. If we or Bayer HealthCare are unable to continue to successfully commercialize EYLEA, our business, prospects, operating results, and financial condition will be materially harmed.

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the nine months ended September 30, 2015 and 2014, EYLEA net sales in the United States represented 64% and 60% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer HealthCare were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer HealthCare are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

We expect that the continued commercial success of EYLEA will depend on many factors, including the following:

- effectiveness of the commercial strategy in and outside the United States for the marketing of EYLEA, including pricing strategy and the continued effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEA as compared to the dosing regimen of Lucentis® (ranibizumab), and the willingness of retinal specialists and patients to switch from Lucentis or off-label use of repackaged Avastin® (bevacizumab) to EYLEA;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our ability to maintain sales of EYLEA in the face of competitive products, including those currently in clinical development; and
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices.

More detailed information about the risks related to the commercialization of EYLEA is provided below.

We and Bayer HealthCare are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA. If we or Bayer HealthCare fail to maintain regulatory compliance for EYLEA, EYLEA marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition.

We and Bayer HealthCare are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA for its currently approved indications in the United States, EU, and other countries where the product is approved. If we or Bayer HealthCare fail to maintain regulatory compliance for EYLEA for its currently approved indications (including for any of the reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain*"), EYLEA marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - *If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales*" below.

Serious complications or side effects in connection with the use of EYLEA could materially harm our business, prospects, operating results, and financial condition.

Serious complications or serious, unexpected side effects in connection with the use of EYLEA could materially harm our business, prospects, operating results, and financial condition. For additional information about some of these risks, see "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition*" below.

Sales of EYLEA are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Our sales in the United States of EYLEA are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in large part, on similar programs in those countries. In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. Economic pressure on state budgets may also have a similar impact. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of EYLEA. Since EYLEA is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "Risks Related to Commercialization of Products - *The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*" below.

The commercial success of EYLEA is subject to strong competition.

The market for eye disease products is very competitive. Novartis and Genentech/Roche are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of wet AMD, macular edema following RVO, DME, visual impairment due to mCNV, diabetic retinopathy in patients with DME, and other eye indications. Lucentis was approved by the FDA in June 2006 for the treatment of wet AMD, in June 2010 for the treatment of macular edema following RVO (including CRVO and BRVO), in August 2012 for the treatment of DME, and in February 2015 for the treatment of diabetic retinopathy in patients with DME. Lucentis was also approved by the EMA for wet AMD in January 2007, for DME in January 2011, for the treatment of macular edema following RVO (including CRVO and BRVO) in June 2011, and for mCNV in July 2013. Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Pfenex Inc. is developing PF582 (currently in a Phase 1b/2a trial in patients with wet AMD), and Formycon AG (in collaboration with bioeq GmbH) is developing FYB201 (currently in a Phase 3 trial in patients with wet AMD). Other competitive or potentially competitive products include Allergan's Ozurdex® (dexamethasone intravitreal implant) (approved by the FDA in June 2009 for the treatment of macular edema following RVO and in September 2014 for the treatment of DME) and Alimera Sciences' Iluvien® (fluocinolone acetonide intravitreal implant) (approved by the FDA in September 2014 for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids.

Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, and RVO, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. For example, Genentech/Roche is developing a Lucentis port delivery system implant (currently in a Phase 2 study in patients with wet AMD). Novartis is developing ESBA1008 (RTH258), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated a non-inferiority Phase 3 trial comparing RTH258 (ESBA1008) and EYLEA in December 2014. Allergan is developing abicipar pegol (an anti-VEGF-A DARPin®) for wet AMD and related conditions (currently studied in Phase 3 trials against Lucentis as a comparator drug). Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, PDGF). Ophthotech Corporation is developing Fovista™, an aptamer directed against platelet-derived growth factor subunit B (PDGF-B), as a product candidate intended to be used in combination with an anti-VEGF therapy in wet AMD. In 2013, Ophthotech initiated Phase 3 trials in AMD evaluating multiple combinations of Fovista, including Lucentis + Fovista, Avastin + Fovista, and EYLEA + Fovista. Genentech/Roche is developing a bi-specific antibody targeting both VEGF and Ang2 for wet AMD (currently in a Phase 2 trial in patients with wet AMD). Competitors are also developing eye-drop formulations, oral therapies, and gene/cell therapies for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

In addition, ophthalmologists are using with success off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, Avastin, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged Avastin in patients with wet AMD presents a significant competitive challenge in this indication. Competitors (including Amgen) are also developing a biosimilar version of Avastin. Long-term, controlled clinical trials comparing Lucentis to Avastin in the treatment of wet AMD are being conducted. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT) were reported in April 2011 and indicated that Avastin dosed monthly was non-inferior to Lucentis dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Two-year data from CATT were reported in April 2012 and indicated that monthly Avastin was non-inferior to monthly Lucentis in mean visual acuity gain; as-needed dosing was *not* non-inferior to monthly dosing. Avastin is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other countries. Furthermore, Lucentis and off-label use of repackaged Avastin present significant competitive challenges as doctors and patients have had significant experience using these medicines. Moreover, the reported results of the CATT study, combined with the relatively low cost of repackaged Avastin in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA faces in this or other eye indications for which it may be approved. Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, and while we believe that ZALTRAP would not be well tolerated if administered directly to the eye, there is a risk that third parties may attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for its approved indications. See also "Risks Related to Commercialization of Products - *We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects*" below.

We rely on our collaboration with Bayer HealthCare for commercializing EYLEA.

While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, our commercialization experience is still relatively limited and we have no sales, marketing, commercial, or distribution capabilities outside the United States.

Under the terms of our license and collaboration agreement with Bayer HealthCare (which is terminable by Bayer HealthCare at any time upon six or twelve months' advance notice), we rely on Bayer HealthCare for sales, marketing, and distribution of EYLEA in countries outside the United States. If we and Bayer HealthCare are unsuccessful in continuing to commercialize EYLEA, our ability to sustain profitability would be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Therefore, termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA, particularly outside the United States. For additional information regarding our collaboration with Bayer HealthCare, see "Risks Related to Our Reliance on Third Parties - *If our collaboration with Bayer HealthCare for EYLEA is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed*" below.

Sales of EYLEA recorded by us and Bayer HealthCare could be reduced by imports from countries where EYLEA may be available at lower prices.

Our sales of EYLEA in the United States and Bayer HealthCare's sales of EYLEA in other countries may be reduced if EYLEA is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer HealthCare, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer HealthCare. Prices for EYLEA in territories outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and our sales of EYLEA in the United States may be reduced if EYLEA marketed in those nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of EYLEA in a particular market or reduce our or Bayer HealthCare's sales, thereby adversely affecting our results of operations. In addition, there have been proposals to legalize the import of pharmaceuticals from outside the United States. If such legislation were enacted, our future revenues derived from EYLEA sales could be reduced.

Risks Related to Commercialization of Praluent

If we and Sanofi are unable to successfully commercialize Praluent, our business, prospects, operating results, and financial condition may be materially harmed.

We expect that the commercial success of Praluent will depend on many factors, including the following:

- effectiveness of the commercial strategy in and outside the United States for the marketing of Praluent, including pricing strategy and the effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- our and Sanofi's ability to effectively communicate to the marketplace the benefits of Praluent;
- the ability of patients and providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our and Sanofi's ability to maintain sales of Praluent in the face of competitive products, including those currently in clinical development;
- the impact of post-approval studies of Praluent (including the ongoing ODYSSEY OUTCOMES trial prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit), whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about Praluent (or data about products similar to Praluent that implicate an entire class of products or are perceived to do so);
- our ability to meet the demand for commercial supplies of Praluent;
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices; and
- maintaining and successfully monitoring commercial manufacturing arrangements for Praluent with third parties who perform fill/finish or other steps in the manufacture of Praluent to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities.

More detailed information about the risks related to the commercialization of Praluent is provided below.

We and Sanofi are subject to significant ongoing regulatory obligations and oversight with respect to Praluent. If we or Sanofi fail to maintain regulatory compliance for Praluent, Praluent marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition.

We and Sanofi are subject to significant ongoing regulatory obligations and oversight with respect to Praluent for its currently approved indications in the United States and the EU. If we or Sanofi fail to maintain regulatory compliance for Praluent for its currently approved indications (including because Praluent does not meet the relevant endpoints of any required post-approval studies, such as the ongoing ODYSSEY OUTCOMES trial, or for any of the other reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain*"), Praluent marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - *If we fail to*

meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales" below.

Serious complications or side effects in connection with the use of Praluent could materially harm our business, prospects, operating results, and financial condition.

Serious complications or serious, unexpected side effects in connection with the use of Praluent could materially harm our business, prospects, operating results, and financial condition. For additional information about some of these risks, see "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition*" below.

Sales of Praluent are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Sales in the United States of Praluent are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of Praluent in other countries are dependent, in large part, on similar programs in those countries.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. For example, pharmacy benefit management companies often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one pharmacy benefit management company to another. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of Praluent. If Praluent is not included within an adequate number of formularies, adequate reimbursement levels are not provided, or the eligible insured patient population for Praluent is limited, this could have a material adverse effect on our and Sanofi's ability to commercialize Praluent.

In the United States, there also is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. Economic pressure on state budgets may also have a similar impact. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of Praluent. Since Praluent is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize Praluent will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "Risks Related to Commercialization of Products - *The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*" below.

The commercial success of Praluent is subject to strong competition.

There is significant actual and potential future competition for Praluent. Amgen's PCSK9 program is currently the most advanced of the competitors, having already received regulatory approval from the FDA and marketing authorization from the European Commission for its PCSK9 inhibitor Repatha™ (evolocumab). Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries. Several other companies, including Pfizer, also have development programs for antibodies against PCSK9. Alnylam, in partnership with The Medicines Company, has a clinical program underway with an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including an oral product. Oral products that lower LDL-C, if approved, may also be competitive with PCSK9 inhibitors, including Praluent. Certain late-stage inhibitors of cholesterylester transfer protein (CETP), such as Merck's anacetrapib, lower LDL-C and may be launched with supporting data from outcomes trials prior to the completion of our own outcomes trial for Praluent. Another oral agent that lowers LDL-C and that may potentially compete with Praluent is Esperion's ETC-1002.

We rely on our Antibody Collaboration with Sanofi for commercializing Praluent.

In accordance with the terms of our Antibody Collaboration with Sanofi, we have elected to co-promote Praluent with Sanofi in the United States. However, we continue to rely in part on Sanofi's sales and marketing organization in the United States. Sanofi also maintains other important responsibilities relating to Praluent in the United States. For example, Sanofi records product sales and cost of sales for Praluent in the United States, serves as the lead regulatory party (*e.g.*, is responsible for regulatory filings and negotiations relating to Praluent in the United States), and leads negotiations with payors. We also rely on Sanofi for sales, marketing, and distribution of Praluent in countries outside the United States. If we and Sanofi are unsuccessful in commercializing Praluent, or if Sanofi terminates the Antibody Collaboration with us, our business, prospects, operating results, and financial condition may be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for Praluent. Therefore, termination of our Antibody Collaboration would create substantial new and additional risks to the successful commercialization of Praluent, particularly outside the United States. For additional information regarding our Antibody Collaboration with Sanofi, see "Risks Related to Our Reliance on Third Parties - *If any of our collaborations with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed*" below.

Sales of Praluent recorded by Sanofi could be reduced by imports from countries where Praluent may be available at lower prices.

Sales of Praluent in the United States and other countries recorded by Sanofi may be reduced if Praluent is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our Antibody Collaboration with Sanofi, pricing and reimbursement for Praluent outside the United States is the responsibility of Sanofi. Prices for Praluent in territories outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and sales of Praluent in the United States that are recorded by Sanofi may be reduced if Praluent marketed in those bordering nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of Praluent in a particular market or the sales recorded by Sanofi, thereby adversely affecting our results of operations. In addition, there have been proposals to legalize the import of pharmaceuticals from outside the United States. If such legislation were enacted, our future revenues derived from Praluent sales could be reduced.

Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products

If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.

We cannot sell or market products without regulatory approval. If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products, the value of our company and our business, prospects, operating results, and financial condition will be materially harmed. If we are unable to obtain regulatory approval for our product candidates, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition may be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible

that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. Its ability to do so has been enhanced by the Food and Drug Administration Amendments Act of 2007, pursuant to which the FDA has the explicit authority to require postmarketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. Standard review can be accomplished in a ten-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within 6 months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending. Even if any of our applications receives a priority review designation, we may not ultimately be able to obtain approval of our application within a time frame consistent with the FDA's stated review goals or at all, and such designation may not actually lead to a faster development or regulatory review or approval process.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, their implementation may not be clearly delineated and may present a challenging task. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, prospects, operating results, and financial condition may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process is similarly likely to be a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities often also have the authority to require post-approval studies, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to Good Laboratory Practices (GLPs) or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. For example, a randomized, double-blind Phase 3 trial (VENICE) that evaluated ZALTRAP as a first-line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone did not meet the pre-specified criterion of improvement in overall survival in April 2011. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP as a first-line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

We are studying our antibody candidates in a wide variety of indications in clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our company.

Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

EYLEA is being studied in diseases of the eye in addition to those covered by its currently approved indications and as a combination product. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize EYLEA. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like EYLEA (such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, and retinal tear), which can cause injury to the eye and other complications. For example, in our Phase 3 trials of EYLEA in wet AMD, the most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. These and other complications or side effects could harm further development and/or commercialization of EYLEA.

The potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing ODYSSEY OUTCOMES trial. There is no guarantee that Praluent will meet the relevant endpoints of this trial. In addition, there are potential safety concerns associated with PCSK9 inhibitor antibodies such as Praluent that may limit our ability to further successfully develop and/or commercialize Praluent, including new-onset diabetes mellitus, injection-site reactions, hypersensitivity, immunogenicity, demyelination, and changes in neurocognitive function. There also are risks inherent in subcutaneous injections, including subcutaneous injections with Praluent, such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. These and other complications or side effects could harm further development and/or commercialization of Praluent.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross-react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so neutralizing antibodies may be detected at a later date, in some cases even after pivotal clinical trials have been completed.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition.

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

Some of our products and, if approved, product candidates may be used with drug delivery devices, which have their own regulatory and other risks.

Some of our products (such as Praluent) are used and, if approved, some of our product candidates may be used in combination with a drug delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. The success of our product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application, our product candidates used with such drug delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. In addition, some of these drug delivery devices may be provided by single-source, third-party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third-party providers or collaborators to supply the devices; to conduct the studies required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our company, our collaborators, or the third-party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product candidate reaching the market. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 1,360,287 has been the subject of opposition proceedings in the European Patent Office, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2014. We have pending patent applications in the United States Patent and Trademark Office, the European Patent Office, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Certain of our U.S. patents may also be challenged by parties who file a request for post-grant review under the America Invents Act of 2011. We expect that post-grant review proceedings will become common in the United States and will be costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to damage awards if we are found to have infringed such patents or rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune* technology, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving our patents. For example, we are currently parties to patent infringement proceedings initiated by us relating to our European Patent No. 1,360,287 and our U.S. Patent No. 8,502,018, both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2014, Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015, and Part II, Item 1. "Legal Proceedings" of this report. In addition, we are currently parties to patent infringement proceedings initiated by Amgen against us and Sanofi relating to Praluent, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2014, Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, and Part II, Item 1. "Legal Proceedings" of this report. We are aware of additional patents and pending applications owned by others that claim antibodies to PCSK9 and methods of treating hypercholesterolemia with such antibodies. We are also aware of patents and pending applications owned by others that respectively claim antibodies to IL-6R and IL-4R and methods of treating rheumatoid arthritis and uveitis and atopic dermatitis and asthma with such antibodies. In addition to Praluent, our late-stage antibody-based pipeline includes sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis and non-infectious uveitis; dupilumab, an antibody to IL-4R, for the treatment of atopic dermatitis, asthma, chronic sinusitis with nasal polyposis, and eosinophilic esophagitis; REGN2222, an antibody targeting RSV-F; and fasinumab, an antibody to NGF. Although we do not believe that any of our late-stage antibody product candidates infringes any valid claim in these patents or patent applications, these other parties could initiate a lawsuit for patent infringement and assert their patents are valid and cover our late-stage antibody product candidates, similar to the patent infringement proceedings initiated by Amgen referred to above. As described in Part II, Item 1. "Legal Proceedings" of this report, we and Sanofi-Aventis U.S. LLC initiated invalidity actions against patents jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product and antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST nor EYLEA is a recombinant antibody. Genentech has licensed these patents to several different companies under confidential license agreements. If we desire a license for any of our antibody products or product candidates as part of a settlement for these invalidity actions and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to make recombinant antibodies in, or to import them into, the United States. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our product candidates infringe such patents.

Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our products or product candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our products or product candidates infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our products or product candidates, which could severely harm our business.

Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "*If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed*," the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the federal Patient Protection and Affordable Care Act, or PPACA, enacted in 2010, there is an abbreviated path in the United States for regulatory approval of biosimilar versions of biological products. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

We rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to continue to successfully commercialize EYLEA, to commercialize Praluent and, if approved, our product candidates or other indications for our marketed products, and to advance our clinical pipeline.

Our manufacturing facilities would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA, Praluent, ZALTRAP, and ARCALYST, and (b) our antibody product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody product candidates, our current manufacturing capacity will likely not be sufficient, and we may depend on our collaborators or contract manufacturers, to produce adequate quantities of drug material for both commercial and clinical purposes. We rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators, contract manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and late-stage product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.

We have commenced construction of additional manufacturing space at our Rensselaer, New York site to increase our manufacturing capacity. In addition, we have acquired and are renovating a 400,000 square foot facility in Limerick, Ireland to expand our manufacturing capacity to support our global supply chain. In the future, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing activities. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures and various regulatory approvals and permits. In addition, the Limerick, Ireland facility remains subject to securing certain permits from the local government, and there is no guarantee that we will be able to obtain the remaining required permits in the contemplated timeframe, or at all. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize EYLEA, Praluent, and ARCALYST and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

Our ability to manufacture products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture EYLEA, Praluent, ZALTRAP, and ARCALYST in our Rensselaer, New York facilities and, in the future, our ability to manufacture our marketed products at additional facilities, or to utilize third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. A judicial or regulatory decision in favor of one or more parties making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of EYLEA do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties.

We have large-scale manufacturing operations in Rensselaer, New York. We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could adversely affect our operating results.

Third-party service or supply failures, or other failures, business interruptions, or other disasters affecting our manufacturing facilities in Rensselaer, New York or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

We currently manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, acts of war or terrorism, or other problems.

Many of our products and product candidates are very difficult to manufacture. As our products and product candidates are biologics, they require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us in a timely manner), could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and insufficient inventory. Also, the complexity of our manufacturing process may make it difficult, time-consuming, and expensive to transfer our technology to our corporate collaborators or contract manufacturers.

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to manufacture or supply marketed products and product candidates, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facility in Rensselaer, New York, including EYLEA, Praluent, ZALTRAP, and ARCALYST, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Risks Related to Commercialization of Products

We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture, market and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payers, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

For a description of additional risks relating specifically to the commercialization of EYLEA and Praluent, see above under "Risks Related to Commercialization of EYLEA" and "Risks Related to Commercialization of Praluent," respectively.

Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition.

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve commercialization of our product candidates, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

The market for eye disease products is very competitive, as described in greater detail above under "Risks Related to Commercialization of EYLEA - *The commercial success of EYLEA is subject to strong competition*."

There is also significant actual and potential future competition for Praluent, the PCSK9 antibody we are developing and commercializing in collaboration with Sanofi, as described in greater detail above under "Risks Related to Commercialization of Praluent - *The commercial success of Praluent is subject to strong competition*."

Our earlier-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune* technology. Our antibody generation technologies and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in partnership with Eli Lilly), Johnson & Johnson, and AbbVie are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (Actemra®) for the treatment of rheumatoid arthritis, and several other companies, including Johnson & Johnson (in partnership with GlaxoSmithKline), Alder Biopharmaceuticals, Ablynx (in partnership with AbbVie), R-Pharm, and Pfizer have antibodies against IL-6 or IL-6R in clinical development. A number of companies are developing antibodies that, if approved, may compete with dupilumab, our IL-4R antibody, if it is approved, including Roche (an antibody against IL-13), Teva (an antibody against IL-5), AstraZeneca (antibodies against IL-5R and IL-13), Novartis (a combination antibody against IL-4 and IL-13), and Amgen (in partnership with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). For muscle-wasting conditions, Pfizer, Eli Lilly, Bristol-Myers Squibb, and Atara Biotherapeutics have anti-GDF8 monoclonal antibodies in development, and Novartis has a competing antibody targeting ActRIIB. For RSV, competitors have antibodies in clinical development, including AstraZeneca (in partnership with AIMM Therapeutics).

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our products candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition.

Our future revenues and profitability will be adversely affected in a material manner if United States and foreign governmental payers, private third-party insurers and payers (such as health maintenance organizations and pharmacy benefit management companies), and other third-party payers, including Medicare and Medicaid, do not adequately defray or reimburse the cost of our products to the patients. If these entities do not provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payers more expensive for patients. Third-party payers may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply and regulatory review of such products. Given cost sensitivities in many health care systems, our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition.

In addition, in order for private insurance and governmental payers (such as Medicare and Medicaid in the United States) to reimburse the cost of our products, we must, among other things, maintain registration of the products in the National Drug Code registry, maintain our re-labeler license, maintain formulary approval by pharmacy benefits managers, and maintain recognition by insurance companies and the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS). There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage) of our current and future products, which may have a material adverse effect on our business.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the United States. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by CMS and other federal and state agencies. Further, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration" in which the OIG details possible savings to the Medicare program by using off-label, repackaged Avastin rather than Lucentis for the treatment of wet AMD. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since EYLEA and Praluent for their currently approved indications will likely continue to be too expensive for most patients to afford without health insurance coverage, if third-party payers, including Medicare and Medicaid in the United States, do not continue to provide adequate coverage and reimbursement for EYLEA or do not provide adequate coverage and reimbursement for Praluent, our ability to successfully market them would be materially adversely impacted. There is a risk that third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse our current and future products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain

profitability. In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.

We sell EYLEA in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the nine months ended September 30, 2015 and 2014, we recorded 67% and 75%, respectively, of our total gross product revenue from sales to a single distributor, Besse Medical, a subsidiary of AmerisourceBergen Corporation. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

Regulatory and Litigation Risks

If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell approved products in a way that violates federal or state healthcare laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services

reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

As part of the PPACA, the federal government has enacted provisions imposing reporting and disclosure requirements on pharmaceutical manufacturers for any "transfers of value" made to U.S. prescribers and certain other healthcare providers and teaching hospitals. These statutory provisions and related regulations (commonly known as the "Sunshine Act") require pharmaceutical manufacturers to report such transfers of value annually to the Secretary of the U.S. Department of Health and Human Services, which in turn aggregates and posts the information on a website managed by the Centers for Medicare & Medicaid Services. We will need to continue to dedicate significant resources to comply with these requirements. The PPACA also includes various provisions designed to strengthen fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, several states and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, and Vermont, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states and already are in effect in a number of jurisdictions outside of the United States. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business, operating results, and financial condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, a number of which have yet to be fully implemented. Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks associated with our operations outside of the United States could adversely affect our business.

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- other laws and regulatory requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "*Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition*");
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- our ability to deploy overseas funds in an efficient manner;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

We may incur additional tax liabilities related to our operations.

We are subject to income tax in the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from a combination of the applicable statutory rates in the various jurisdictions in which we operate. We record liabilities that involve significant management judgment for uncertain tax positions. The Internal Revenue Service or other domestic or foreign taxing authorities may disagree with our interpretation of tax law as applied to the operations of Regeneron and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns. Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country, the availability of the U.S. research and development tax credit, and changes in tax laws and regulations.

We face potential liability related to the privacy of health information we obtain from research institutions and our collaborators.

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, is collaborating with the Geisinger Health System, which is subject to such regulations, and may enter into collaboration arrangements with additional institutions in the future. Regeneron is not a HIPAA-covered entity and our clinical research efforts are not directly regulated by HIPAA, so we are not subject to civil penalties under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it, may apply to some or all of the clinical data obtained from our collaborators outside of the U.S. Failure by those collaborators to comply with the strict rules on the transfer of personal data outside of the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

Risks Related to Our Reliance on Third Parties

If any of our collaborations with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from Sanofi to support our target discovery and antibody research and development programs, as well as our immuno-oncology research and development programs. Sanofi has committed to reimburse us for up to (i) $405 million of the costs of our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets under our Antibody Discovery Agreement and (ii) $825 million of the costs of our efforts to identify and validate potential immuno-oncology targets and develop fully-human therapeutic antibodies against such targets under the IO Discovery and Development Agreement. Sanofi also initially funds almost all of the development expenses incurred in connection with the clinical development of product candidates (i) that Sanofi elects to co-develop with us under our Antibody Collaboration and (ii) for which Sanofi is the principal controlling party under our IO Collaboration. In addition, Sanofi initially funds half of the development expenses incurred in connection with the clinical development of product candidates for which we are the principal controlling party under our IO Collaboration. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us under our Antibody Collaboration (such as Praluent, sarilumab, and dupilumab) or for which Sanofi is the principal controlling party under our IO Collaboration, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. Following regulatory approval, we also rely on Sanofi to lead (i) the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us under our Antibody Collaboration and (ii) the commercialization efforts outside the Unites States to support all products that are co-developed by Sanofi and us under our IO Collaboration (as well as the commercialization efforts in the United States to support all products for which Sanofi is the principal controlling party under our IO Collaboration).

If Sanofi does not elect to co-develop the product candidates that we discover or opts out of their development under our Antibody Collaboration or our IO Collaboration, unless we enter into a collaboration agreement with another party, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. For example, Sanofi has elected not to continue co-development of fasinumab, REGN2222, and REGN1033, and decided not to opt in to the REGN1193, evinacumab, and other programs.

If Sanofi terminates any of the collaborations with us or fails to comply with its payment obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. If Sanofi does not perform its obligations with respect to the product candidates that it elects to co-develop, our ability to develop, manufacture, and commercialize these product candidates will be significantly adversely affected. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for products commercialized under our Antibody Collaboration, such as Praluent. Termination of our Antibody Collaboration would create substantial new and additional risks to the successful development and commercialization of Praluent, particularly outside the United States.

If our collaboration with Bayer HealthCare for EYLEA is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development, and the commercialization outside the United States, of EYLEA. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global EYLEA development program. As the EYLEA program continues, we will continue to rely on Bayer HealthCare to assist with funding the EYLEA development program, continue to lead the development of EYLEA outside the United States, obtain and maintain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen Pharmaceuticals Co. Ltd. pursuant to a Co-Promotion and Distribution Agreement with Bayer HealthCare's Japanese affiliate. We cannot assure you that regulatory approvals will be received for EYLEA in additional indications outside the United States or that EYLEA will be successfully commercialized outside the United States. If Bayer HealthCare and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEA outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our collaborator, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of EYLEA outside the United States and result in substantial additional costs to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA, particularly outside the United States.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.

We depend upon third-party collaborators, including Sanofi, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers, fill/finish, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these third parties in connection with the commercialization of our marketed products and our late-stage product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, GLPs, or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates.

We and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators' arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed products will suffer.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; George D. Yancopoulos, M.D., Ph.D., President, Regeneron Laboratories and our Chief Scientific Officer; and Neil Stahl, Ph.D., our Executive Vice President, Research and Development. As we continue to commercialize EYLEA and Praluent and begin to commercialize other products assuming the receipt of required regulatory approvals, we are also highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may provide access to our confidential information to such third parties and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Such disruptions and breaches of security could result in legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, and damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Financial Results, Liquidity, and Need for Additional Financing

If we cannot sustain profitability, our business, prospects, operating results, and financial condition would be materially harmed.

Beginning in the first quarter of 2012, we reported profitability; prior to that, we generally incurred net losses. If we cannot sustain profitability, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products on an ongoing basis, including our sales of EYLEA, and our share of the profits from Bayer HealthCare's sales of EYLEA outside the United States, or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the commercialization of EYLEA and Praluent and the anticipated commercial launches of our late-stage product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody product candidates we are developing on our own (without Sanofi), and expenses related to the requirement, following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates being developed in collaboration with Sanofi.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable terms or at all. Our ability to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we are able to obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable

to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of EYLEA, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

Changes in foreign currency exchange rates could have a material adverse effect on our operating results.

Our revenue from outside of the United States will increase as our products, whether marketed by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, British pound sterling, and Australian dollar. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Likewise, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our company.

Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.

As of September 30, 2015, we had $654.6 million in cash and cash equivalents and $922.4 million in marketable securities (including $27.5 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests. If any of our investments suffer market price declines that are other than temporary, their value could be impaired, which may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- fluctuations in our operating results, in particular net product sales of EYLEA;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and fluctuations in market share for, our marketed products, especially EYLEA and Praluent;
- whether our net products sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and pharmacy benefit management companies) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;

- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "*Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings*" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders, and our largest shareholder, Sanofi, has been increasing its ownership of our Common Stock. As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2015, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 47.7% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2015. As of September 30, 2015, Sanofi beneficially owned 23,016,992 shares of our Common Stock, representing approximately 22.5% of the shares of Common Stock then outstanding. Under our January 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time may not be sold until the later of (i) December 20, 2020 and (ii) the expiration of our Antibody Discovery Agreement with Sanofi relating to our Antibody Collaboration (as amended) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our company. In February 2013, we received from Sanofi a notification under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 that it intends to acquire additional Common Stock through open market purchases and direct purchases from shareholders. In July 2014, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase additional shares of our Common Stock to progressively increase its beneficial ownership in 2014 and 2015 up to the maximum allowed under the “standstill” provisions of our amended and restated investor agreement with Sanofi, or 30% of our Class A Stock and Common Stock (taken together). If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2015, holders of Class A Stock held 15.8% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of September 30, 2015:

- our current executive officers and directors beneficially owned 10.0% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2015, and 21.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2015; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 47.7% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2015. In addition, these five shareholders plus our Chief Executive Officer held approximately 53.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2015.

Pursuant to the January 2014 amended and restated investor agreement with us, Sanofi has agreed to vote its shares as recommended by our board of directors, except that it may elect to vote proportionally with the votes cast by all of our other shareholders with respect to certain change-of-control transactions and to vote in its sole discretion with respect to liquidation or dissolution of our company, stock issuances equal to or exceeding 20% of the then outstanding shares or voting rights of Common Stock and Class A Stock (taken together), and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

In addition, upon Sanofi reaching 20% ownership of our then outstanding shares of Class A Stock and Common Stock (taken together), we are required under the amended and restated investor agreement to appoint an individual agreed upon by us and Sanofi to our board of directors. Subject to certain exceptions, we are required to use our reasonable efforts (including recommending that our shareholders vote in favor) to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains an equity interest in us that is the lower of (i) the highest percentage ownership Sanofi attains following its acquisition of 20% of our then outstanding shares of Class A Stock and Common Stock (taken together) and (ii) 25% of our then outstanding shares of Class A Stock and Common Stock (taken together). This designee is required to be "independent" of our company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant of Sanofi. In April 2014, Sanofi notified us that it had reached the 20% ownership threshold and designated Robert A. Ingram as its designee. On April 4, 2014, following recommendation of the Corporate Governance and Compliance Committee, the board of directors elected Mr. Ingram as a director and a member of the Compensation Committee. Mr. Ingram was subsequently elected as a Class I director at our 2014 Annual Shareholder Meeting for a term expiring at the 2016 Annual Shareholder Meeting.

The convertible note hedges and warrant transactions we entered into in connection with our convertible senior notes issuance may affect the trading price of our Common Stock.

In connection with our offering of our 1.875% convertible senior notes due October 1, 2016, we entered into convertible note hedge transactions with four financial institutions (the hedge counterparties), the purpose of which was to reduce the potential dilution to our Common Stock and/or offset potential cash payments in excess of the principal amount of the notes (as applicable) upon conversion of the notes. In the event that the hedge counterparties fail to deliver shares to us or potential cash payments (as applicable) as required under the convertible note hedge documents, we would not receive the benefit of such transactions. Separately, we also entered into warrant transactions with the hedge counterparties. The warrant transactions could separately have a dilutive effect from the issuance of Common Stock pursuant to the warrants. As of September 30, 2015, an aggregate principal amount of $33.1 million of the notes and 2,225,068 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

In connection with hedging these transactions, the hedge counterparties and/or their affiliates may have entered into various derivative transactions with respect to our Common Stock, and may enter into, or may unwind, various derivative transactions and/or purchase or sell our Common Stock or other securities of ours in secondary market transactions prior to maturity of the notes (and are likely to do so during any conversion period related to any conversion of the notes). These activities could have the effect of increasing or preventing a decline in, or could have a negative effect on, the value of our Common Stock and could have

the effect of increasing or preventing a decline in the value of our Common Stock during any cash settlement averaging period related to a conversion of the notes.

In addition, we intend to continue to exercise options under the convertible note hedge transactions whenever notes are converted. In order to unwind their hedge position with respect to the options we exercise, the hedge counterparties and/or their affiliates may sell shares of our Common Stock or other securities in secondary market transactions or unwind various derivative transactions with respect to our Common Stock during the cash settlement averaging period for the converted notes. The effect, if any, of any of these transactions and activities on the trading price of our Common Stock or the notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our Common Stock and the value of the notes. The derivative transactions that the hedge counterparties and/or their affiliates expect to enter into to hedge these transactions may include cash-settled equity swaps referenced to our Common Stock. In certain circumstances, the hedge counterparties and/or their affiliates may have derivative positions that, when combined with the hedge counterparties' and their affiliates' ownership of our Common Stock, if any, would give them economic exposure to the return on a significant number of shares of our Common Stock.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements and our convertible senior notes and related warrant and hedge transactions, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder," a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.*"

Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our License and Collaboration Agreement with Sanofi relating to our Antibody Collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party having more than 10% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our company.

Similarly, under our 2014 PDGFR-beta license and collaboration agreement with Bayer HealthCare, Bayer HealthCare is prohibited from seeking to influence the control of our company or acquiring more than 20% of our then outstanding Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) the public announcement of a tender offer, exchange offer, or other proposal that would constitute a change of control of our company; (iii) the acquisition (other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our then outstanding Class A Stock and Common Stock (taken together); (iv) the issuance of

shares of capital stock to another party (other than to an underwriter in a public offering) that would result in such party's having more than 7% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such third party enters into a standstill agreement containing terms substantially similar to the standstill obligations of Bayer HealthCare; or (v) other specified events, such as a liquidation or dissolution of our company.

The holders of our convertible senior notes have fundamental change purchase rights, which require us to purchase all or a portion of their notes upon the occurrence of a fundamental change, as defined in the indenture governing the notes. In addition, the indenture contains provisions requiring an increase to the conversion rate for conversions in connection with make-whole fundamental changes. These rights and provisions may in certain circumstances delay or prevent a takeover of us and the removal of incumbent management that might otherwise be beneficial to investors. In addition, upon the occurrence of certain extraordinary events, the hedge transactions would be exercised upon the conversion of notes, and the warrant transactions may be terminated. It is possible that the proceeds we receive upon the exercise of the convertible note hedge transactions would be significantly lower than the amounts we would be required to pay upon termination of the warrant transactions. Such differences may result in the acquisition of us being on terms less favorable to our shareholders than it would otherwise be.

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, provide for severance benefits in the event of termination as a result of a change in control of our company. Also, stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan and our 2014 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plans. Further, under the amended and restated investor agreement between us and Sanofi, we are required under certain circumstances to appoint an individual agreed upon by us and Sanofi to our board of directors and to use our reasonable efforts to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains a specified equity interest in us. As described above under "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management*," a Sanofi designee has served on our board of directors since April 2014. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In the third quarter of 2015, we settled the conversion of $2.0 million principal amount of our 1.875% convertible senior notes through the payment of $2.0 million in cash (equal to the principal amount of the converted notes) and issuance of 20,218 shares of our Common Stock to the holders of the notes surrendered for conversion. We issued and sold the notes in October 2011 in a private placement in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. In connection with this conversion, we exercised a proportionate amount of our convertible note hedges, as a result of which we received from our hedge counterparties 20,212 shares of our Common Stock.

Issuer Purchases of Equity Securities

The following table reflects shares of Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan or the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan in the third quarter of 2015.

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
9/1/2015-9/30/2015	3,277	$ 538.42	—	—

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number		Description
10.1	*	Immuno-oncology Discovery and Development Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between Regeneron Pharmaceuticals, Inc. (the "Registrant") and Sanofi Biotechnology SAS.
10.2	*	Immuno-oncology License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS.
10.3	*	Amendment No. 1 to Amended and Restated Discovery and Preclinical Development Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc.
10.4	*	Amendment No. 2 to Amended and Restated License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc.
10.5		Second Amendment, dated as of August 5, 2015, to the Master Terms and Conditions for Warrants, between Morgan Stanley & Co. International plc and the Registrant.
10.6		Seventeenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 10, 2015.
10.7	*	Collaboration Agreement, dated as of September 29, 2015, by and between Regeneron Ireland and Mitsubishi Tanabe Pharma Corporation.
31.1		Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2		Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32		Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101		Interactive Data File
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema
101.CAL		XBRL Taxonomy Extension Calculation Linkbase
101.DEF		XBRL Taxonomy Extension Definition Document
101.LAB		XBRL Taxonomy Extension Label Linkbase
101.PRE		XBRL Taxonomy Extension Presentation Linkbase

_____

* Portions of this document have been omitted and filed separately with the Securities and Exchange Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: November 4, 2015

By: /s/ Robert E. Landry

Robert E. Landry
Senior Vice President, Finance and
Chief Financial Officer
(Duly Authorized Officer)

Exhibit 10.1

IMMUNO-ONCOLOGY DISCOVERY AND DEVELOPMENT AGREEMENT

By and Between

SANOFI BIOTECHNOLOGY SAS

and

REGENERON PHARMACEUTICALS, INC.

Dated as of July 1, 2015

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY. SUCH OMITTED PORTIONS, WHICH ARE MARKED WITH BRACKETS AND THREE ASTERISKS [***], HAVE BEEN SEPARATELY FILED WITH THE COMMISSION.

TABLE OF CONTENTS

IMMUNO-ONCOLOGY DISCOVERY AND DEVELOPMENT AGREEMENT

THIS IMMUNO-ONCOLOGY DISCOVERY AND DEVELOPMENT AGREEMENT ("Agreement"), dated as of July 1, 2015 (the "Effective Date"), and executed as of July 27, 2015 (the "Execution Date") is by and between Sanofi Biotechnology SAS ("Sanofi"), a societe par actions simplifee, organized under the laws of France, having a principal place of business at 54, rue La Boétie, 75008 Paris, France, an indirect wholly owned subsidiary of Sanofi, a company organized under the laws of France with its principal headquarters at 54, rue La Boétie, 75008 Paris, France ("Sanofi Parent"), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, Regeneron and Sanofi, as successor-in-interest to Aventis Pharmaceuticals Inc., have undertaken a broad therapeutic antibody discovery and development program under that certain Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009 (as amended from time-to-time, including in connection with the execution and delivery of this Agreement, the "Existing Discovery Agreement"), with the objective of identifying and validating potential drug discovery targets for the purpose of discovering antibody product candidates targeting those targets under the terms set forth in the Existing Discovery Agreement and in the Existing License and Collaboration Agreement (as defined in ARTICLE 1); and

WHEREAS, the Parties are interested in entering into a new collaboration with the objective of Regeneron utilizing its research capabilities and suite of discovery technologies to identify, discover and validate potential drug discovery targets for the purpose of discovering antibody product candidates in the field of immuno-oncology, further developing such antibodies through POC (as defined in ARTICLE 1) and granting Sanofi the co-exclusive (with Regeneron) rights granted to Sanofi hereunder during the term of the IO Discovery Program, including the Tail Period, if any, as well as an option to license certain rights to the resulting antibodies under the terms set forth in this Agreement and in the IO License and Collaboration Agreement (as defined in ARTICLE 1) executed and delivered as of the date hereof.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

"Abandoned Candidate" shall have the meaning set forth in Section 5.3(c).

"Accounting Standards" shall mean, with respect to either Party, GAAP or IFRS, in each case, as generally and consistently applied throughout the Party's organization. Each Party shall promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained.

"Acquired IO Antibody" shall mean, with respect to a Party, an IO Antibody that is not an Excluded Candidate, the rights to which are acquired by such Party or its Affiliate from a Third Party, whether such acquisition is by direct acquisition, by license or through the acquisition of a Third Party that owns or controls such IO Antibody.

"Acquired IO Antibody Report" shall have the meaning set forth in Section 2.5(e)(i).

"Additional IO Discovery Program Costs" shall have the meaning set forth in Section 4.2(a).

"Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by, or is under common control with such first Person. For purposes of this definition, a Person shall be deemed to "control" another Person if such first Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract, or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to "control" another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside of the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence; provided, that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of Sanofi's Affiliates be deemed Affiliates of Regeneron or any of Regeneron's Affiliates nor shall Regeneron or any of Regeneron's Affiliates be deemed Affiliates of Sanofi or any of Sanofi's Affiliates.

"Agreement" shall have the meaning set forth in the preamble, including all Schedules and Exhibits.

"Alliance Manager" shall have the meaning set forth in Section 3.2.

"Ancillary Agreement" shall mean the IO License and Collaboration Agreement, the Existing Discovery Agreement, the Existing License and Collaboration Agreement, and any supply agreement entered into by the Parties in connection with any of the foregoing.

"Ancillary Collaboration Agreements" shall mean the IO License and Collaboration Agreement, the Existing Discovery Agreement and the Existing License and Collaboration Agreement.

"Antibody" shall mean [***]. Notwithstanding the foregoing, "Antibody" shall not include [***], CAR-T Cell Therapies, or Immunoconjugates.

"Applicable Opt-In Period" shall have the meaning set forth in Section 5.2(g)(v).

"Arbitrable Matter" shall have the meaning set forth in Section 13.2(a).

"Arm" shall mean [***].

"Base IO Discovery Program Costs" shall have the meaning set forth in Section 4.2(a).

"Bi-Specific/Multi-Specific" shall mean [***].

"Breakthrough Opt-In Period" shall have the meaning set forth in Section 5.2(d).

"Breakthrough Opt-In Report" shall have the meaning set forth in Section 5.2(d).

"Budget Dispute" shall mean a dispute between the Parties regarding the commercial reasonableness of a Tail Period Budget to be established pursuant to Section 2.6 or any update thereof.

"Budget Expiration Date" shall mean the date on which the IO Discovery Budget (which, for clarity, does not include the Tail Period Budget) has been exhausted in accordance with this Agreement or the termination of this Agreement, if earlier.

"Business Acquired IO Antibody" shall have the meaning set forth in Section 2.5(e)(iv).

"Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States or Paris, France are authorized or required by Law to remain closed.

"CAR-T Cell Therapies" shall mean [***].

"Collaboration Purpose" shall have the meaning ascribed to such term in the IO License and Collaboration Agreement.

"Combination Product" shall have the meaning set forth in the definition of "Net Sales."

"Combination Therapy" shall have the meaning set forth in Section 2.10(a).

"Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on an IO Discovery Program Target Profile-by-IO Discovery Program Target Profile and IO Discovery Program Antibody-by-IO Discovery Program Antibody basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including the possibility that significant increases in the CPI over the Term will lead to an increase in the cost of external services and a reduction in the number of FTEs funded under the IO Discovery Program. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the payments made or required to be made hereunder nor the profit sharing anticipated by the IO License and Collaboration Agreement shall be a factor weighed (that is, a Party may not apply lesser resources or efforts in support of an IO Discovery Program Antibody because it must make any payments hereunder or share profits from sales of such IO Discovery Program Antibody if Sanofi exercises its Opt-In Rights thereto). In no event shall Regeneron be required to incur Program Costs in excess of the IO Discovery Budget during the Discovery Budget Term or the Tail Period Budget (if any) during the Tail Period (if any).

"Competing Refused Candidate" shall mean any Refused Candidate [***].

"Competing Third Party Product" shall mean, with respect to an IO Discovery Program Antibody, any other IO Antibody owned or controlled by a Third Party that [***].

"Confidential Information" shall have the meaning set forth in Section 9.1.

"Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2015, and each succeeding twelve (12) month period thereafter during the Term (except that the last Contract Year shall end on the effective date of any termination or expiration of this Agreement).

"Controlling Party" shall have the meaning set forth in Section 2.10(b).

"CPI" shall mean the Consumer Price Index – All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

"Damages" shall have the meaning set forth in Section 10.1(a).

"Default Interest Rate" shall have the meaning set forth in Section 4.7.

"Deferral Notice" shall have the meaning set forth in Section 5.2(c).

"Deferred Opt-In Period" shall have the meaning set forth in Section 5.2(c).

"Deferred Opt-In Report" shall have the meaning set forth in Section 5.2(c).

"Development Costs" shall have the meaning set forth in the IO License and Collaboration Agreement.

"Disclosing Party" shall have the meaning set forth in Section 9.1.

"Discovery Budget Term" shall mean the period from and after the Effective Date through and until the Budget Expiration Date.

"Disputed Budget" shall mean the Tail Period Budget or any update thereof that is the subject of a Budget Dispute.

"Disputed Plan Components" shall have the meaning set forth in Section 5.2(g)(i).

"Dollars" or "$" shall mean United States Dollars.

"Effective Date" shall have the meaning set forth in the preamble.

"Evaluable Subject" shall mean a human subject enrolled in a clinical trial of an IO Discovery Program Antibody (excluding any Sanofi Funded Trial) who has (a) been [***] and (b) (i) been [***], and (ii) had [***], in each case ((i) and (ii)), in accordance with the protocol for such clinical trial.

"Excess IO Discovery Program Costs" shall have the meaning set forth in Section 4.2(a).

"Excluded Candidates" shall mean (a) any IO Antibody targeting an Excluded Target Profile, and (b) each External Candidate that (i) has been offered by an Offering Party and rejected by the non-Offering Party pursuant to Section 2.5(b)(iii), and (ii) [***].

"Excluded Target Profile" shall mean [***].

"Ex-Collaboration Product" shall mean any product that (a) is owned or controlled by Regeneron or Sanofi or any of their respective Affiliates and (b) is not an IO Discovery Program Antibody, an Existing Collaboration Product or an IO Licensed Product; provided, that "Ex-Collaboration Product" shall include (i) any Excluded Candidates and any Refused Candidates under this Agreement, (ii) any "Opt-Out Product" or "Terminated Licensed Product," each as defined in and under the Existing License and Collaboration Agreement, (iii) any "Terminated IO Product" under the IO License and Collaboration Agreement, or (iv) any "Excluded Candidate" or "Refused Candidate" under the Existing Discovery Agreement.

"Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Sanofi Parent or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

"Execution Date" shall have the meaning set forth in the preamble.

"Existing Agreements" shall mean the Existing Discovery Agreement and the Existing License and Collaboration Agreement.

"Existing Collaboration Product" shall mean (a) a Licensed Product under the Existing License and Collaboration Agreement, or (b) any Antibody that (i) is the subject of development under the Existing Discovery Program and (ii) is not an IO Antibody, a Multi-Indication Antibody or a "Refused Candidate" under and as defined in the Existing Discovery Agreement.

"Existing Discovery Agreement" shall have the meaning set forth in the recitals.

"Existing Discovery Program" shall have the meaning ascribed to the term "Discovery Program" in the Existing Discovery Agreement (which includes, for clarity, any "Tail Period" under and as defined in the Existing Discovery Agreement, to the extent applicable).

"Existing Discovery Term" shall have the meaning ascribed to the term "Term" in the Existing Discovery Agreement (which includes, for clarity, any "Tail Period" under and as defined in the Existing Discovery Agreement, to the extent applicable).

"Existing License and Collaboration Agreement" shall mean the Amended and Restated License and Collaboration Agreement, among Sanofi, as successor-in-interest to Aventis Pharmaceuticals Inc., sanofi-aventis amerique du nord and Regeneron, dated as of November 10, 2009, as the same may be amended from time-to-time.

"Expert Panel" shall have the meaning set forth in Section 13.3(b)(i).

"Expert Panel Dispute" shall mean [***].

"Extended Opt-In Period" shall have the meaning ascribed to such term in Section 5.2(g)(v).

"External Candidate" shall have the meaning set forth in Section 2.5(b)(ii).

"External Candidate Report" shall have the meaning set forth in Section 2.5(b)(ii).

"FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

"FDA Breakthrough Therapy Designation" shall mean, with respect to an IO Discovery Program Antibody, a designation by FDA that such IO Discovery Program Antibody is a Breakthrough Therapy pursuant to Section 506(a) of the FDCA, as amended by Section 902 of the Food and Drug Administration Safety and Innovation Act, Public Law No. 112-144.

"Force Majeure" shall have the meaning set forth in ARTICLE 11.

"FTE" shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by Regeneron (or its Affiliate) and assigned to perform specified work under the IO Discovery

Program, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [***] hours per year.

"FTE Cost" shall mean, for all activities performed under the IO Discovery Program, the product of (a) the number of FTEs performing activities under the IO Discovery Program and (b) the FTE Rate.

"FTE Rate" shall mean, with respect to any Contract Year, a rate equal to the Development FTE Rate for such Contract Year under the IO License and Collaboration Agreement, as it may be adjusted from time-to-time in accordance with the terms of the IO License and Collaboration Agreement. If the Parties agree to a separate FTE rate for contractors performing development activities under the IO License and Collaboration Agreement pursuant to Section 1.39 thereof, such FTE rate will be the FTE Rate applicable under this Agreement for contractors performing work under the IO Discovery Program.

"GAAP" shall mean generally accepted accounting principles as applicable in the United States.

"Governmental Authority" shall mean any court, agency, authority, department, regulatory body, or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city, or other political subdivision of any such government or any supranational organization of which any such country is a member.

"HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. §18a), as amended.

"HSR Filing" has the meaning set forth in Section 5.7.

"IFRS" shall mean International Financial Reporting Standards adopted by the International Accounting Standards Board.

"Immuno-Oncology Steering Committee" or "IOSC" shall mean the Immuno-Oncology Steering Committee described in Section 3.1(a).

"Immunoconjugate" shall mean [***].

"IND" shall mean, with respect to an IO Antibody, an Investigational New Drug Application filed with the FDA with respect to such IO Antibody pursuant to 21 C.F.R. § 312 before the commencement of clinical trials involving such IO Antibody, including all amendments and supplements to such application, or any equivalent filing with any Regulatory Authority outside the United States.

"IND Preparation" shall mean all drug development activities in support of an IO Antibody up to the filing of the IND for the Phase I Clinical Trial, including assay development, sample analysis, preclinical toxicology, preclinical pharmacokinetics and toxicokinetics, pharmacological assessment (if applicable), cell line development and protein chemistry

sciences, formulation development, clinical trial protocol development, IND drafting and data compilation, and manufacturing preclinical and clinical supplies.

"Indemnified Party" shall have the meaning set forth in Section 10.2(a).

"Indemnifying Party" shall have the meaning set forth in Section 10.2(a).

"Indication" shall mean any disease, state or condition.

"Initial Opt-In Period" shall have the meaning set forth in Section 5.2(b).

"Initial Opt-In Report" shall have the meaning set forth in Section 5.2(a).

"Interim Antibody" shall have the meaning as set forth in Section 2.6(b).

"Interim Period" shall have the meaning as set forth in Section 2.6(b).

"Interim Target Profile" shall have the meaning as set forth in Section 2.6(b).

"Interim Target Report" shall have the meaning as set forth in Section 2.6(b).

"IO Antibody" shall mean an Antibody that has a (a) [***] (for the avoidance of doubt, not including CAR-T Cell Therapies or Immunoconjugates). Any IO Antibodies [***], shall constitute IO Antibodies. Notwithstanding the foregoing, "IO Antibody" shall not include REGN2810. For clarity, if the binding of [***]. Furthermore, it is generally expected that Antibodies that [***], are not IO Antibodies.

"IO Development Balance" shall have the meaning set forth in the IO License and Collaboration Agreement.

"IO Discovery Budget" shall mean one billion and ninety million Dollars ($1,090,000,000), or such other amount as mutually agreed on by the Parties in writing.

"IO Discovery Program" shall mean all discovery, research and development activities to be performed under this Agreement by or on behalf of (a) Regeneron, including IO Target identification, discovery and validation, IND Preparation and IND filing for IO Discovery Program Antibodies, Refused Candidates [***] and IO Licensed Products [***] and clinical trials as part of POC Development for such IO Antibodies, or (b) either Party, with respect to Sanofi Funded Trials. The IO Discovery Program shall include (i) discovery research activities directed at IO Target identification, validation, and selection, (ii) IO Antibody discovery, (iii) IO Discovery Program Antibody identification, characterization, pharmacological assessment (if applicable) and selection, (iv) the production of IO Discovery Program Antibodies for preclinical experiments and clinical studies, (v) IND Preparation and the filing of INDs, (vi) the conduct of non-clinical and clinical tests and studies to achieve POC, including clinical translational studies, Phase I Clinical Trials and Phase II Clinical Trials, and (vii) the development of companion diagnostics for use with IO Discovery Program Antibodies. For clarity, the IO Discovery Program shall include the foregoing activities performed with respect to any Tail Period

Antibodies during the Tail Period or any Tail Early Opt-In Antibody after the Tail Expiration Date, and any activities conducted pursuant to Section 5.4 or Section 5.5.

"IO Discovery Program Antibody" shall mean, (a) with respect to any point in time during the Discovery Budget Term, any IO Antibody that is, or at any time has been, the subject of development under the IO Discovery Program, and (b) with respect to any point in time during the Tail Period, any IO Antibody that is, or at any time has been, a Tail Period Antibody. For clarity, from and after such time (if any) as an IO Antibody becomes a Refused Candidate, or the [***] becomes an [***], such IO Antibody will no longer be an IO Discovery Program Antibody.

"IO Discovery Program Plan" shall have the meaning set forth in Section 2.2(a).

"IO Discovery Program Target Profile" shall mean, (a) with respect to any point in time during the Discovery Budget Term, any IO Target Profile that is the target of any IO Discovery Program Antibody that is, or at any time has been, the subject of development under the IO Discovery Program, and (b) with respect to any point in time during the Tail Period, any IO Target Profile that is, or at any time has been, a Tail Period Target Profile. For clarity, [***].

"IO License and Collaboration Agreement" shall mean the Immuno-Oncology License and Collaboration Agreement by and between Sanofi and Regeneron, dated as of the Effective Date, as the same may be amended from time to time.

"IO Licensed Product" shall have the meaning ascribed to such term in the IO License and Collaboration Agreement.

"IO Licensed Target Profile" shall have the meaning ascribed to such term in the IO License and Collaboration Agreement.

"IO Reimbursement Payments" shall have the meaning set forth in Section 4.1(b).

"IO Royalty Product" shall mean [***].

"IO Target" shall mean any gene, receptor, ligand, or other molecule (a) [***] (i) [***], (ii) [***] and (iii) be modified by direct interaction with an Antibody, or (b) that is targeted by an IO Antibody.

"IO Target Profile" shall mean (a) with respect to an IO Antibody that is [***], and (b) with respect to an IO Antibody that is [***]. For clarity, (x) each Target that is targeted by an IO Antibody [***], and (y) the IO Target Profile of an IO Antibody that is [***].

"Joint Inventions" shall have the meaning set forth in Section 6.1(b).

"Joint Patent Rights" shall mean Patent Rights that cover or claim a Joint Invention.

"Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, data, test results, knowledge, techniques,

discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.

"KRM" shall mean a key results memorandum prepared by or on behalf of a Party that summarizes all key results and findings of an interim or final analysis based on cleaned data of the primary and, if applicable, secondary endpoints from a clinical trial undertaken pursuant to the IO Discovery Program, including any Sanofi Funded Trial.

"Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions, or ordinances of any Governmental Authority.

"Lead Candidate" shall mean an IO Antibody that the Party developing it reasonably believes in good faith is ready to begin IND Preparation.

"Licensed Product" shall have the meaning ascribed to such term in the Existing License and Collaboration Agreement.

"Manufacturing Cost" shall mean the fully burdened cost (without mark-up) of (a) manufacturing (i) IO Discovery Program Antibodies for the IO Discovery Program, and (ii) [***], and (b) providing dedicated manufacturing capacity for such IO Discovery Program Antibodies, in each case, as calculated in accordance with Schedule 3.

"Marketing Approval" shall mean an approval, registration, license or authorization from the applicable Regulatory Authority necessary for the marketing and sale of an IO Antibody in an indication in any country, but excluding any separate pricing approval.

"Maximum Evaluable Subjects" shall have the meaning set forth in Section 5.2(c).

"Measurement Period" shall mean the Contract Years 2015, 2016 and 2017.

"Mice" or "Mouse" shall mean [***].

"Mice-Derived Therapeutic (or Diagnostic) Candidate" or "MTC" shall mean [***].

"Modified Clause" shall have the meaning set forth in Section 14.6.

"Multi-Indication Antibody" shall have the meaning set forth in Section 2.1(d).

[***]

"Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of IO Royalty Products in the Territory by or on behalf of Regeneron, or its Affiliates or sublicensees to Third Parties, less the following deductions, determined in accordance with Regeneron's Accounting Standards, consistently applied:

(a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such IO Royalty Products;

(b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;

(c) chargebacks and other amounts paid on sale or dispensing of IO Royalty Products;

(d) Third Party cash rebates and chargebacks related to sales of IO Royalty Products, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) compulsory refunds, credits, rebates and co-pay assistance directly related to the sale of IO Royalty Products, accrued, paid or deducted pursuant to agreements (including managed care agreements) or governmental regulations;

(g) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering IO Royalty Products that are separately identified on the invoice or other documentation;

(h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of IO Royalty Products, which are separately identified on the invoice or other documentation;

(i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such IO Royalty Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof; and

(j) invoiced amounts that are written off as uncollectible in accordance with Regeneron's or its Affiliates' or sublicensees' respective accounting principles as applied consistently.

Net Sales in currency other than Dollars shall be translated into Dollars according to the provisions of Section 4.6.

Sales between the Parties, or between Regeneron and its Affiliates or sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of an IO Royalty Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Regeneron or its Affiliates or sublicensee sells such IO Royalty Products in the form of a combination product containing any IO Royalty Product and one or more active ingredients

(whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the first commercial sale of such Combination Product, the Parties shall agree on the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, [***].

"Non-IO Indication" shall mean any Indication that is [***]. For clarity, any [***] a Non-IO Indication.

"Non-Prosecuting Party" shall have the meaning set forth in Section 6.2(c).

"Non-Tail Opt-In Notice" shall have the meaning set forth in Section 5.2(e).

"Offering Party" shall mean the Party offering for inclusion in the IO Discovery Program either (a) an External Candidate pursuant to Section 2.5(b) or (b) an Acquired IO Antibody pursuant to Section 2.5(e).

"Opt-In Notice" shall mean a written notice, delivered by Sanofi in the form annexed hereto as Exhibit A, that Sanofi is exercising its Opt-In Rights with respect to a Product Candidate or Tail Early Offer Antibody.

"Opt-In Period" shall mean Initial Opt-In Period, Deferred Opt-In Period, Breakthrough Opt-In Period, or Tail Early Opt-In Period, as applicable.

"Opt-In Report" shall mean Initial Opt-In Report, Deferred Opt-In Report, Breakthrough Opt-In Report, or Tail Early Opt-In Report, as applicable.

"Opt-In Rights" shall mean, with respect to a Product Candidate or Tail Early Offer Antibody, Sanofi's right to elect, pursuant to Section 5.2(b), Section 5.2(c), Section 5.2(d) or Section 5.2(f), as applicable, to jointly (with Regeneron) develop and commercialize such Product Candidate or Tail Early Offer Antibody as an IO Licensed Product under the terms and conditions set forth in the IO License and Collaboration Agreement.

"Opt-Out" shall have the meaning set forth in Section 5.3.

"Opt-Out Product" shall have the meaning ascribed to such term in the IO License and Collaboration Agreement.

"Other Product" shall mean (a) any Other Proprietary Product, (b) any product that is owned or controlled by a Third Party (for clarity, whether or not such product is an IO Antibody), and (c) any product that is in the public domain.

"Other Proprietary Product" shall mean (a) an IO Licensed Product, (b) an Existing Collaboration Product, and (c) an Ex-Collaboration Product.

"Other Shared Expenses" shall have the meaning ascribed to such term in the IO License and Collaboration Agreement.

"Out-of-Pocket Costs" shall mean the costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with Regeneron's Accounting Standards) by Regeneron (or its Affiliate) directly in connection with the performance of the IO Discovery Program, except as expressly provided under Section 2.11(c) or otherwise in this Agreement.

"Outer Year IO Discovery Program Costs" shall mean, with respect to each Contract Year during the Discovery Budget Term after the Measurement Period, all Program Costs that are not Sanofi Funded Trial Costs incurred by Regeneron or its Affiliates in such Contract Year.

"Outer Year Regeneron Funding Percentage" shall mean [***].

"Outer Year Sanofi Funding Percentage" shall mean [***].

"Party" or "Parties" shall have the meaning set forth in the preamble.

"Patent Application" shall mean any application for a Patent.

"Patent Rights" shall mean unexpired Patents and Patent Applications.

"Patents" shall mean patents together with all substitutions, divisions, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, reissues, reexaminations, extensions, registrations, patent term adjustments or extensions, supplemental protection certificates and renewals of any of the foregoing, and all counterparts thereof in any country in the Territory.

"Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

"Phase I Clinical Trial" shall mean the first (1st) clinical trial of an IO Discovery Program Antibody following IND Preparation or a clinical trial intended to determine the safety and recommended dosing regimen of an IO Discovery Program Antibody or a combination of an IO Discovery Program Antibody with another product or therapy.

"Phase II Clinical Trial" shall mean a clinical trial under the IO Discovery Program that is intended to initially evaluate the effectiveness of an IO Discovery Program Antibody for a particular indication or indications in patients with the disease or indication under study or would otherwise satisfy the requirements of 21 C.F.R. § 312.21(b) (or its equivalent under the Laws of any country in the Territory other than the United States).

"Phase III Clinical Trial" shall mean a clinical trial under the IO Discovery Program that is intended to gather further evidence of safety and efficacy of an IO Discovery Program Antibody as a monotherapy or in combination with one or more other IO Discovery Program Antibodies or other products or therapies (and to help evaluate its overall risks and benefits) for a

particular indication or indications and is intended to support Marketing Approval for such IO Discovery Program Antibody for such indication or indications in one or more countries or that would otherwise satisfy the requirements of 21 C.F.R. § 312.21(c) (or its equivalent under the Laws of any country in the Territory other than the United States).

"Plans" shall mean, collectively, the IO Discovery Program Plan, each POC Development Plan (if any), each Sanofi Funded Trial Plan (if any), the Tail Period Plan (if any), and each Tail Early Opt-In Development Plan (if any), or any of them, as the context requires.

"POC" shall mean, with respect to an IO Discovery Program Antibody [***].

"POC Development" shall mean any development activities with respect to an IO Antibody targeting a tumor type or hematological malignancy other than Phase III Clinical Trials with respect to such tumor type or hematological malignancy.

"POC Development Plan" shall have the meaning set forth in Section 2.2(b).

"Post-POC Development Plan" shall have the meaning set forth in Section 5.2(a).

"Post-POC Plan Dispute" shall have the meaning set forth in Section 5.2(g)(iv).

"Post-POC Plan Dispute Notice" shall have the meaning set forth in Section 5.2(g)(iv).

"Post-POC Principal Party" shall have the meaning ascribed to such term in the IO License and Collaboration Agreement.

"Product Candidate" shall have the meaning set forth in Section 5.2(a).

"Product Patent Rights" shall mean any Patent or Patent Application having a specification which supports a claim that may be infringed by making, using, selling, importing or exporting an IO Discovery Program Antibody, including any derivatives, fragments, compositions of matter or uses thereof.

"Program Costs" shall mean all Out-of-Pocket Costs, FTE Costs and Manufacturing Costs incurred by Regeneron or its Affiliates after the Effective Date directly in connection with (a) the performance of the IO Discovery Program, and (b) the performance of any other activities that are to be reimbursed as Program Costs hereunder, except as otherwise expressly provided hereunder, including under Section 2.5(b)(iii) and Section 2.10(b)(ii).

"Prosecuting Party" shall have the meaning set forth in Section 6.2(c).

"Publishing Party" shall have the meaning set forth in Section 9.3.

"Receiving Party" shall have the meaning set forth in Section 9.1.

"Refused Candidate" shall have the meaning set forth in Section 5.3(a).

"Regeneron" shall have the meaning set forth in the preamble.

"Regeneron Indemnitees" shall have the meaning set forth in Section 10.1(a).

"Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and the Regeneron Know-How.

"Regeneron Know-How" shall mean any and all Know-How as of the Effective Date or thereafter during the Term that is owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to license or sublicense the same necessary or useful for the performance of the IO Discovery Program or any Sanofi Funded Trial.

"Regeneron Patent Rights" shall mean those Patent Rights as of the Effective Date or thereafter during the Term that are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions) with the right to license or sublicense the same and which include at least one (1) claim which, absent a license from Regeneron or any of its Affiliates, would be infringed by the research, development, manufacture, commercialization or use of any IO Discovery Program Antibody or IO Discovery Program Target Profile (or any Target contained therein) by Sanofi.

"Regeneron Sole Inventions" shall have the meaning set forth in Section 6.1(a).

"Regeneron Target IP" shall mean only those claims in Patent Rights within the Regeneron Patent Rights in existence on the Budget Expiration Date (or, with respect to Tail Period Target Profiles (and any Targets contained therein) and Tail Period Antibodies, if any, the Tail Expiration Date) that, absent a license from Regeneron or any of its Affiliates, would be infringed by the making, using, developing, selling, or importing by Sanofi of an IO Antibody discovered or developed in the IO Discovery Program (including an IO Royalty Product) [***].

"REGN2810" shall have the meaning ascribed to such term in the IO License and Collaboration Agreement. For clarity, from and after the Effective Date, REGN2810 is an IO Licensed Product under the IO License and Collaboration Agreement.

"Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the activities conducted under the IO Discovery Program.

"Reimbursable Program Costs" shall have the meaning set forth in Section 4.1(b).

"Royalty Term" shall have the meaning set forth in Section 4.5.

"Sanofi" shall have the meaning set forth in the preamble.

"Sanofi Aggregate Funding Cap" shall mean Seven Hundred and Fifty Million Dollars ($750,000,000).

"Sanofi Funded Additional IO Discovery Program Costs" shall mean any portion of the Additional IO Discovery Program Costs funded by Sanofi in accordance with Section 4.2(a).

"Sanofi Funded Trial" shall have the meaning set forth in Section 2.1(c).

"Sanofi Funded Trial Costs" shall mean Program Costs incurred by either Party or their respective Affiliates in connection with a Sanofi Funded Trial.

[***]

"Sanofi Funded Trial Plan" shall have the meaning set forth in Section 2.1(c).

"Sanofi Indemnitees" shall have the meaning set forth in Section 10.1(b).

"Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.

"Sanofi Know-How" shall mean any and all Know-How as of the Effective Date or thereafter during the Term that is owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to license or sublicense the same necessary or useful for the research, development, manufacture, commercialization or use of any IO Antibody or any IO Target Profile (or any Target contained therein) that is or was, at any time during the Term, an IO Discovery Program Antibody or IO Discovery Program Target Profile (or any Target contained therein), respectively, including any Refused Candidate, any other IO Royalty Product and any other Excluded Candidate that was, at any time during the Term, an IO Discovery Program Antibody, and the IO Target Profile (or any Target contained therein) that is targeted by any such Refused Candidate, other IO Royalty Product or other Excluded Candidate.

"Sanofi Patent Rights" shall mean those Patent Rights as of the Effective Date or thereafter during the Term that are owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions) with the right to license or sublicense the same and which include at least one (1) claim which, absent a license from Sanofi or any of its Affiliates, would be infringed by the research, development, manufacture, commercialization or use by Regeneron of any IO Antibody or any IO Target Profile (or any Target contained therein) that is or was, at any time during the Term, an IO Discovery Program Antibody or IO Discovery Program Target Profile (or any Target contained therein), respectively, including any Refused Candidate, any other IO Royalty Product and any other Excluded Candidate that was, at any time during the Term, an IO Discovery Program Antibody, and the IO Target Profile (or any Target contained therein) that is targeted by any such Refused Candidate, other IO Royalty Product or other Excluded Candidate.

"Sanofi Proposed Combination Trial" shall have the meaning set forth in Section 2.10(b)(i).

"Sanofi Restricted Antibody" shall have the meaning set forth in Section 5.3(c).

"Sanofi Sole Inventions" shall have the meaning set forth in Section 6.1(a).

"Sanofi Target IP" shall mean only those claims in Patent Rights within the Sanofi Patent Rights in existence on the Budget Expiration Date (or, with respect to Tail Period Target Profiles (including any Target contained therein) and Tail Period Antibodies, if any, the Tail Expiration Date) that, absent a license from Sanofi or any of its Affiliates, would be infringed by the making, using, developing, selling, or importing by Regeneron of an IO Antibody that is or was, at any time during the Term, and IO Discovery Program Antibody, including IO Royalty Products and any Excluded Candidate that was worked on under the IO Discovery Program [***]. [***]

"Sole Inventions" shall have the meaning set forth in Section 6.1(a).

"Tail Early Offer Antibody" shall have the meaning set forth in Section 5.2(f).

"Tail Early Opt-In Antibody" shall have the meaning set forth in Section 5.2(f).

"Tail Early Opt-In Costs" shall have the meaning set forth in Section 5.2(f).

"Tail Early Opt-In Development Plan" shall have the meaning set forth in Section 5.2(f).

"Tail Early Opt-In Period" shall have the meaning set forth in Section 5.2(f).

"Tail Early Opt-In Report" shall have the meaning set forth in Section 5.2(f).

"Tail Early Opt-In Termination Notice" shall have the meaning set forth in Section 5.2(f)(ii).

"Tail Expiration Notice" shall have the meaning set forth in Section 5.2(f).

"Tail Expiration Notice Date" shall have the meaning set forth in Section 5.2(f).

"Tail Expiration Date" shall have the meaning set forth in Section 2.6(a).

"Tail Offer Antibodies" shall have the meaning set forth in Section 2.6(a).

"Tail Offer Target Profile" shall have the meaning set forth in Section 2.6(a).

"Tail Period" shall have the meaning set forth in Section 2.6(a).

"Tail Period Antibody" shall have the meaning set forth in Section 2.6(a).

"Tail Period Budget" shall have the meaning set forth in Section 2.6(a).

"Tail Period Notice Date" shall have the meaning set forth in Section 2.6(a).

"Tail Period Plan" shall have the meaning set forth in Section 2.6(a).

"Tail Period Target Profile" shall have the meaning set forth in Section 2.6(a).

"Tail POC Report" shall have the meaning set forth in Section 5.2(f).

"Target" shall mean any gene, receptor, ligand, or other molecule (a) potentially associated with a disease activity, and (b) that potentially has a biological activity that is modified by direct interaction with an Antibody, including any MTC, or (c) to which an Antibody, including any MTC, binds.

"Term" shall have the meaning set forth in Section 12.1.

"Territory" shall mean all the countries and territories of the world.

"Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

"Third Party Claim" shall have the meaning set forth in Section 10.1(a).

"Upfront Payment" shall have the meaning set forth in Section 4.1(a).

"Valid Claim" shall mean a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) that has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Government Authority of competent jurisdiction from which no appeal may be or has been taken, and that has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

ARTICLE 2
IO DISCOVERY PROGRAM

2.1 IO Discovery Program.

(a) General. From the Execution Date, the objective of the IO Discovery Program is for Regeneron to discover, identify or validate promising IO Targets and IO Target Profiles, generate IO Discovery Program Antibodies targeting such IO Target Profiles, and develop certain selected IO Discovery Program Antibodies through POC Development to offer to Sanofi Product Candidates for joint development and commercialization under the terms set forth herein and in the IO License and Collaboration Agreement.

(b) Conduct and Consultation. Upon the terms and subject to the conditions hereof, Regeneron will have sole responsibility for the design and conduct of all activities (except for Sanofi Funded Trials conducted by Sanofi in accordance with Section 2.1(c), for which Sanofi will have sole responsibility) under the IO Discovery Program, including decisions relating to initiation and termination of programs and activities, manufacturing activities, and staffing and resource allocation between different programs and

activities in the IO Discovery Program. Sanofi, through the IOSC, will provide consultation and advice to support Regeneron's efforts under the IO Discovery Program, which consultation and advice shall be considered in good faith by Regeneron.

(c) Sanofi Funded Trials. Sanofi may propose to Regeneron Phase II Clinical Trials for any IO Discovery Program Antibody that [***]. Subject to Section 2.10, in the event that Sanofi proposes any such clinical trial [***] as provided in the foregoing sentence, and Regeneron declines to conduct such clinical trial [***], Sanofi may provide written notice to Regeneron that Sanofi wishes to fund such clinical trial [***]. Such notice shall include [***]. Upon Sanofi's written notice to Regeneron that it wishes to fund such clinical trial for an IO Discovery Program Antibody or a Sanofi Proposed Combination Trial and, [***], Sanofi shall have the right to conduct such clinical trial using the IO Discovery Program Antibody initially proposed by Sanofi (which Regeneron shall supply) or if Sanofi requests that Regeneron conduct such clinical trial, Regeneron may, in its sole discretion, conduct such clinical trial itself. Each clinical trial conducted pursuant to the foregoing sentence shall be a "Sanofi Funded Trial." In the event of any dispute between the Parties as to whether a proposed Sanofi Funded Trial is not reasonably likely to have a material negative impact on the IO Discovery Program or the development or commercialization of any IO Discovery Program Antibody or IO Licensed Product or supply of any IO Discovery Program Antibody or IO Licensed Product [***]. Each permitted Sanofi Funded Trial shall become part of the IO Discovery Program, be conducted pursuant to a Sanofi Funded Trial Plan as reviewed, discussed and agreed on by the IOSC, and [***]; provided that if Regeneron chooses to conduct such clinical trial, [***]. Notwithstanding the foregoing, unless otherwise agreed to by the Parties in writing, in no event shall any Sanofi Funded Trial operate to (y) delay or extend the timing of any Opt-In Report to be delivered by Regeneron with respect to any IO Discovery Program Antibody pursuant to ARTICLE 5, or (z) delay or extend any Opt-In Period with respect to any IO Discovery Program Antibody. For clarity, the [***] in a Sanofi Funded Trial shall not be [***] and Regeneron shall be under no obligation to consider the [***].

(d) Multi-Indication Antibodies. If any IO Discovery Program Antibody is also an Antibody being developed in any Non-IO Indication under the Existing Discovery Agreement (a "Multi-Indication Antibody"), then [***] under the [***] and [***], except to the extent that [***] the results of which may be useful for development in an immuno-oncology Indication as well as Non-IO Indications (e.g., process development work and cell line scale up), [***] and [***], and (ii) [***]. In the event of any dispute between the Parties as to which Indication of a Multi-Indication Antibody is [***], then [***]. For clarity, any preclinical development costs for a Multi-Indication Antibody incurred [***].

2.2 IO Discovery Plans.

(a) IO Discovery Program Plan. Within ninety (90) days after the Execution Date, Regeneron will prepare and deliver to the IOSC an initial IO Discovery Program plan (the "IO Discovery Program Plan"), which shall set forth the overall strategy for conducting research on IO Discovery Program Target Profiles and IO Discovery Program

Antibodies, and preclinically developing IO Discovery Program Antibodies under the IO Discovery Program through IND Preparation. Regeneron shall provide an updated IO Discovery Program Plan to the IOSC (as defined below) prior to its first meeting, and thereafter shall have the right to amend the IO Discovery Program Plan from time to time in its sole discretion. Regeneron will promptly present any material updates to the IO Discovery Program Plan to the IOSC for review and discussion until the Budget Expiration Date.

(b) POC Development Plan. At the outset of clinical development for each IO Discovery Program Antibody that has completed IND Preparation and IND filing, Regeneron will prepare and deliver to the IOSC a POC Development plan (including the estimated budget) for such IO Discovery Program Antibody (each, a "POC Development Plan"), which shall set forth the overall strategy and plan for developing an IO Discovery Program Antibody during the IO Discovery Program from completion of IND Preparation and IND filing through POC Development for such IO Discovery Program Antibody. Each POC Development Plan will specify, in a reasonable level of detail, the tumor types or hematological malignancies to be evaluated as well as an estimated timeline and budget for achieving POC across such proposed tumor types or hematological malignancies and shall be designed with [***]. Regeneron shall have the right to amend each POC Development Plan from time to time in its sole discretion. Regeneron will promptly present to the IOSC any material updates to the POC Development Plan with respect to an IO Discovery Program Antibody (and any material changes in the estimated budget) until the earlier of (i) the Budget Expiration Date or (ii) such time as such IO Discovery Program Antibody becomes an Excluded Candidate, a Refused Candidate or an IO Licensed Product.

2.3 Commercially Reasonable Efforts; Compliance with Laws.

(a) During the Discovery Budget Term, (i) Regeneron will use Commercially Reasonable Efforts to identify, discover and develop IO Discovery Program Antibodies and to achieve POC for IO Discovery Program Antibodies; provided that (A) the foregoing obligation to use Commercially Reasonable Efforts shall apply with respect to the IO Discovery Program taken as a whole and shall not apply with respect to any IO Discovery Program Antibody individually, and (B) any decision by Regeneron to discontinue or toll the development of one or more IO Discovery Program Antibodies shall not constitute a failure to use Commercially Reasonable Efforts unless such discontinuance or tolling is a failure to use Commercially Reasonable Efforts with respect to the IO Discovery Program as a whole, (ii) upon the achievement of POC for an IO Discovery Program Antibody, Regeneron shall be obligated to offer it for license to Sanofi pursuant to the Opt-In Rights in accordance with this Agreement, and (iii) to the extent Regeneron has agreed to conduct a Sanofi Funded Trial pursuant to Section 2.1(c), Regeneron will use Commercially Reasonable Efforts to conduct the Sanofi Funded Trials in accordance with Section 2.1(c).

(b) During the Tail Period, (i) Regeneron will use Commercially Reasonable Efforts to develop Tail Period Antibodies in accordance with the Tail Period Plan and upon the achievement of POC for a Tail Period Antibody, Regeneron shall be obligated to offer it for license to Sanofi pursuant to the Opt-In Rights; provided that in no event shall

Regeneron be obligated to (A) undertake activities during the Tail Period that would cause Regeneron to incur Program Costs in excess of the Tail Period Budget unless Sanofi agrees in writing to increase the Tail Period Budget to cover such excess costs, or (B) conduct the Tail Period Plan after the Tail Period, and (ii) Sanofi, and to the extent Regeneron has agreed to conduct a Sanofi Funded Trial pursuant to Section 2.1(c), Regeneron will use Commercially Reasonable Efforts to conduct any Sanofi Funded Trials with respect to Tail Period Antibodies in accordance with Section 2.1(c).

(c) Each Party hereby covenants and agrees to comply with applicable Laws in performing all activities connected with the IO Discovery Program.

2.4 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations, or orders required to be obtained or made in connection with the authorization, execution, and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions, or changes suggested in connection therewith. Each Party will furnish all information required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.5 Exclusivity.

(a) In General. Subject to the other subparagraphs in this Section 2.5, (i) during the Discovery Budget Term, neither Party nor any of their respective Affiliates will, either directly, or with or through any Third Party, work to discover, develop or commercialize IO Antibodies, (ii) during the Tail Period (if any), neither Party nor any of their respective Affiliates will, either directly, or with or through any Third Party, work to discover, develop or commercialize any Tail Period Antibody, or [***], and (iii) during the Interim Period (if any), neither Sanofi nor any of its Affiliates will, either directly, or with or through any Third Party, work to discover, develop or commercialize IO Antibodies, except in each case ((i), (ii) and (iii)) pursuant to this Agreement, including as expressly permitted under Section 2.10, or the IO License and Collaboration Agreement (or, solely as provided in Section 2.1(d) hereof, the Existing Discovery Agreement).

(b) Preclinical IO Antibodies and IO Target Profiles.

(i) Subject to Section 5.3(c) with respect to Sanofi, each Party and its Affiliates shall have the right, outside of this Agreement or the IO License and

Collaboration Agreement, at such Party's own expense, and in accordance with, and subject to, the remainder of this Section 2.5(b), to identify, discover and develop, through, using the proprietary technology of, or otherwise in collaboration with one or more Third Parties (or, with respect to Sanofi only, independently using its own proprietary technology), IO Antibodies, before and until any IO Antibody developed by or on behalf of such Party or its Affiliates [***]; provided, that neither a Party nor any of its Affiliates may grant rights to any Third Party with respect to any such IO Antibody that would preclude such Party from including such IO Antibody in this Agreement as provided in this Section 2.5(b). For clarity, the foregoing proviso shall not preclude a Party or any of its Affiliates from [***], in each case, in connection with the development, manufacturing or commercialization of any such IO Antibodies. For clarity, this Section 2.5(b) shall be without limitation to the Parties' rights with respect to Excluded Candidates, subject to Section 5.3(c) and the terms and conditions of this Agreement, and Regeneron's rights with respect to Refused Candidates under Section 5.3 or otherwise under this Agreement.

(ii) If either Party (or its Affiliate) has developed an IO Antibody in collaboration with one or more Third Parties (or, with respect to Sanofi only, independently using its own proprietary technology) pursuant to Section 2.5(b)(i) and such IO Antibody [***] (any such IO Antibody that [***], an "External Candidate"), the Offering Party must promptly provide the other Party with a report containing [***] information known to the Offering Party about such External Candidate, the IO Target Profile (and any Target contained therein) that it targets, and [***], that the other Party should reasonably require in order to decide whether to include such External Candidate in the IO Discovery Program (the "External Candidate Report"). The External Candidate Report shall include a description of any financial or other obligations of the Offering Party to, and any rights of, Third Parties with respect to the applicable External Candidate ([***]), and shall include a copy of any such agreement with a Third Party relating thereto (which may be redacted to exclude any unrelated information). During the [***] day period referred to in Section 2.5(b)(iii), the Offering Party shall also promptly provide, if, as and when available, such other Party with updated information of the type required to be included in the External Candidate Report, and any other information regarding the External Candidate (or other applicable IO Discovery Program Antibodies) that such other Party reasonably requests to the extent in the Offering Party's possession and control or in the Offering Party's control and accessible by the Offering Party consistent with the Offering Party's regular business practices.

(iii) Within [***] days of receipt from the Offering Party of (A) an External Candidate Report and (B) any such additional information as may be requested by the other Party pursuant to Section 2.5(b)(ii), the other Party shall accept into this Agreement or reject the External Candidate; provided, that [***]. If such other Party rejects an External Candidate that [***]; provided, that this Section 2.5(b)(iii) shall not [***]. If such other Party rejects an External Candidate that [***] that is not [***], the Offering Party shall thereafter be free to pursue the further development and commercialization of such External Candidate outside of this Agreement, and such

External Candidate and only such External Candidate [***] shall become an Excluded Candidate. For clarity, [***] shall become [***] by operation of this Section 2.5(b)(iii). If such other Party accepts into this Agreement an External Candidate offered by the Offering Party, then such External Candidate and related [***] shall be deemed to be included in the IO Discovery Program as an IO Discovery Program Antibody and [***], respectively and as applicable, and shall be subject to further development by Regeneron and, to the extent permitted pursuant to Section 2.1(c), Sanofi, under the IO Discovery Program. [***] the out-of-pocket costs and expenses incurred by the Offering Party related to such External Candidate [***] prior to the other Party accepting such External Candidate into this Agreement shall be [***]. [***].

(c) Excluded Candidates. Subject to Section 2.5(b)(iii), Section 2.10(b)(iii), Section 5.3(b), and Section 5.3(c), (i) Sanofi and its Affiliates shall have the right to develop, manufacture and commercialize Excluded Candidates that are neither (A) Refused Candidates, nor (B) with respect to the applicable period, Sanofi Restricted Antibodies, and (ii) Regeneron shall have the right to develop, manufacture and commercialize Excluded Candidates and Refused Candidates, including for use with one (1) or more other IO Antibodies (including IO Antibodies controlled by Regeneron or its Affiliates or by other Persons), and may practice and use any Regeneron Intellectual Property, including the Mice, in connection with the development of Excluded Candidates, in each cause ((i) and (ii)) either directly, or with or through any Third Party, outside this Agreement or the IO License and Collaboration Agreement without restriction; provided, that Sanofi shall have no rights under this Agreement to any Excluded Candidates that were at any time IO Discovery Program Antibodies, and Regeneron shall have and retain exclusive rights to (x) any Excluded Candidates that were at any time IO Discovery Program Antibodies, and (y) any data or other Know-How or Patent Rights to the extent relating thereto.

(d) Refused Candidates. Regeneron (and its Affiliates) shall have the exclusive right to develop, manufacture and commercialize Refused Candidates, either directly, or with or through any Third Party, outside this Agreement and the IO License and Collaboration Agreement as set forth in Section 5.3, unless such Refused Candidate is a Competing Refused Candidate, in which case Regeneron (either directly, or with or through an Affiliate or Third Party) may not develop the Competing Refused Candidate [***], unless otherwise expressly agreed in writing by Sanofi.

(e) Acquired IO Antibodies.

(i) If an Offering Party (or its Affiliates) acquires an Acquired IO Antibody, and such acquisition (A) occurs prior to the Budget Expiration Date, or (B) occurs during the Tail Period (if any) and such Acquired IO Antibody [***], then, in either case ((A) or (B)), the Offering Party shall, within [***] (or, in the case of a Business Acquired IO Antibody, as soon as reasonably practicable, but in no event more than [***]) following such acquisition, provide the other Party with a report containing [***] information known to the Offering Party about the Acquired IO Antibody (and related IO Target Profile (including any Target contained therein)) that the other Party

should reasonably require in order to decide whether or not to include the Acquired IO Antibody in the IO Discovery Program (the "Acquired IO Antibody Report"). During the [***] period referred to in Section 2.5(e)(ii), the Offering Party shall also promptly provide, if, as and when available, such other Party with updated information of the type required to be included in the Acquired IO Antibody Report, and any other information regarding the Acquired IO Antibody that such other Party reasonably requests to the extent in the Offering Party's possession and control or in the Offering Party's control and accessible by the Offering Party consistent with the Offering Party's regular business practices.

(ii) The other Party shall promptly (and in no event later than [***] after receipt of the Acquired IO Antibody Report) notify the Offering Party whether or not it wishes to include the Acquired IO Antibody in the IO Discovery Program by providing written notice of such decision to the Offering Party (and if no such notice is provided to the Offering Party during such [***] period, the Acquired IO Antibody shall not be included in the IO Discovery Program); provided, that such Acquired IO Antibody shall not be included within the IO Discovery Program unless and until the Parties reach mutually agreeable financial terms relating thereto; provided, further, that if the other Party receives material information regarding the Acquired IO Antibody within [***] prior to the expiration of such [***] period, such [***]. Notwithstanding the foregoing, the Parties may mutually agree in writing to include such Acquired IO Antibody in the IO License and Collaboration Agreement as an IO Licensed Product instead of including such Acquired IO Antibody as an IO Discovery Program Antibody in the IO Discovery Program. If the Acquired IO Antibody does not come into either the IO Discovery Program or the IO License and Collaboration Agreement for any reason, then the Offering Party (and its Affiliates) shall immediately cease all activities relating thereto (except for promptly winding down any ongoing development activities or as required by Law or ethical considerations) until [***].

(iii) If the Acquired IO Antibody [***], then notwithstanding the other provisions of this Section 2.5(e), such Acquired IO Antibody shall be governed by Section 2.5(b) and Section 2.5(e)(i), but not Section 2.5(e)(ii).

(iv) Notwithstanding anything to the contrary in this Section 2.5, where an Offering Party or its Affiliate acquires rights to an Acquired IO Antibody by the acquisition of a Third Party or part or the whole of its business (a "Business Acquired IO Antibody"), the Offering Party may as an alternative to any obligations herein, divest such Acquired IO Antibody [***] within [***] of the acquisition, and, for the avoidance of doubt, [***]) with respect to such Acquired IO Antibody during such [***] period.

(f) Technology Licenses. Regeneron shall have the right to grant non-exclusive licenses to its Mice and other technologies and other Regeneron Intellectual Property related to the Mice and other technologies to Third Parties, including universities and for profit and not-for-profit Third Parties; provided, that [***]. Regeneron may receive contract fees, milestones, and royalties based on future sales of IO Antibodies discovered by

such Third Party licensees. In addition, under the terms of such agreements where Regeneron retains a license, or a right to acquire a license, to develop and commercialize MTCs discovered by such Third Parties and any such MTC so discovered and licensed to Regeneron is an IO Antibody, [***]. If Regeneron acquires such license (A) during the Tail Period (if any) and such IO Antibody does not [***], or (B) after the later of the Tail Expiration Date and the Budget Expiration Date but during the term of the IO License and Collaboration Agreement, and in either case ((A) and (B)), such IO Antibody [***], such IO Antibody shall be an "Acquired Competing Product" as defined in the IO License and Collaboration Agreement and subject to Section 2.6(b) thereof.

2.6 Tail Period and Interim Period.

(a) Tail Period Opt-In. At such time that is [***] prior to the date that Regeneron reasonably expects that the IO Discovery Budget will be exhausted, Regeneron shall provide Sanofi with written notice thereof (the date of such notice, the "Tail Period Notice Date"), which notice shall include or shall be provided in connection with the delivery of all material information related to the Tail Offer Antibodies and [***], and at Sanofi's sole option, exercisable by providing written notice of such exercise to Regeneron within [***] after the Tail Period Notice Date, Sanofi shall have the right to extend the IO Discovery Program (i) for specific Tail Offer Antibodies selected by Sanofi and specified in such notice, and (ii) for an additional period to end on a later date specified in such notice, which date shall in no event be later than the later of (A) the eighth (8^{th}) anniversary of the Effective Date, and (B) [***] (such specified date, the "Tail Expiration Date", and the period from and after the Budget Expiration Date until the Tail Expiration Date, the "Tail Period"). Any IO Discovery Program Antibody that is, as of the Tail Period Notice Date, [***] that has been developed under the IO Discovery Program shall be referred to herein as a "Tail Offer Antibody", and [***]. If Sanofi fails to provide such written notice within [***] after the Tail Period Notice Date, the IO Discovery Program and this Agreement shall expire on the Budget Expiration Date, and there shall be no Tail Period and Sanofi shall have no further rights under this Section 2.6. Within [***] of receipt of Sanofi's notice, Regeneron shall prepare and deliver to the IOSC a plan to conduct further development activities with respect to such Tail Offer Antibodies through achievement of POC during the Tail Period (the "Tail Period Plan"), and an associated budget to be approved by the IOSC, which shall be on a cost basis (the "Tail Period Budget"). The Parties shall use good faith efforts to agree on the Tail Period Budget prior to the Budget Expiration Date. For clarity, any costs and expenses incurred by Regeneron with respect to Tail Period Antibodies and Tail Period Target Profiles from and after the Budget Expiration Date until the approval of the initial Tail Period Plan and initial Tail Period Budget shall be Program Costs reimbursable by Sanofi pursuant to Section 4.2(e). Regeneron will also promptly present to the IOSC, if, as and when available, any material updates to the Tail Period Plan, and any other information regarding the Tail Period that Sanofi reasonably requests to the extent in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices, including any proposed updates to the Tail Period Budget (which budget updates will be subject to IOSC approval subject to Section 13.3) until the Tail Expiration Date. Any Tail Offer Antibodies that are the subject of development activities under the IO

Discovery Program pursuant to a Tail Period Plan and Tail Period Budget shall be referred to herein as "Tail Period Antibodies", and the IO Target Profiles that are targeted by such Tail Period Antibodies shall be referred to herein as "Tail Period Target Profiles". For clarity, the Tail Period Antibodies shall be IO Discovery Program Antibodies [***] for so long as such IO Antibodies and [***] remain the subject of development under the IO Discovery Program.

(b) Interim Period Opt-In. If during the period, if any, from and after the [***] through and until [***] (the "Interim Period"), Regeneron proposes [***] for any IO Antibody (for clarity, excluding Excluded Candidates and Refused Candidates) and such IO Antibody [***] (any such IO Antibody, an "Interim Antibody" and the IO Target Profile that it targets, an "Interim Target Profile"), Regeneron shall first provide Sanofi with a report containing the material scientific, legal (including copies of all regulatory filings and material written correspondence with Governmental Authorities), and commercial information known to Regeneron about any such Interim Target Profile and any Interim Antibodies developed by Regeneron that target such Interim Target Profile that Sanofi should reasonably require in order to decide whether to include such Interim Antibodies and Interim Target Profile in the IO Discovery Program (the "Interim Target Report"). The Interim Target Report shall also include, if applicable, a description of any financial or other obligations of Regeneron to, and any rights of, Third Parties with respect to the applicable Interim Target Profile (and any Targets contained therein) and all applicable Interim Antibodies, and shall include a copy of any such agreement with a Third Party relating thereto (which may be redacted to exclude any unrelated information). Sanofi shall have the right, at Sanofi's sole option, exercisable by providing written notice of such exercise to Regeneron within [***] after receipt of the Interim Target Report on an Interim Antibody-by-Interim Antibody or Interim Target Profile-by-Interim Target Profile basis, to include such Interim Target Profile or Interim Antibody into the IO Discovery Program during the remainder of the Tail Period. If Sanofi fails to provide such written notice within such [***] period with respect to an Interim Antibody and its Interim Target Profile, Regeneron shall thereafter be free to pursue the further development and commercialization of such Interim Antibody and such Interim Target Profile, [***], outside of this Agreement. During such [***] period following Sanofi's receipt of an Interim Target Report, Regeneron shall also promptly provide, if, as and when available, Sanofi with updated information of the type required to be included in the Interim Target Report, and any other information regarding the Interim Antibody that Sanofi reasonably requests to the extent in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices. If Sanofi provides such written notice within such [***] period, within [***] after Regeneron's receipt of such notice, Regeneron shall prepare and deliver to the IOSC an updated Tail Period Plan for Regeneron to perform further development activities with respect to the designated Interim Target Profile or Interim Antibodies during the remainder of the Tail Period, together with an updated Tail Period Budget to be approved by the IOSC. For clarity, any costs and expenses incurred by Regeneron with respect to Interim Antibodies and Interim Target Profiles that Sanofi has designated to become Tail Period Antibodies and Tail Period Target Profiles that are incurred from and after Sanofi's written notice until the approval of the updated Tail Period Plan and Tail Period Budget pursuant to the foregoing sentence shall be Program Costs reimbursable by Sanofi pursuant to Section 4.2(e). Regeneron will also promptly present to the IOSC, if, as

and when available, any material updates to the Tail Period Plan, and any other information regarding the Tail Period Plan that Sanofi reasonably requests to the extent in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices, including any proposed updates to the Tail Period Budget (which budget updates will be subject to IOSC approval subject to Section 13.3) until the Tail Expiration Date. Any such designated Interim Antibodies and Interim Target Profiles that become the subject of development activities under the IO Discovery Program pursuant to such an updated Tail Period Plan and Tail Period Budget shall be Tail Period Antibodies and Tail Period Target Profiles, respectively (and, for clarity, IO Discovery Program Antibodies and IO Discovery Program Target Profiles, respectively), for so long as such Interim Antibodies and Interim Target Profiles remain the subject of development under the IO Discovery Program.

(c) Tail Period Budget; Program Costs. If (i) Sanofi has properly exercised its rights to include any Tail Offer Antibody or Tail Offer Target Profile into the IO Discovery Program pursuant to Section 2.6(a), or to include any Interim Antibody or Interim Target Profile into the IO Discovery Program pursuant to Section 2.6(b), but (ii) the IOSC does not agree on a Tail Period Budget pursuant to Section 2.6(a), or any update to the Tail Period Budget pursuant to Section 2.6(b), then [***]. If a Tail Period Budget is established (whether pursuant to this Section 2.6 or Section 13.3), Sanofi shall be responsible for one hundred percent (100%) of the total Program Costs incurred in connection with development activities with respect to any Tail Period Antibodies or Tail Period Target Profiles pursuant to the IOSC-approved Tail Period Plan in accordance with such Tail Period Budget, and shall reimburse Regeneron for such Program Costs pursuant to Section 4.1(b).

(d) Tail Period Excluded Candidates. Without limitation to Section 5.3, from and after [***], any (x) IO Antibody that is not designated by Sanofi as a Tail Period Antibody pursuant to Section 2.6(a) or Section 2.6(b), and that [***], shall be an Excluded Candidate hereunder, and (y) [***].

2.7 Program Licenses; Licenses Generally. Each Party hereby grants to the other Party and its Affiliates a non-exclusive, non-transferable, worldwide, royalty-free license, with the right to sublicense, under the Regeneron Intellectual Property and the Sanofi Intellectual Property, respectively, solely to perform the IO Discovery Program and, with respect to Sanofi as grantor, to research, develop, manufacture, commercialize or use the Mice or any IO Target Profile (or any Target contained therein) or IO Antibody to exploit Excluded Candidates (other than Excluded Candidates that were External Candidates for which Sanofi was the Offering Party or that [***] as of the Execution Date), [***] and IO Royalty Products. Except as expressly provided for herein, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly or by implication or estoppel). Except as expressly provided for in this Section 2.7 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights or Know-How, either expressly or by implication, estoppel or otherwise.

2.8 Non-Exclusive License to Sanofi. Regeneron hereby grants Sanofi and its Affiliates a perpetual, worldwide, non-exclusive, non-transferable, royalty-free license, without the right to sublicense, under Regeneron Intellectual Property discovered directly in connection with the performance of the IO Discovery Program claiming IO Target Profiles or methods of use related to the inhibition or use of such IO Target Profiles for use by Sanofi and its Affiliates in connection with the manufacture, use, sale, offer to sell, and import of small molecule drug and diagnostic products (other than diagnostics intended for use as companion diagnostics with any IO Antibody).

2.9 Invention Assignment . All of the employees, officers and consultants of each Party who are supporting the performance of such Party's obligations under this Agreement shall have executed agreements or have existing obligations under Law requiring, in the case of employees and officers, assignment to such Party of all inventions made during the course of and as the result of their association with such Party and, in the case of employees, officers and consultants, obligating the individual to maintain as confidential such Party's Confidential Information which such Party may receive, to the extent required to support such Party's obligations under this Agreement.

2.10 Combination Therapy .

(a) General. The IOSC shall discuss whether to include in the IO Discovery Program the development of IO Discovery Program Antibodies for use with Other Products (each, a "Combination Therapy"), including Other Proprietary Products and Other Products that are owned or controlled by a Third Party or that are in the public domain. Subject to this Section 2.10, each Party shall have the right to propose to the IOSC Other Products for co-development with IO Discovery Program Antibodies under the IO Discovery Program.

(b) Combination Therapies with Other Proprietary Products. No development of a Combination Therapy of an IO Discovery Program Antibody with an Other Proprietary Product may be incorporated into the IO Discovery Program Plan or otherwise pursued as part of the IO Discovery Program without [***]; provided that [***]. With respect to a Combination Therapy of an IO Discovery Program Antibody with an IO Licensed Product, [***]. The Parties acknowledge and agree that [***]. The "Controlling Party" with respect to an Other Proprietary Product shall be determined as follows: (A) if such product is an IO Licensed Product under the IO License and Collaboration Agreement, [***] shall be the Controlling Party (subject to the terms of the IO License and Collaboration Agreement), (B) if such product is an Existing Collaboration Product, then [***] shall be the Controlling Party ([***]), and (C) if such Other Proprietary Product is an Ex-Collaboration Product, the [***] shall be the Controlling Party. For clarity, references hereunder to the Party that is or is not the Controlling Party (including to the non-Controlling Party) with respect to an Other Proprietary Product shall refer to [***].

(i) Combination Therapies with IO Licensed Products. If the Parties agree to the development of a Combination Therapy of an IO Discovery Program Antibody with an IO Licensed Product, the development of such Combination Therapy

shall be conducted [***], and [***] percent ([***]%) of the costs and expenses associated with developing such IO Licensed Product in combination with the proposed IO Discovery Program Antibody, including ([***]%) of Manufacturing Costs for clinical supply thereof, shall be [***]. If Sanofi proposes a clinical trial to develop a Combination Therapy of an IO Discovery Program Antibody with an IO Licensed Product and [***], Sanofi shall have the right to propose to conduct a clinical trial of such Combination Therapy as a Sanofi Funded Trial pursuant to Section 2.1(c) (a "Sanofi Proposed Combination Trial").

(ii) Combination Therapies with Existing Collaboration Products.

(A) If the Parties agree to the development of a Combination Therapy of an IO Discovery Program Antibody with an Existing Collaboration Product, unless otherwise agreed by the Parties, the development of such Combination Therapy shall be conducted [***]. Unless the Parties otherwise agree, [***] percent ([***]%) of the costs and expenses associated with developing the proposed Existing Collaboration Product in combination with the proposed IO Discovery Program Antibody, including the cost of clinical supply of the Existing Collaboration Product, which shall be provided by the Controlling Party to the developing party pursuant to the terms of the applicable Existing Agreement at Manufacturing Cost, shall be [***], and [***] percent ([***]%) of such costs and expenses shall be [***].

(B) If [***], the [***] shall have the right, subject to the terms and conditions of the applicable Existing Agreement(s), to [***].

(C) If [***] shall have the right, notwithstanding anything to the contrary in the Existing Agreement(s), to [***].

(D) For clarity, nothing in this Section 2.10(b) is intended or shall be construed to limit Regeneron's right to develop Combination Therapies with Other Products that are not Other Proprietary Products, which shall be governed by Section 2.10(c).

(iii) Combination Therapies with Ex-Collaboration Products. If the Parties agree to the development of a Combination Therapy of an IO Discovery Program Antibody with an Ex-Collaboration Product, unless otherwise agreed by the Parties, the development of such Combination Therapy shall be conducted [***], and [***] shall be responsible for [***] percent ([***]%) of the costs and expenses [***] associated with developing the proposed Ex-Collaboration Product in combination with the proposed IO

Discovery Program Antibody, including the cost of clinical supply, which shall be [***]. Without limitation to the obligations of either Party under Section 2.5, if the [***], the [***] shall be free to [***].

(c) Combination Therapies with Third Party Other Products. For clarity, any Combination Therapy of an IO Discovery Program Antibody that does not involve an Other Proprietary Product (e.g., an Other Product owned or controlled by a Third Party or that is in the public domain) shall [***] and the applicable IO Antibody in such Combination Therapy shall be treated as [***], and [***] percent ([***]%) of [***] costs and expenses associated with the development of any such Combination Therapy shall be [***].

(d) Without Limitation to Exclusivity. Except as expressly provided in this Section 2.10, nothing in this Section 2.10 is intended or shall be construed to modify the rights and obligations of the Parties under Section 2.5.

2.11 Third Party Licenses. The Parties acknowledge that, during the Term, one (1) or more licenses from one (1) or more Third Parties [***]. In such an event the following provisions shall apply:

(a) License by Regeneron. Regeneron shall determine, in its sole discretion, whether to, and shall have the right to, obtain and maintain any Third Party licenses to any Patent Rights relating to [***], including research necessary for [***]; provided, that Regeneron shall consult with Sanofi with respect thereto and shall consider in good faith Sanofi's comments in connection therewith.

(b) License by Sanofi. In the event that Regeneron [***] or the Parties decide that [***], Sanofi shall have the right to obtain and maintain such Third Party licenses.

(c) Payment. If, as a result of either Party obtaining and maintaining such Third Party licenses, [***], such payments shall be [***] and shall not be [***] or [***].

ARTICLE 3
INFORMATION EXCHANGE AND UPDATES

3.1 Immuno-Oncology Steering Committee.

(a) Formation, Composition and Membership. The Parties will establish an Immuno-Oncology Steering Committee, or IOSC, which shall consist of at least three (3) senior representatives appointed by each of Regeneron and Sanofi having, in each case, the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the IOSC. The IOSC established under this Agreement may have the same members as the IOSC established under the IO License and Collaboration Agreement, and such members may meet to simultaneously discuss matters within the jurisdiction of the IOSC under this Agreement and the IOSC under the IO License and Collaboration Agreement, respectively. Each Party may replace its IOSC members upon written notice to the other Party; provided, that (i) such replacement has

comparable standing and authority within that Party's organization as the person he or she is replacing (or is otherwise reasonably acceptable to the other Party) and (ii) unless otherwise agreed by the Parties, at all times, one of Sanofi's representatives on the IOSC must be Sanofi's President of Research and Development, or equivalent senior-most executive responsible for research and development, and one of Regeneron's representatives on the IOSC must be Regeneron's President of Research and Development, or equivalent senior-most executive responsible for research and development. The IOSC will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi.

(b) Meetings of the IOSC. The IOSC shall meet at least once every calendar quarter, unless the IOSC co-chairpersons otherwise agree in writing. All IOSC meetings may be conducted by telephone, video-conference or in person as determined by the IOSC co-chairpersons; provided, that the IOSC shall meet in person at least once each calendar year, unless the Parties mutually agree to meet by alternative means. Unless otherwise agreed by the Parties, all in-person meetings for IOSC shall be held on an alternating basis between Regeneron's facilities and Sanofi's facilities. Further, in addition to the regularly scheduled quarterly meetings, the IOSC shall meet upon the reasonable request of either Party's co-chairperson. The co-chairpersons, with the assistance of the Alliance Managers, shall coordinate activities to prepare and circulate an agenda in advance of each meeting and prepare and issue draft minutes of each meeting within fourteen (14) days thereafter and final minutes within thirty (30) days thereafter. With the consent of the Parties (not to be unreasonably withheld, conditioned or delayed), a reasonable number of other representatives of a Party may attend any IOSC meeting as non-voting observers (provided, that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in ARTICLE 9). Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in IOSC meetings.

(c) Duties. The IOSC shall:

(i) review and discuss the IO Discovery Program, including the IO Discovery Program Plan, any POC Development Plan and any Tail Period Plan;

(ii) in accordance with Section 2.1(c), review and discuss each Sanofi Funded Trial Plan for each Sanofi Funded Trial that is conducted under the IO Discovery Program;

(iii) review and discuss the then-current progress of the IO Discovery Program, including Regeneron's identification, selection and prioritization of IO Discovery Program Antibodies and IO Discovery Program Target Profiles;

(iv) review and discuss whether to develop IO Discovery Program Antibodies as Combination Therapies, including for use with Other Products (including Other Proprietary Products);

(v) review and discuss whether to continue any POC Development for a Product Candidate under this Agreement using the IO Discovery Budget after the date that Regeneron receives an Opt-In Notice from Sanofi for such Product Candidate;

(vi) review and discuss proposed endpoints for clinical trials conducted under the IO Discovery Program for an IO Discovery Program Antibody;

(vii) review and discuss Sanofi's suggestions for the IO Discovery Program, including proposals from Sanofi (A) to include assets controlled by Sanofi or its Affiliates in the IO Discovery Program, and (B) to conduct Sanofi Funded Trials;

(viii) review and discuss on a Tail Period Plan and Tail Period Budget in the event that Sanofi exercises its rights to extend the IO Discovery Program into a Tail Period pursuant to Section 2.6(a), and any updates to such Tail Period Plan and Tail Period Budget in the event that Sanofi exercises its rights with respect to Interim Antibodies or Interim Target Profiles pursuant to Section 2.6(b);

(ix) attempt in good faith to resolve any Post-POC Plan Disputes referred to the IOSC pursuant to Section 5.2(g);

(x) consider and act upon such other matters as specified in this Agreement or as otherwise agreed to by the Parties; and

(xi) make any such decisions as are expressly allocated to the IOSC under this Agreement.

(d) Decision Making. The IOSC shall review and discuss the matters before it in good faith such that the perspectives of each Party's representatives on the IOSC are given due consideration; provided, that, except as otherwise expressly set forth in this Agreement, (i) Sanofi's chairperson of the IOSC (or his or her designee) shall have the right to make the final decision on any matter relating to [***], and (ii) Regeneron's chairperson of the IOSC (or his or her designee) shall have the right, consistent with Regeneron's obligations hereunder, to make the final decision on any other matter properly before the IOSC in accordance with this Agreement. For clarity, Regeneron's final decision-making authority shall not extend to any Arbitrable Matter or Expert Panel Dispute.

3.2 Alliance Management . Each of Sanofi and Regeneron shall appoint a senior representative who possesses a general understanding of research, clinical, and regulatory issues to act as its Alliance Manager ("Alliance Manager"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for providing single-point communication for responding to reasonable information requests between quarterly IOSC meetings and seeking consensus both internally within the respective Party's organization and with the other Party's organization, including facilitating review of external corporate communications.

3.3 Obligations of the Parties and their Affiliates . The Parties shall cause their respective designees on the IOSC to take the actions and make the decisions provided herein to be taken and made by such respective designees in the manner and within the applicable time periods provided herein.

3.4 Exchange of Information. Each of Regeneron and, to the extent Sanofi conducts any Sanofi Funded Trials pursuant to Section 2.1(c), Sanofi, will provide regular and fulsome updates to the other Party, through the IOSC, concerning the progress of the IO Discovery Program, including to promptly notify the other Party of (a) any material correspondence with a Governmental Authority, (b) any submission to the FDA [***] and any decision of the FDA [***] and (c) any KRMs with respect to any clinical trials conducted by such Party under such Plan. Without limiting the foregoing, each Party will provide to the other Party's representatives on the IOSC a written report (in electronic form) summarizing the material activities undertaken and any material information with respect to each IO Discovery Program Antibody and IO Discovery Program Target Profile then being developed under a Plan, including (x) any of the information set forth in clauses (a), (b) or (c) and Schedule 5, to the extent not previously provided to the IOSC, (y) updates to the POC Development Plan, if any, and (z) a summary of the results achieved by such Party under the IO Discovery Program, and each Party will its Commercially Reasonable Efforts to provide such written report at least ten (10) days prior to each regular quarterly meeting of the IOSC during the Term.

ARTICLE 4
PAYMENTS

4.1 Payments to Regeneron.

(a) Upfront Payment. Within ten (10) Business Days of Sanofi's receipt of an invoice from Regeneron (which invoice may be delivered electronically) following the Execution Date, Sanofi shall pay to Regeneron a non-refundable, non-creditable amount of Two Hundred and Sixty Five Million Dollars ($265,000,000) (the "Upfront Payment") as consideration for access to Regeneron's research capabilities and suite of discovery technologies and the exclusive right to have Regeneron utilize their research capabilities for the discovery or development of IO Antibodies in accordance with this Agreement.

(b) IO Reimbursement Payments. Within forty-five (45) days following the end of each calendar quarter, Regeneron shall deliver electronically to Sanofi a written report setting forth in reasonable detail the Program Costs or, if applicable, Tail Early Opt-In Costs incurred by Regeneron or any of its Affiliates in such calendar quarter (including, for clarity, any Out-of-Pocket Costs, FTE Costs and Manufacturing Costs incurred by Regeneron or any of its Affiliates in such calendar quarter attributable to any Sanofi Funded Trial), and, with respect to the amount, if any, of such Program Costs or Tail Early Opt-In Costs that are to be funded by Sanofi in accordance with Section 4.2 ("Reimbursable Program Costs"), an invoice for such amount. Unless otherwise agreed to by the Parties in writing, the cumulative amount of all Reimbursable Program Costs (not including any Reimbursable Program Costs in respect of Sanofi Funded Trials or any Tail Early Opt-In Costs) invoiced by Regeneron to Sanofi under this Section 4.1(b) shall not exceed the sum of (i) Seventy-Five Million Dollars

($75,000,000) plus (ii) the Sanofi Aggregate Funding Cap, and (iii) if Sanofi exercises its rights with respect to a Tail Period pursuant to Section 2.6(a) or Section 2.6(b), the Tail Period Budget (as may be amended from time-to-time in accordance with Section 2.6(a) or Section 2.6(b)). Sanofi shall, within thirty (30) days after its receipt of an invoice therefor, reimburse Regeneron for all Reimbursable Program Costs set forth in each invoice that are not subject to a good faith dispute between the Parties (such reimbursement payments, the "IO Reimbursement Payments").

(c) IO Discovery Budget Planning. [***] prior to the date that Regeneron reasonably expects that the IO Discovery Budget will be exhausted, Regeneron shall provide Sanofi a written notice specifying to Sanofi such anticipated exhaustion date, solely for Sanofi's planning purposes.

4.2 Discovery Program Costs.

(a) The Parties shall be responsible for paying all IO Discovery Program Costs actually incurred in any Contract Year during the Measurement Period as follows:

	2015	2016	2017
"Base IO Discovery Program Costs"	First $[***] of Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%	First $[***] of Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%	
"Additional IO Discovery Program Costs"	Next $[***] of Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%	Next $[***] of Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%	Next $[***] of Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%
"Excess IO Discovery Program Costs"	All Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year in excess of $[***]. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%	All Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year in excess of $[***]. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%	All Program Costs (excluding Sanofi Funded Trial Costs) incurred in such year in excess of $[***]. Funding Responsibility: Sanofi: [***]% Regeneron: [***]%
"Sanofi Funded Trial Costs"	[***]		

(b) With respect to each Contract Year after the Measurement Period and during the Discovery Budget Term, all Outer Year IO Discovery Program Costs actually incurred in such Contract Year shall be funded as between the Parties as follows:

(i) Sanofi: the amount of such Outer Year IO Discovery Program Costs multiplied by the Outer Year Sanofi Funding Percentage; and

(ii) Regeneron: the amount of such Outer Year IO Discovery Program Costs multiplied by the Outer Year Regeneron Funding Percentage;

For clarity, [***] incurred by either Party after the Measurement Period and during the Term shall be [***].

(c) Notwithstanding any other provision of this Agreement, in no event shall the aggregate amount of Additional IO Discovery Program Costs and Excess IO Discovery Program Costs paid by Sanofi exceed the Sanofi Aggregate Funding Cap.

(d) For clarity, the following Program Costs and only the following Program Costs shall count against the IO Discovery Budget: Base IO Discovery Program Costs plus the Additional IO Discovery Program Costs plus the Excess IO Discovery Program Costs.

(e) If Sanofi exercises its rights with respect to a Tail Period pursuant to Section 2.6(a) or Section 2.6(b), Sanofi shall be responsible for one hundred percent (100%) of the total Program Costs under the IO Discovery Program during the Tail Period. The cumulative amount of such Program Costs, excluding any Program Costs incurred in connection with a Sanofi Funded Trial, shall not exceed the Tail Period Budget.

(f) If Sanofi exercises its Opt-In Rights with respect to any Tail Early Offer Antibodies pursuant to Section 5.2(f), Sanofi shall be responsible for one hundred percent (100%) of the total Tail Early Opt-In Costs in respect of each such Tail Early Offer Antibody from and after such time as it becomes a Tail Early Opt-In Antibody in accordance with Section 5.2(f)(ii).

(g) To the extent that Sanofi performs any activities under the IO Discovery Program (including conducting any Sanofi Funded Trial), it shall do so at its sole cost and expense and such costs and expenses shall not be treated as Program Costs except as provided in Section 2.1(c), and in no event shall any Sanofi Funded Trial Costs incurred by either Party be reimbursed from or count against the IO Discovery Budget.

(h) The Parties acknowledge that the Program Costs and Tail Early Opt-In Costs are research and development expenses, as defined in the U.S. Internal Revenue Code Section 41, and agree that any and all credits or deductions to which either Party may be entitled on account of such Program Costs and Tail Early Opt-In Costs shall be allocated to Sanofi.

4.3 IO Development Balance.

(a) Fifty percent (50%) of the total Program Costs and Tail Early Opt-In Costs attributable to clinical development (i.e., in connection with the conduct of clinical trials, including clinical supply therefor, but excluding, e.g., toxicology, process development, and formulation development) of IO Discovery Program Antibodies under the IO Discovery Program or Tail Early Opt-In Antibodies as provided in Section 5.2(f) shall be added to the IO Development Balance under the IO License and Collaboration Agreement. For clarity, no costs and expenses of a Sanofi Funded Trial conducted pursuant to Section 2.1(c) shall be added to the IO Development Balance except as provided in Section 4.3(b).

(b) If and only if [***], then [***] percent ([***]%) of the Sanofi Funded Trial Costs incurred directly in connection with the conduct of such Sanofi Funded Trial

(including any IO Reimbursement Payments actually paid to Regeneron in respect thereof) in accordance with the Sanofi Funded Trial Plan shall be added to the IO Development Balance under the IO License and Collaboration Agreement. For clarity, no Sanofi Funded Trial Costs shall count against the IO Discovery Budget, Sanofi Aggregate Funding Cap or the Tail Period Budget (if any).

4.4 Royalty Payments for IO Royalty Products. If Regeneron or its Affiliate or licensee successfully develops and commercializes an IO Royalty Product, then Regeneron shall pay to Sanofi, within sixty (60) days following the end of each calendar quarter during the applicable Royalty Term, a royalty payment of [***] percent ([***]%) on the aggregate Net Sales of such IO Royalty Product. Notwithstanding anything to the contrary in this Agreement or any Ancillary Collaboration Agreement, Regeneron shall not owe any royalty payment to Sanofi under any Ancillary Collaboration Agreement with respect to any product that is an IO Royalty Product (including any Refused Candidate) under this Agreement. For clarity, Regeneron shall not owe any royalty payment to Sanofi under this Agreement with respect to any product that is a Licensed Product under the Existing License and Collaboration Agreement or an IO Licensed Product under the IO License and Collaboration Agreement. In the event that any license fees, milestones or royalties would become payable to any Third Party pursuant to any Sanofi Intellectual Property licensed to Sanofi and sublicensed to Regeneron and its Affiliates pursuant to Section 2.7 as a result of the development, manufacture, sale, offer for sale, commercialization or use of any IO Royalty Product by Regeneron or its Affiliate or licensee then Sanofi shall provide written notice to Regeneron specifying any license fees, milestones or royalties that Sanofi is required to pay to a Third Party that are specifically tied and reasonably allocable to such IO Royalty Product no later than thirty (30) days after the date on which a product first becomes an IO Royalty Product hereunder (or, if such license or sublicense is entered into by Sanofi after such product becomes an IO Royalty Product, then within thirty (30) days after Sanofi first enters into such license), and such payments shall [***]; provided that with respect to any Sanofi Intellectual Property contained in any such sub-license, Regeneron shall have the right, exercisable in Regeneron's sole discretion upon written notice to Sanofi, to exclude such Sanofi Intellectual Property from the license granted to Regeneron in Section 2.7 with respect to any IO Royalty Product or all IO Royalty Products, and Sanofi shall not [***].

4.5 Royalty Term and Reporting. The royalties payable by Regeneron under Section 4.4 shall each be paid for the period of time, as determined on an IO Royalty Product-by-IO Royalty Product and country-by-country basis, commencing on the Effective Date and ending on the later to occur of (a) [***] or (b) [***] (the "Royalty Term"). During the applicable Royalty Term, Regeneron shall deliver to Sanofi with each royalty payment a report detailing in reasonable detail the information necessary to calculate the royalty payments due under this Agreement for such calendar quarter, including the following information, specified on an IO Royalty Product-by-IO Royalty Product and country-by-country basis: (i) total gross invoiced amount from sales of each IO Royalty Product by Regeneron, its Affiliates and sublicensees; (ii) all relevant deductions from gross invoiced amounts to calculate Net Sales; (iii) Net Sales; and (iv) royalties payable.

4.6 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in Dollars. In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, such amounts shall be converted to Dollars using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into Dollars, using the spot rates (the "Mid Price Close" found on Thomson Reuters Eikon, or any other source as agreed to by the Parties) from the last Business Day of the month of the period to which the payment relates.

4.7 Late Payments . The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to one month London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted on Thomson Reuters Eikon (or any other source as agreed to by the Parties) effective for the date on which the payment was due, [***] (such sum being referred to as the "Default Interest Rate").

4.8 Right to Offset Payments. Subject to Section 4.9, each Party shall have the right to offset any amount owed by the other Party to such first Party under or in connection with this Agreement [***], including pursuant to this ARTICLE 4 or in connection with any breach, against any payments owed by such first Party to such other Party under this Agreement; provided, however, that no such offset shall be permitted to the extent and for so long as such other Party is contesting in good faith its obligation to make any such payment to such first Party under the applicable dispute resolution procedures of this Agreement [***]. Such offsets shall be in addition to any other rights or remedies available under this Agreement and applicable Law.

4.9 Taxes. Any withholding or other taxes that either Party or its Affiliates is required by Law to withhold or pay on behalf of the other Party with respect to any payments to such other Party hereunder shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, that the withholding Party shall furnish the other Party with proper evidence, including any self-reporting documentation, of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

4.10 Invoices and Documentation. The Parties shall approve the form of any invoices or necessary documentation relating to any payments hereunder. All payments otherwise due and owing under this Agreement shall be supported by, and, if any such payment is due hereunder within a specified time period, such specified time period shall not start running until receipt by the owing Party of, an invoice delivered (whether electronically or physically) to the Party owing such amount, except as provided in Section 4.1.

4.11 Program Costs Forecasts. By no later than [***], Regeneron will provide Sanofi with a good faith estimate of a forecast, by calendar quarter, of the projected Program Costs and Tail Early Opt-In Costs for [***], and by no later than [***], Regeneron will provide Sanofi with a good faith estimate of a re-forecast of the projected Program Costs and Tail Early Opt-In Costs, by calendar quarter, for [***]. Furthermore, by [***], Regeneron will also provide Sanofi with a good faith estimate of projected Program Costs and Tail Early Opt-In Costs, on an annual basis, for the [***]. Regeneron shall deliver to Sanofi, [***], a good faith forecast of the anticipated Program Costs to be incurred for the last [***].

ARTICLE 5
OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES

5.1 Opt-In Rights Generally. Sanofi shall have the Opt-In Rights described in this ARTICLE 5. Subject to each Party's rights under Section 2.5 and the other terms of this Agreement, while the Opt-In Rights are in effect with respect to an IO Discovery Program Antibody, except as provided in Section 2.5(c) and Section 5.4, Regeneron will not grant to any Third Party rights to such IO Discovery Program Antibody that would preclude or restrict Sanofi from exercising its Opt-In Rights hereunder with respect to such IO Discovery Program Antibody. The Opt-In Rights will expire, and Sanofi will no longer have any rights or licenses to any IO Discovery Program Antibodies under this Agreement, upon the Budget Expiration Date or, with respect to Tail Period Antibodies only, the Tail Expiration Date (or in each case, if later, with respect to any specific IO Discovery Program Antibody, expiration of any Opt-In Period in effect at the Budget Expiration Date or Tail Expiration Date, as applicable). For the avoidance of doubt, (a) Sanofi shall have no Opt-In Rights to Excluded Candidates or any IO Antibodies that [***], and (b) Sanofi may only exercise its Opt-In Rights with respect to an IO Discovery Program Antibody during the applicable Opt-In Period(s) therefor as specified in Section 5.2, and after expiry of such Opt-In Period(s) (if Sanofi has not timely exercised its Opt-In Rights therefor), such Antibody shall become a Refused Candidate and Sanofi shall have no further Opt-In Rights or other rights with respect to such IO Antibody.

5.2 Opt-In Periods .

(a) Initial Opt-In Report. As soon as reasonably practicable following [***] (any such IO Discovery Program Antibody, a "Product Candidate"), Regeneron will provide Sanofi with a written report (the "Initial Opt-In Report") containing, (A) to the extent in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices, the information and other data set forth on Schedule 6 with respect to such Product Candidate (for all Indications, [***]) and the IO Target Profile that it targets, whether obtained or generated in the IO Discovery Program or otherwise under this Agreement, or under the Existing Discovery Agreement, (B) a reasonably detailed outline of Regeneron's initial proposal with respect to the plan and yearly detailed budget for the planned development activities for such Product Candidate through the completion of Phase III Clinical Trials to support an initial filing for Marketing Approval for such Product Candidate (the "Post-POC Development Plan"), as well as a separate itemization of any planned development activities and related budget(s) for such Product Candidate [***],

and (C) for any preclinical or clinical data provided pursuant to (A) that relates to [***], specification of whether such data was obtained or generated under the IO Discovery Program or any Ancillary Collaboration Agreement or otherwise, and an estimate of all costs and expenses incurred by Regeneron (x) in accordance with this Agreement and the Existing Discovery Agreement, and (y) after expiration of the Existing Discovery Agreement, in each case ((x) and (y)) in connection with obtaining or generating such data outside of the IO Discovery Budget, the Tail Period Budget (if any) or the Existing Discovery Program (which costs and expenses shall be reimbursed by Sanofi in accordance with and subject to Section 9.2(c) of the IO License and Collaboration Agreement). The Initial Opt-In Report shall include [***].

(b) Initial Opt-In Period. Sanofi has the right to exercise its Opt-In Rights with respect to a Product Candidate by delivering to Regeneron an Opt-In Notice during the [***] period following Sanofi's receipt of the Initial Opt-In Report for such Product Candidate (such period, as it may be extended as provided in this Section 5.2(b), the "Initial Opt-In Period"). During the Initial Opt-In Period, Regeneron shall also promptly provide, if, as and when available, Sanofi with all material new information of the type required to be set forth in the Initial Opt-In Report regarding the Product Candidate, and any other material information regarding the Product Candidate that Sanofi reasonably requests to the extent in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices. If Sanofi receives material information regarding the Product Candidate on or after the date that is [***] Sanofi shall be permitted to deliver an Opt-In Notice [***].

(c) Deferred Opt-In Period. If [***], then Sanofi may, at its option (exercisable upon delivery of written notice to Regeneron within [***] after receipt of the Initial Opt-In Report (a "Deferral Notice")), elect to defer its Opt-In Rights with respect to such Product Candidate to a point in time when [***] for such Product Candidate [***]. If Sanofi provides Regeneron with a Deferral Notice, as soon as reasonably practicable following the point in time when [***], provide Sanofi with an updated written report (a "Deferred Opt-In Report") containing any additional information of the type required to be set forth in the Initial Opt-In Report for the applicable Product Candidate that has become available to Regeneron since the delivery of such Initial Opt-In Report (including, if available, any KRMs and individual patient data). Following a Deferral Notice, Sanofi shall have the right to exercise its Opt-In Rights with respect to the applicable Product Candidate by delivering to Regeneron an Opt-In Notice during the [***] period following Sanofi's receipt of the Deferred Opt-In Report for such Product Candidate (such period, as it may be extended as provided in this Section 5.2(c), the "Deferred Opt-In Period"). During the Deferred Opt-In Period, Regeneron shall also promptly provide, if, as and when available, Sanofi with all new material information of the type required to be set forth in the Initial Opt-In Report regarding the Product Candidate, and any other material information regarding the Product Candidate that Sanofi reasonably requests to the extent in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices. If Sanofi receives material information regarding the Product Candidate on or after the date that is [***] Sanofi shall be permitted to deliver an Opt-In Notice [***].

(d) FDA Breakthrough Therapy Designation. If an FDA Breakthrough Therapy Designation is received in respect of an IO Discovery Program Antibody, then such IO Discovery Program Antibody shall be deemed to be a Product Candidate irrespective of whether such IO Discovery Program Antibody has met the requirements of a Product Candidate as set forth in Section 5.2(a). Following receipt of FDA Breakthrough Designation for a Product Candidate, if (i) Regeneron has not provided an Initial Opt-In Report for such Product Candidate or (ii) Regeneron has provided an Initial Opt-In Report, Sanofi has timely provided Regeneron with a Deferral Notice, and Regeneron has not provided a Deferred Opt-In Report with respect to such Product Candidate, then in either case ((i) or (ii)) Regeneron shall have the right to provide Sanofi with a written report (a "Breakthrough Opt-In Report") containing all information of the type that would be required to be set forth in (x) an Initial Opt-In Report for such Product Candidate, if Regeneron has not previously provided to Sanofi an Initial Opt-In Report in respect of such Product Candidate pursuant to Section 5.2(a), or (y) a Deferred Opt-In Report for such Product Candidate, if Regeneron has previously provided to Sanofi an Initial Opt-In Report in respect of such Product Candidate pursuant to Section 5.2(a). Sanofi has the right to exercise its Opt-In Rights with respect to such Product Candidate by delivering to Regeneron an Opt-In Notice during the period following Sanofi's receipt of the Breakthrough Opt-In Report for such Product Candidate and ending on the earlier to occur of (A) the end of the [***] period following Sanofi's receipt of the Breakthrough Opt-In Report, and (B) if Regeneron has provided to Sanofi a Deferred Opt-In Report in respect of such Product Candidate pursuant to Section 5.2(c), the end of the Deferred Opt-In Period (such period, as it may be extended as provided in this Section 5.2(d), the "Breakthrough Opt-In Period"). During the Breakthrough Opt-In Period, Regeneron shall also promptly provide, if, as and when available, Sanofi with all new material information of the type required to be set forth in the Initial Opt-In Report regarding the Product Candidate, and any other material information regarding the Product Candidate that Sanofi reasonably requests to the extent in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices. If Sanofi receives material information regarding the Product Candidate on or after the date that is ten (10) Business Days prior to the expiration of the Breakthrough Opt-In Period, the Breakthrough Opt-In Period shall be extended by an additional ten (10) Business Days following the expiration of the original Breakthrough Opt-In Period and Sanofi shall be permitted to deliver an Opt-In Notice during such extension. Notwithstanding anything to the contrary in Section 5.2, if Sanofi does not exercise its Opt-In Rights with respect to such Product Candidate within the Breakthrough Opt-In Period, Sanofi shall be deemed to have provided an Opt-Out (as defined below) with respect to such Product Candidate, and such Product Candidate shall immediately become a Refused Candidate pursuant to Section 5.3.

(e) Effect of Exercise of Sanofi's Opt-In Rights with respect to Product Candidates. If Sanofi properly exercises its Opt-In Rights with respect to a Product Candidate (but not, for clarity, a Tail Early Offer Antibody) by delivering an Opt-In Notice (a "Non-Tail Opt-In Notice") during the Initial Opt-In Period (or the Deferred Opt-In Period or Breakthrough Opt-In Period, if and as applicable) therefor, then such Product Candidate shall, from and after the first day of the month in which Sanofi's delivers such Non-Tail Opt-In Notice for such Product Candidate, as applicable, be deemed an IO Licensed Product under

the IO License and Collaboration Agreement for all Indications, including any Non-IO Indication. For clarity, in the event that Sanofi exercises its Opt-In Rights by delivering a Non-Tail Opt-In Notice during the Initial Opt-In Period, Deferred Opt-In Period, or Breakthrough Opt-In Period, if and as applicable, therefor, all costs and expenses incurred by Regeneron with respect to such Product Candidate following the delivery of the Initial Opt-In Report or, if earlier, the delivery of the Breakthrough Opt-In Report, and prior to first day of the month in which Sanofi delivers such Non-Tail Opt-In Notice shall be treated as Program Costs and counted against the IO Discovery Budget or the Tail Period Budget, as applicable, and all costs and expenses incurred after such first day shall be treated as Development Costs under the IO License and Collaboration Agreement; provided that Regeneron may continue to incur Program Costs in respect of such Product Candidate after receipt of Sanofi's Non-Tail Opt-In Notice solely to the extent provided by Section 5.5. For clarity, (i) if Sanofi Opts-In to a Product Candidate (but not, for clarity, a Tail Early Offer Antibody), Regeneron shall have the right to develop, under the IO Discovery Program, [***], and (ii) if Sanofi Opts-Out with respect to any Product Candidate or any Tail Early Offer Antibody developed under the IO Discovery Program, Regeneron shall have the right to develop and commercialize such Product Candidate or Tail Early Offer Antibody as a Refused Candidate pursuant and subject to Section 2.5(d) and Section 5.3(b).

(f) Tail Early Opt-In Period; Effect of Exercise of Sanofi's Opt-In Rights with respect to Tail Early Offer Antibodies.

(i) At such time that is [***] prior to the Tail Expiration Date (such date of notice, the "Tail Expiration Notice Date"), Regeneron shall provide Sanofi with written notice (a "Tail Expiration Notice") containing a list of the Tail Period Antibodies for which, prior to the Tail Expiration Notice Date, [***] (each, a "Tail Early Offer Antibody"). Sanofi shall thereafter have the right, for a period of [***] after delivery of the Tail Expiration Notice, to provide a written notice to Regeneron requesting a summary of the material information with respect to any Tail Early Offer Antibody with respect to which Sanofi has a good faith interest in exercising its Opt-In Rights, and Regeneron shall, within [***] after receipt of Sanofi's written request, provide a report containing any such information to the extent not previously made available to Sanofi and in Regeneron's possession and control or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices (a "Tail Early Opt-In Report"), together with a plan for the continued POC Development of such Tail Early Offer Antibody until the achievement of POC together with an associated budget (a "Tail Early Opt-In Development Plan"). Sanofi shall thereafter have the right to exercise its Opt-In Rights with respect to any Tail Early Offer Antibody for which Regeneron has provided a Tail Early Opt-In Report by delivering to Regeneron an Opt-In Notice within the [***] period following Sanofi's receipt of the Tail Early Opt-In Report, but in no event later than the Tail Expiration Date (such period, the "Tail Early Opt-In Period"). Any Tail Early Offer Antibody with respect to which Sanofi provides an Opt-In Notice during the Tail Early Opt-In Period pursuant to this Section 5.2(f) shall be referred to herein as a "Tail Early Opt-In Antibody". Any Tail Early Offer Antibody with respect to

which Sanofi does not provide an Opt-In Notice during the Tail Early Opt-In Period pursuant to this Section 5.2(f) shall become a Refused Candidate pursuant to Section 5.3.

(ii) If Sanofi properly exercises its Opt-In Rights with respect to a Tail Early Offer Antibody during the Tail Early Opt-In Period for such Tail Early Offer Antibody, then such Tail Early Offer Antibody shall, from and after the Tail Expiration Date, be deemed an IO Licensed Product under the IO License and Collaboration Agreement for all Indications, including any Non-IO Indication; provided that (A) Regeneron shall continue to have the right to conduct POC Development in respect of such Tail Early Opt-In Antibody under the applicable Tail Early Opt-In Development Plan under this Agreement, and shall remain subject to the same reporting obligations pursuant to Section 3.4 with respect to such Tail Early Opt-In Antibody as Regeneron would be obligated with respect to an IO Discovery Program Antibody for so long as Regeneron is conducting such POC Development under such Tail Early Opt-In Development Plan, and (B) Regeneron's costs and expenses in respect thereof ("Tail Early Opt-In Costs") shall be reimbursed by Sanofi to Regeneron pursuant to Section 4.1(b) of this Agreement and shall not constitute Development Costs under the IO License and Collaboration Agreement except as provided in this Section 5.2(f)(ii). Upon such time as a Tail Early Opt-In Antibody first becomes a Product Candidate (for clarity, Sanofi shall not have the right to provide a Deferral Notice for any IO Antibody after the Tail Expiration Note Date), Regeneron will provide Sanofi with a written report containing all information of the type that would be required to be included in an Initial Opt-In Report if such Tail Early Opt-In Antibody was a Product Candidate, including, for clarity, a Post-POC Development Plan with respect thereto (a "Tail POC Report"). Upon such time as Regeneron delivers a Tail POC Report with respect to a Tail Early Opt-In Antibody, the Post-POC Principal Party for such Tail Early Opt-In Antibody shall be selected in accordance with Section 5.2 of the IO License and Collaboration Agreement as if such Tail Offer Opt-In Antibody became an IO Licensed Product at the time that Regeneron delivered such Tail POC Report (and not, for clarity, as if such Tail Early Opt-In Antibody became an IO Licensed Product as of the Tail Expiration Date). [***], Regeneron shall provide Sanofi with written notice thereof (a "Tail Early Opt-In Termination Notice"), but shall not be required to deliver a Tail POC Report with respect to such Tail Early Opt-In Antibody. Upon delivery of such notice by Regeneron, such Tail Early Opt-In Antibody shall become a Refused Candidate. All costs and expenses incurred by Regeneron with respect to a Tail Early Opt-In Antibody from and after the first day of the month in which the Tail POC Report is delivered to Sanofi for such Tail Early Opt-In Antibody shall be treated as Development Costs under the IO License and Collaboration Agreement; provided that Regeneron may continue to incur Tail Early Opt-In Costs in respect of such Tail Early Opt-In Antibody after delivery of the Tail POC Report solely to the extent provided in Section 5.4 or Section 5.5.

(iii) Notwithstanding the foregoing, this Section 5.2(f) shall not apply with respect to any Product Candidate for which Regeneron has provided an Initial Opt-In Report pursuant to Section 5.2(a), a Deferred Opt-In Report pursuant to Section 5.2(c), or Breakthrough Op-In Report pursuant to Section 5.2(d).

(g) Post-POC Plan Disputes.

(i) If Sanofi would be the Post-POC Principal Party with respect to a Product Candidate for which Regeneron delivers an Initial Opt-In Report pursuant to Section 5.2(a), and Sanofi wishes to modify the Post-POC Development Plan contained in such Initial Opt-In Report, then Sanofi may [***].

(ii) If Sanofi would be the Post-POC Principal Party with respect to a Product Candidate for which Regeneron delivers a Deferred Opt-In Report pursuant to Section 5.2(c), and Sanofi wishes to modify the Post-POC Development Plan contained in such Deferred Opt-In Report, then Sanofi may [***].

(iii) If Sanofi would be the Post-POC Principal Party with respect to a Product Candidate for which Regeneron delivers a Breakthrough Opt-In Report pursuant to Section 5.2(d), and Sanofi wishes to modify the Post-POC Development Plan contained in such Breakthrough Opt-In Report, and (A) such Breakthrough Opt-In Report is delivered prior to the delivery of an Initial Opt-In Report with respect to such Product Candidate, or (B) such Breakthrough Opt-In Report is delivered after the delivery of an Initial Opt-In Report with respect to such Product Candidate and Sanofi has previously provided a Deferral Notice but Regeneron has not provided a Deferred Opt-In Report with respect to such Product Candidate, then, in either case ((A) or (B)), Sanofi may [***].

(iv) Any matter submitted to the IOSC pursuant to and in accordance with Section 5.2(g)(i), Section 5.2(g)(ii) or Section 5.2(g)(iii) shall be referred to herein as a "Post-POC Plan Dispute". In the event that the IOSC is not able to resolve a Post-POC Plan Dispute referred to it within [***] after such matter is first so referred, such Post-POC Plan Dispute shall be referred to the dispute resolution process set forth in Section 13.3 and the Parties shall use diligent and good faith efforts to cause the completion of any such dispute process as soon as reasonably practicable.

(v) In the event that [***] at least [***] prior to the expiry of the Opt-In Period during which Sanofi [***] (the "Applicable Opt-In Period"), then such Applicable Opt-In Period shall be extended such that it expires [***]; provided, that if any Post-POC Plan Dispute is not fully resolved in accordance with Section 13.3 at least [***] prior to the expiration of such [***] period, and such failure or delay is caused by (1) any failure by Regeneron to appoint an individual to the Expert Panel pursuant to Section 13.3(b)(ii) within the time period specified therein, or to submit to the Expert Panel Regeneron's proposed version of the Disputed Plan Components pursuant to Section 13.3(b)(viii) within the time period specified therein, or (2) any failure by the two individuals appointed to the Expert Panel by Regeneron and Sanofi to agree on an additional expert pursuant to Section 13.3(b)(iii) within the time period specified therein, then the Extended Opt-In Period shall be further extended by the number of days of delay beyond the time periods referenced in clauses (1) and (2) resulting from the failures identified therein; except in each case to the extent that any such failure or delay is attributable to any act or omission by Sanofi or its Affiliates. To the extent that the

Expert Panel does not render a decision at least [***] prior to the expiration of the Extended Opt-In Period, and solely to the extent that such failure is not attributable to any act or omission by Sanofi or its Affiliates, then the Extended Opt-In Period shall be further extended by [***]. For clarity, the foregoing shall not limit the Parties obligations under Section 5.2(g)(iv) or Section 13.3(b).

(vi) In the event that a Post-POC Plan Dispute with respect to a Product Candidate is not fully resolved within the last-to-expire of the Initial Opt-In Period, Deferred Opt-In Period, Breakthrough Opt-In Period, or Extended Opt-In Period, if and as applicable, and (A) Sanofi timely provides an Opt-In Notice for such Product Candidate, then such Product Candidate shall become an IO Licensed Product pursuant to Section 5.2(e) and the most recent Post-POC Development Plan provided by Regeneron in the latest Opt-In Report provided with respect to such Product Candidate shall be the Post-POC Development Plan for such Product Candidate under the IO License and Collaboration Agreement, or (B) Sanofi fails to timely provide an Opt-In Notice for such Product Candidate, then Sanofi shall be deemed to have provided an Opt-Out with respect to such Product Candidate and Section 5.3 shall apply.

5.3 Refused Candidates. If (v) Regeneron has provided an Initial Opt-In Report with respect to a Product Candidate and Sanofi fails to exercise its Opt-In Rights with respect to such Product Candidate during the Initial Opt-In Period (if any) therefor (or to provide a Deferral Notice within thirty (30) days, or to provide a Post-POC Plan Dispute Notice within thirty (30) days, after receipt of an Initial Opt-In Report therefor), (w) Sanofi has timely provided a Deferral Notice with respect to a Product Candidate but fails to exercise its Opt-In Rights during the Deferred Opt-In Period, or Extended Opt-In Period (if and as applicable) therefor, (x) Regeneron has provided a Breakthrough Opt-In Report with respect to a Product Candidate and Sanofi fails to exercise its Opt-In Rights within the Breakthrough Opt-In Period or Extended Opt-In Period (if and as applicable) therefor, (y) Regeneron has provided a Tail Expiration Notice with respect to one or more Tail Early Offer Antibodies and Sanofi fails to exercise its Opt-In Rights within the Tail Early Opt-In Period therefor, or (z) if Sanofi notifies Regeneron in writing that it will not exercise its Opt-In Rights with respect to a Product Candidate or Tail Early Offer Antibody during the Initial Opt-In Period (or the Deferred Opt-In Period, the Breakthrough Opt-In Period, the Tail Offer Opt-In Period or the Extended Opt-In Period, if and as applicable) therefor (each such action or inaction described in clauses (v)-(z) (inclusive), an "Opt-Out"), then, in each such case, the following shall apply:

(a) Refused Candidate. Sanofi's Opt-In Rights shall expire with respect to such Product Candidate or Tail Early Offer Antibody, and such Product Candidate or Tail Early Offer Antibody shall automatically become a "Refused Candidate" hereunder. All licenses granted in Section 2.7 shall automatically expire with respect to each Product Candidate or Tail Early Offer Antibody upon such Product Candidate or Tail Early Offer Antibody becoming a Refused Candidate. Following such time as a Product Candidate or Tail Early Offer Antibody becomes a Refused Candidate, Sanofi shall no longer have any rights to such Product Candidate or Tail Early Offer Antibody under this Agreement or the IO License and Collaboration Agreement. If Sanofi Opts-Out with respect to a Product Candidate prior to

the Budget Expiration Date (or, if such Product Candidate is a Tail Period Antibody, prior to the Tail Expiration Date), Regeneron may continue using funds in the IO Discovery Budget (or if such Product Candidate is a Tail Period Antibody, the Tail Period Budget) for the costs and expenses incurred by Regeneron and its Affiliates (to the extent such costs and expenses would or do constitute Program Costs) (x) in connection with the development of such Product Candidate following delivery of the Opt-In Report until such time as Sanofi Opts-Out with respect to such Product Candidate, subject to Section 5.5, and (y) in connection with winding down such activities in accordance with applicable Law (to the extent they are actually wound down as required by Law or ethical considerations) or if applicable Law or ethical considerations dictate that such activities continue, the conduct of such activities, in each case from and after such Opt-Out. Except as provided in this Section 5.3(a), any costs and expenses incurred by Regeneron or its Affiliates in connection with the development of a Refused Candidate following Opt-Out shall not constitute Program Costs hereunder. Notwithstanding anything to the contrary in this Agreement or any Ancillary Collaboration Agreement, upon such time as a Product Candidate or Tail Early Offer Antibody becomes a Refused Candidate, such Product Candidate or Tail Early Offer Antibody shall automatically become an "Excluded Candidate" under the Existing Discovery Agreement. For [***] Regeneron shall not owe any royalty or other payments to Sanofi under any Ancillary Collaboration Agreement with respect to any such Refused Candidate.

(b) Regeneron Rights. Regeneron may (i) continue to develop, manufacture and commercialize (on its own or with one or more Third Parties) any Refused Candidate without restriction outside of this Agreement and any Ancillary Collaboration Agreement unless the Refused Candidate is a Competing Refused Candidate, in which case, Section 2.5(d) shall apply, and (ii) practice and use [***]. For clarity, subject to Section 2.10, Regeneron may continue to develop and commercialize such IO Antibodies for use with one (1) or more other IO Antibodies (including IO Antibodies controlled by Regeneron or its Affiliates or by other Persons).

(c) Sanofi Rights and Obligations. Neither Sanofi nor its Affiliates, either directly, or with or through any Third Party, may develop or commercialize (i) any Refused Candidate or (ii) any IO Antibody that targets the same IO Target Profile as such Refused Candidate, other than Excluded Candidates that were External Candidates for which Sanofi was the Offering Party that did not [***], until the later of [***], and any such IO Antibody shall be referred to herein as a "Sanofi Restricted Antibody" for [***]; provided, that (1) if, as a result of [***], then such IO Antibodies shall cease to be Sanofi Restricted Antibodies upon the [***], and such restriction shall not apply, and Sanofi and its Affiliates shall be free to develop [***], during and after such period, or (2) with respect to any Tail Early Offer Antibody that becomes a Refused Candidate (I) pursuant to Section 5.2(f)(i), if Regeneron [***] at least [***] after [***], or (II) pursuant to Section 5.2(f)(ii), then, without limiting Sanofi's obligations with respect to any other Refused Candidate [***], such [***] will no longer apply with respect to such [***]. For clarity, any IO Antibody that [***] that was listed on Schedule 1 as of the Execution Date shall not, at any time during the Term or thereafter be considered an IO Discovery Program Antibody or a Refused Candidate under this Agreement.

5.4 Additional Development Prior to Opt-In. From and after Regeneron's delivery to Sanofi of an Initial Opt-In Report, Deferred Opt-In Report, Breakthrough Opt-In Report or Tail Early Opt-In Report with respect to a Product Candidate or a Tail Early Offer Antibody until Sanofi's exercise of its Opt-In Rights (or an Opt-Out) with respect to such Product Candidate or Tail Early Offer Antibody, [***]. After delivery of an Initial Opt-In Report or, if earlier, a Breakthrough Opt-In Report or Tail Early Opt-In Report with respect to a Product Candidate or a Tail Early Offer Antibody, as applicable, to Sanofi and prior to Sanofi exercising its Opt-In Rights (or an Opt-Out) with respect to such Product Candidate or Tail Early Offer Antibody, as applicable:

(a) Regeneron shall have the right to continue (or commence) any and all research and development activities that constitute POC Development (for the avoidance of doubt, other than Phase III Clinical Trials) with respect to such Product Candidate or Tail Early Offer Antibody, including with respect to [***], in each case, under the IO Discovery Program using the IO Discovery Budget or, with respect to (i) a Product Candidate that is a Tail Period Antibody or (ii) a Tail Early Offer Antibody, the Tail Period Budget; and

(b) Regeneron may, with the prior consent of Sanofi, conduct development activities with respect to such Product Candidate or Tail Early Offer Antibody that do not constitute POC Development but are reasonably intended to support or enable post-POC activities, including with respect to [***], in each case, under the IO Discovery Program using the IO Discovery Budget or, with respect to a Product Candidate that is a Tail Period Antibody or a Tail Early Offer Antibody, the Tail Period Budget; provided, that (i) if Sanofi Opts-In with respect to a Product Candidate, the costs of such development activities shall be handled in accordance with Section 5.2(e), (ii) if Sanofi Opts-In with respect to a Tail Early Offer Antibody, the costs of such development activities shall be handled in accordance with Section 5.2(f), and (iii) if Sanofi Opts-Out with respect to the Product Candidate or Tail Early Offer Antibody, the costs and expenses incurred by Regeneron and its Affiliates (to the extent such costs and expenses would or do constitute Program Costs) in connection with winding down such activities in accordance with applicable Law (to the extent they are actually wound down as required by Law or ethical considerations) or if applicable Law or ethical considerations dictate that such activities continue, the conduct of such activities, shall be funded under the IO Discovery Budget or the Tail Period Budget, as applicable, and Regeneron shall be solely responsible for any other costs associated with such development activities outside of the IO Discovery Program.

(c) In the event of a Post-POC Plan Dispute with respect to a Post-POC Development Plan and a Product Candidate, Regeneron [***]. If Sanofi exercises its Opt-In Rights with respect to a Product Candidate for which Regeneron has initiated or conducted portions of the Post-POC Development Plan pursuant to this Section 5.4(c), and thereafter Sanofi requests that Regeneron transfer the conduct of one or more of such activities to Sanofi, Regeneron and Sanofi shall work together in good faith to promptly transition such activities in a smooth and orderly manner.

5.5 Additional Development Following Opt-In. Notwithstanding anything to the contrary in this Agreement or the IO License and Collaboration Agreement, from and after the date that Regeneron receives an Opt-In Notice from Sanofi with respect to a Product Candidate or Tail Early Offer Antibody (in each case, which shall thereupon become an IO Licensed Product) or delivers a Tail POC Report to Sanofi with respect to such Tail Early Opt-In Antibody, Regeneron shall have the right to continue any POC Development clinical trials for such IO Licensed Products that have commenced (i.e., first patient first visit has occurred) at the time of Regeneron receives the applicable Opt-In Notice, and the costs and expenses of such post-Opt-In Notice clinical trials shall be treated as Program Costs and counted against the IO Discovery Budget or the Tail Period Budget, as applicable; provided, for the avoidance of doubt, that this Section 5.5 shall not apply to REGN2810.

5.6 Rights with respect to IO Antibodies that are also non-IO Antibodies. Notwithstanding anything to the contrary in this Agreement or the IO License and Collaboration Agreement, but subject to Section 5.3(a) of this Agreement, in the event that Sanofi exercises its opt-in rights under the Existing Discovery Agreement with respect to a Multi-Indication Antibody that targets an IO Target Profile, and such Multi-Indication Antibody becomes a Licensed Product under the Existing License and Collaboration Agreement, such Multi-Indication Antibody shall automatically cease to be an IO Antibody (and an IO Discovery Program Antibody, Tail Period Antibody or Tail Early Offer Antibody, if and as applicable) under this Agreement and shall instead be governed by the Existing License and Collaboration Agreement, and any ongoing costs and expenses in connection with such Multi-Indication Antibody shall be reimbursed by Sanofi under the Existing License and Collaboration Agreement. Notwithstanding anything to the contrary in this Agreement or the Existing Discovery Agreement, if any Multi-Indication Antibody becomes a "Refused Candidate" (as defined in the Existing Discovery Agreement) pursuant to Section 5.6 of the Existing Discovery Agreement, Regeneron shall have the right to develop such Multi-Indication Antibody for any Non-IO Indication outside of the IO Discovery Program at its own cost and expense.

5.7 Further Assurances and Transaction Approvals in Connection with Opt-In. Sanofi shall specify in each Opt-In Notice provided with respect to a Product Candidate or Tail Early Offer Antibody pursuant to this Article 5 whether, in Sanofi's reasonable opinion, the Parties would be required by applicable Law to file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any notification and report form under the HSR Act (an "HSR Filing") with respect to the exercise of Sanofi's Opt-In Rights with respect to the applicable Product Candidate or Tail Early Offer Antibody. The Parties will cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Sanofi shall be responsible for the filing fees associated with any such HSR Filing. The Parties shall each use commercially reasonable efforts to ensure that applicable waiting period under the HSR Act or any applicable comparable foreign law in the Territory expires or is terminated as soon as practicable. Notwithstanding the foregoing, nothing in this Section 5.7 shall require (a) either Party to disclose to the other Party any information that is subject to obligations of confidentiality owed to Third Parties (nor shall either Party be required to conduct joint meetings with any Governmental Authority in which such information might be shared with the other Party), or (b) either Party or any of its Affiliates to commit to any

divestiture, license (in whole or in part) or any arrangement to hold separate (or any similar arrangement) with respect to any of its products or assets.

ARTICLE 6
NEWLY CREATED INVENTIONS

6.1 Ownership of Newly Created Intellectual Property.

(a) Each Party shall exclusively own all intellectual property (including Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created solely by such Party, its employees, agents and consultants under this Agreement ("Sole Inventions"). Sole Inventions made solely by Sanofi, its employees, agents and consultants are referred to herein as "Sanofi Sole Inventions." Sole Inventions made solely by Regeneron, its employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's intellectual property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's intellectual property, other than the license rights expressly granted hereunder.

(b) The Parties shall jointly own all intellectual property (including Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under this Agreement that is discovered, invented, authored or otherwise created jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi (or for which ownership vests in Sanofi by operation of Law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron (or for which ownership vests in Regeneron by operation of Law), on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions").

(c) Notwithstanding Section 6.1(b), (i) for purposes of determining whether a an invention of patent-eligible subject matter is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws, (ii) for purposes of determining whether a work eligible for copyright protection is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright Laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work, Patents and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the Laws of the State of New York, United States, as determined in each case ((i), (ii) and (iii)), if necessary, by an independent Third Party.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under this Agreement vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby

does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) The Parties hereby agree that each Party's use of the Joint Inventions shall be governed by the terms and conditions of this Agreement, including the following: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement or the IO License and Collaboration Agreement); provided, that (i) each of the Parties acknowledges that it receives no rights to any intellectual property of the other Party underlying or necessary for the use of any Joint Invention, except as otherwise set forth herein or in the IO License and Collaboration Agreement, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 6.1(e), (iii) until the latest of (A) the Budget Expiration Date, (B) the fifth (5^{th}) anniversary of the Effective Date, or (C) with respect to any Tail Period Antibodies or [***], the Tail Expiration Date, each Party agrees not to license its interest in any Joint Invention with the right to use such Joint Invention for developing, manufacturing or commercializing Antibodies (except for developing, manufacturing or commercializing a Party's Antibodies in accordance with the terms and conditions of Section 2.5 or any Ancillary Collaboration Agreement) and (iv) nothing in this ARTICLE 6 shall relieve a Party or its Affiliates of its or their obligations under ARTICLE 9 with respect to Confidential Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have any obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of this Agreement and the IO License and Collaboration Agreement. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, including being brought as a third party to such action, if necessary, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld, conditioned or delayed.

6.2 Prosecution and Maintenance of Patent Rights.

(a) Subject to the terms of the IO License and Collaboration Agreement with respect to IO Licensed Products, Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights and Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities to the extent they are Product Patent Rights. With respect to the preparation, filing, prosecution and maintenance of those Patents and Patent Applications that are Product Patent Rights, (i) Regeneron shall [***], except that all provisional applications, priority applications and PCT applications [***]; (ii) Regeneron shall use Commercially Reasonable Efforts to provide to Sanofi for review and comment a draft of any priority Patent Application in the Territory at least sixty (60) days prior to the filing of any such priority Patent Application by

Regeneron; (iii) Regeneron shall [***]; and (iv) Regeneron shall [***]. Sanofi shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Sanofi Patent Rights; provided, that, with respect to the preparation, filing, prosecution and maintenance of those Patents and Patent Applications that are Product Patent Rights, Sanofi shall confer with and keep Regeneron reasonably informed regarding the status of such activities and [***], except that all provisional applications, priority applications and PCT applications [***].

(b) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of Regeneron. Regeneron shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners using outside counsel reasonably acceptable to Sanofi, except, at Regeneron's option, all provisional applications, priority applications and PCT applications [***].

(c) The Parties shall have the following obligations with respect to the filing, prosecution and maintenance of any Joint Patent Rights, as well as any Product Patent Rights: (i) the prosecuting Party (the "Prosecuting Party") shall provide the other Party (the "Non-Prosecuting Party") with notice and a copy of a substantially completed draft of any Patent Application at least thirty (30) days prior to the filing of any such Patent Application by the Prosecuting Party and incorporate all reasonable comments provided by the Non-Prosecuting Party within such thirty (30) day period unless the Prosecuting Party reasonably believes that such comments will adversely affect the scope or validity of the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) the Prosecuting Party shall notify the Non-Prosecuting Party prior to its filing of a Patent Application; (iii) the Prosecuting Party shall consult with the Non-Prosecuting Party promptly following the filing of the Patent Application to mutually determine in which countries it shall file any Patent Applications claiming priority to the filed Patent application, including Patent applications filed under the Paris Convention for the Protection of Industrial Property claiming priority to the filed Patent Application or any regional or national phase Patent Applications derived from an international (PCT) Patent Application claiming priority to the filed Patent Application; (iv) the Prosecuting Party shall provide the Non-Prosecuting Party promptly with copies of all material communications received from or filed in patent offices with respect to such applications and incorporate all reasonable comments provided by the Non-Prosecuting Party, unless the Prosecuting Party reasonably believes that such comments will adversely affect the validity or scope of the Patent Application or resulting Patent for both Parties; and (v) the Prosecuting Party shall provide the Non-Prosecuting Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but (unless the period permitted by the applicable patent office for taking an action is less than sixty (60) days) in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office (including substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or

perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction such that the Non-Prosecuting Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances, including assuming the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right or Joint Patent Right and becoming the Prosecuting Party. With respect to Joint Inventions, it is understood that the Parties shall use all reasonable efforts to reach agreement on all material filings and amendments and no such material filings or amendments shall be made by the Prosecuting Party without the prior written agreement of the Non-Prosecuting Party, such agreement not to be unreasonably withheld, conditioned or delayed. In addition, in the event that the Prosecuting Party materially breaches the foregoing obligations and such material breach is not cured within thirty (30) days of a written notice from the Non-Prosecuting Party describing such breach in reasonable detail, or in the event that the Prosecuting Party fails to undertake the filing of a Patent Application within the earlier of (A) ninety (90) days of a written request by the Non-Prosecuting Party to do so, and (B) sixty (60) days prior to the anticipated filing date, the Non-Prosecuting Party may assume the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right and will thereafter be deemed the Prosecuting Party for purposes hereof. Notwithstanding the foregoing, the Prosecuting Party may withdraw from, abandon or allow to expire any Patent or Patent Application on thirty (30) days' prior notice to the Non-Prosecuting Party (provided, that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the Non-Prosecuting Party the right to assume the prosecution or maintenance thereof.

(d) All costs and expenses incurred in the filing, prosecution and maintenance, including any administrative proceedings, such as Inter Partes Reviews and Oppositions, of any Joint Patent Rights and Product Patent Rights and in performing freedom to operate analyses on IO Target Profiles (including any Targets contained therein) or IO Discovery Program Antibodies shall be shared equally (50%/50%) by the Parties.

(e) Neither Party shall have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004 (Pub. L. 108-453, 118 Stat. 3596 (2004)) (the "CREATE Act") by making filings or undertaking other activities under pre-AIA (Leahy-Smith America Invents Act), 35 U.S.C. § 103(c)(2)-(c)(3), or post-AIA, 35 U.S.C. § 102(c), with respect to Joint Inventions, without the prior written consent of the other Party. In the event that a Party intends to so invoke the CREATE Act, as permitted by the preceding sentence, it shall notify the other Party and the Parties shall reasonably cooperate and coordinate their activities with respect to any such submissions, filings or other activities. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act, pre-AIA, 35 U.S.C. § 103(c)(2)-(c)(3), and post-AIA, 35 U.S.C. § 102(c). For the avoidance of doubt, nothing in this Section 6.2(e) shall amend or modify the determination of ownership of intellectual property as set forth in Section 6.1.

6.3 Third Party Claims. In the normal course of business, Regeneron shall carry out patent searches in relation to the IO Discovery Program Target Profiles and IO Discovery

Program Antibodies. If either Party or its Affiliates becomes aware of a Third Party claim, assertion or certification that the activities under the IO Discovery Program infringe or otherwise violate the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this claim, assertion or certification. As soon as reasonably practical after the receipt of such notice, the Parties shall cause their respective legal counsel to meet to confer on such allegation of infringement. In particular, with regard to issues related to freedom to operate concerning any IO Discovery Program Target Profiles, IO Discovery Program Antibodies or Product Candidates pursued under this Agreement, the Parties shall conduct and maintain ongoing and regular communications between their legal/intellectual property departments.

ARTICLE 7
FINANCIAL BOOKS AND RECORDS; AUDITS AND ADJUSTMENTS

7.1 Financial Books and Records . Each Party shall keep proper books of record and account in which full, true and correct entries (in conformity with the principles set forth in Section 7.3) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall permit auditors, as provided in Section 7.2, to visit and inspect, during regular business hours and under the guidance of its employees, the books of record and account of such Party to the extent relating to this Agreement and discuss its affairs, finances and accounts to the extent relating to this Agreement.

7.2 Audits and Adjustments.

(a) Audit Timing. Each Party shall have the right, upon no less than thirty (30) days' advance written notice and at such reasonable times and intervals and to such reasonable extent as the Party shall request, not more than once during any Contract Year, to have the books and records of the other Party maintained pursuant to Section 7.1 to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable, appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided, that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) Audit Results. The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days of delivery. If a Party over billed or underpaid an amount due under this Agreement resulting in a cumulative discrepancy of amounts paid during any year of more than [***], it shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the Party initiating the audit in all other cases). Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement, the Parties shall cause such accountants to enter into a reasonably acceptable confidentiality agreement with the audited Party and obligating such firm to retain all such

financial information in confidence pursuant to terms no less stringent than those set forth in ARTICLE 9.

(c) Adjustments. If any examination or audit of the records described above discloses an overpayment or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 7.2(d), (i) the Party that underpaid shall pay any amounts due plus, if such underpayment is the underpaying Party's fault, interest thereon at the Default Interest Rate accruing from the date of such underpayment, or (ii) the Party that received an overpayment shall refund such overpayment plus, if such overpayment is the fault of the Party refunding such payment, interest thereon at the Default Interest Rate accruing from the date of such overpayment, in each case (i) and (ii) within thirty (30) days after receipt of the written results of such audit.

(d) Disputes. Subject to the first (1st) sentence of Section 7.2(b), any disputes with respect to the results of any audit conducted under this Section 7.2 shall be resolved by binding arbitration in accordance with Section 13.1.

7.3 IFRS/GAAP. Except as otherwise provided herein, all of a Party's costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with such Party's Accounting Standards, as generally and consistently applied.

ARTICLE 8
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Mutual Representations and Warranties. Each Party hereto represents and warrants to the other Party, as of the Execution Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents or any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of applicable Laws; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium and other Laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity); (e) such Party is not prohibited by the terms of any agreement to which it is a party from performing the IO Discovery Program or granting the rights or licenses hereunder; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.

8.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, except for any event, circumstance, condition or other matter disclosed in any report and other document furnished to or filed with the United States Securities and Exchange Commission, as of the Execution Date, there is no claim, announced investigation,

suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator, or other Governmental Authority that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

8.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, except for any event, circumstance, condition or other matter disclosed in any report and other document furnished to or filed with the United States Securities and Exchange Commission by Regeneron or as otherwise discussed between Regeneron and Sanofi, as of the Execution Date:

(a) Regeneron owns or has a valid license to all Regeneron Patent Rights in existence as of the Execution Date;

(b) Regeneron has the right and authority to grant the rights (including the Opt-In Rights) granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted, and will not grant during the Term, any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;

(c) there is no pending litigation of which Regeneron has received notice that alleges that any of Regeneron's activities relating to the Mice or the Regeneron Intellectual Property have violated, or would violate, a Valid Claim of any Third Party (nor has it received any written communication threatening such litigation);

(d) to Regeneron's knowledge, no litigation has been otherwise threatened that alleges that any of its activities relating to the Mice or the Regeneron Intellectual Property have violated or would violate, a Valid Claim of any Third Party;

(e) to Regeneron's knowledge, after due inquiry, the use of the Mice and the Regeneron Intellectual Property generally in the IO Discovery Program (but not with respect to a specific MTC, IO Antibody, IO Target Profile or Target) do not and will not infringe or otherwise violate a claim of any Patent of any Third Party that is issued and unexpired on the Execution Date and claims genetically modified mice or the use thereof to make Antibodies;

(f) to Regeneron's knowledge, neither the development or reproduction of the Mice nor the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has constituted or involved the misappropriation of (i) trade secrets or (ii) other rights of any Person;

(g) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;

(h) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings; and

(i) neither Regeneron nor any of its Affiliates shall transfer ownership, assign ownership, grant a security interest in or otherwise encumber any of its rights in, to or under any Regeneron Intellectual Property in a way that will impair Sanofi's rights or Regeneron ability to perform its obligations under this Agreement.

8.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 9
CONFIDENTIALITY

9.1 Confidential Information. During the Term and for a period of five (5) years thereafter, each Party (in such capacity, the "Receiving Party") shall keep confidential, and other than as provided herein or in the IO License and Collaboration Agreement, shall not use or disclose, directly or indirectly, any and all trade secrets or other proprietary information, including, any proprietary data, inventions, documents, ideas, information, discoveries, or materials, owned, developed, or possessed by the other Party (in such capacity, the "Disclosing Party"), whether in tangible or intangible form, the confidentiality of which the Disclosing Party takes reasonable measures to protect, including Regeneron Know-How and Sanofi Know-How disclosed by the Disclosing Party under this Agreement or the Existing Discovery Agreement (collectively, the "Confidential Information"). Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party to any Third Party except to its employees, agents, consultants or any other Person under its authorization; provided, that such employees, agents, consultants or other Persons are subject in writing to confidentiality obligations applicable to the Disclosing Party's Confidential Information no less strict than those set forth herein.

(a) Notwithstanding the foregoing, Confidential Information shall not be deemed to include information and materials (and such information and materials shall not be considered Confidential Information under this Agreement) to the extent that it can be established by written documentation by the Receiving Party that such information or material is: (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the Receiving Party or any Person to whom the Receiving

Party provided such information; (ii) is or was already in the possession of the Receiving Party at the time of disclosure by the Disclosing Party; provided, that this clause (ii) shall not apply with respect to Confidential Information received by the Receiving Party from the Disclosing Party prior to the Effective Date; (iii) is disclosed to the Receiving Party on an unrestricted basis from a Third Party not under an obligation of confidentiality to the Disclosing Party or any Affiliate of the Disclosing Party with respect to such information; or (iv) information that has been independently created by the Receiving Party (or its Affiliate), as evidenced by written or electronic documentation, without any aid, application or use of the Disclosing Party's Confidential Information.

(b) Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information to the extent such disclosure is made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the Receiving Party, such disclosure is otherwise required by Law, including any securities Laws; provided, that the Receiving Party (i) uses reasonable efforts to give the Disclosing Party advance notice of such required disclosure in sufficient time to enable the Disclosing Party to seek confidential treatment for such information, and provides all reasonable cooperation to assist the Disclosing Party to so protect the confidentiality of such information and (ii) limits the disclosure to that information which is legally required to be disclosed in response to such court or governmental order.

(c) Information and other Know-How that is discovered by Regeneron in the course of conducting the IO Discovery Program (other than Sanofi Funded Trials) will be considered Regeneron's Confidential Information, except to the extent it relates to an IO Licensed Product, in which case it shall be Confidential Information of both Parties, subject to the terms of the IO License and Collaboration Agreement or a Sanofi Funded Trial conducted by Regeneron, in which case it shall be Confidential Information of both Parties.

(d) Specific aspects or details of Confidential Information will not be deemed to be within the public knowledge or in the prior possession of a Person merely because such aspects or details of the Confidential Information are embraced by general disclosures in the public domain. In addition, any combination of Confidential Information will not be considered in the public knowledge or in the prior possession of a Person merely because individual elements thereof are in the public domain or in the prior possession of such Person unless (i) the combination and its principles are in the public knowledge or in the prior possession of such Person and (ii) the combination is documented, in a single contemporaneous document, as in the public knowledge or in the prior possession of such Person.

(e) Notwithstanding anything else in this Agreement to the contrary, each Party (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or

to any employee, representative, or other agent of any Party) relating to such tax treatment or tax structure; provided, that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities Laws. This authorization of disclosure is retroactively effective immediately upon commencement of the first discussions regarding the transactions contemplated herein, and the Parties aver and affirm that this tax disclosure authorization has been given on a date which is no later than thirty (30) days from the first (1st) day that any Party (or any employee, representative, or other agent of any Party) first made or provided a statement as to the potential tax consequences that may result from the transactions contemplated hereby.

9.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties under this Agreement are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged Party will be entitled to seek in any court of competent jurisdiction.

9.3 Publications. If either Sanofi or Regeneron (the "Publishing Party") desires to publish or publicly present any results from the IO Discovery Program in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance final copy of any proposed publication or summary of a proposed oral presentation relating to such information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to preserve the confidentiality of its Confidential Information and to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it as a result of the publication or disclosure, to which the Publishing Party shall give due consideration. If such other Party informs the Publishing Party, within thirty (30) days of receipt (or such other period agreed to by the IOSC) of an advance copy of a proposed publication or summary of a proposed oral presentation, that such publication in its reasonable judgment should not be published or presented, the Publishing Party shall delay or prevent such disclosure or publication as proposed by the other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a Patent Application(s) or application(s) for a certificate of invention on the information involved. The Parties shall establish a publication review process to ensure compliance with this Section 9.3. Regeneron shall have the sole right to publish or publicly present results from the IO Discovery Program related to any Excluded Candidate (other than Excluded Candidates that were External Candidates for which Sanofi was the Offering Party), [***] or Refused Candidate without the consent of, and without providing any notice to, Sanofi, and any such publication or presentation shall not be subject to this Section 9.3.

9.4 Disclosures Concerning this Agreement. The Parties will mutually agree on the contents of their respective press releases with respect to the execution of this Agreement, the IO License and Collaboration Agreement and the amendments to the Existing Discovery Agreement and Existing License and Collaboration Agreement, which press releases shall be issued simultaneously by each Party on the Execution Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided, that the Party intending to disclose such information shall (a) use reasonable efforts to (i) provide the other Party advance notice of such required disclosure and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and (ii) assist the other Party to protect such information and (b) limit the disclosure to the information that is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements that incorporate information concerning this Agreement or any activities contemplated hereunder that was included in a press release or public disclosure that was previously disclosed under the terms of this Agreement or that contains only non-material factual information regarding this Agreement. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement or adjudication of any Arbitrable Matter or Expert Panel Dispute, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this ARTICLE 9 without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. Each Party acknowledges that the other Party, as a publicly traded company, is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with one another and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE 10
INDEMNITY

10.1 Indemnity.

(a) Indemnification by Sanofi. Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees, sublicensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement (a "Third Party Claim") against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions of Sanofi or its Affiliates (or their respective agents, contractors, sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement, including in connection with the IO Discovery Program (including any Sanofi Funded Trial); or

(ii) material breach by Sanofi (or conduct or omission of any of its Affiliates which, if performed or failed to be performed by Sanofi, would be a material breach by Sanofi) of the terms of, or any representation or warranty made by it in, this Agreement;

except in each case ((i) and (ii)) to the extent that Damages arise out of the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions committed by Regeneron or its Affiliates (or their respective agents, contractors, sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement or the material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of this Agreement.

(b) Indemnification by Regeneron. Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and its and their respective officers, directors, employees and agents ("Sanofi Indemnitees") from and against all Damages arising from a Third Party Claim a Sanofi Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions of Regeneron or its Affiliates (or their respective agents, contractors, sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement, including in connection with the IO Discovery Program (including any Sanofi Funded Trial conducted by Regeneron); or

(ii) material breach by Regeneron (or conduct or omission of any of its Affiliates which, if performed or failed to be performed by Regeneron, would be a material breach by Regeneron) of the terms of any representation or warranty made by it in, this Agreement; or

(iii) except in each case ((i) and (ii)) to the extent that Damages arise out of the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions committed by Sanofi or its Affiliates (or their respective agents, contractors, sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement or the material breach by Sanofi (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Sanofi would be a material breach by Sanofi) of the terms of this Agreement.

10.2 Indemnity Procedure.

(a) Notice. The Party entitled to indemnification under this ARTICLE 10 (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of being notified of any claim or claims asserted or threatened against the Indemnified Party that could give rise to a right of indemnification under this Agreement; provided, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices the Indemnifying Party.

(b) Right to Defend. If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending a claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld, conditioned or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed); provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

(c) Participation by Indemnified Party. The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to Section 10.2(b) and shall bear its own costs and expenses with respect to such participation; provided, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.

(d) Cooperation. Regardless of whether the Indemnifying Party assumes the defense of any claim pursuant to this Section 10.2, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to, reasonably cooperate in the defense or prosecution thereof, and, if the Indemnifying Party assumes the defense of any such claim, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals, in each case, as may be reasonably requested in connection therewith. Such cooperation shall include access upon reasonable notice during normal business hours afforded to the Indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and to the extent the Indemnified Party is entitled to indemnification pursuant to this ARTICLE 10, the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection with providing such assistance.

10.3 Insurance. During the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by applicable Law, each of Regeneron and Sanofi will (a) use Commercially Reasonable Efforts to procure and maintain commercial general liability and product liability insurance in an amount not less than [***] per occurrence and in the annual aggregate or (b) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Sanofi, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party under Section 10.1 with respect to such Damages.

ARTICLE 11
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, acts of terrorism, acts of war

(whether war be declared or not), insurrections, strikes, riots, civil commotions, or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance, unless the affected Party has caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances. In the event of a Force Majeure, the performance of the Party giving such notification shall be abated and any time deadlines shall be extended for so long as the performance is prevented by Force Majeure; provided, that notwithstanding the foregoing, in no event will any Force Majeure or such abatement extend beyond one hundred eight (180) days.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. The "Term" of this Agreement shall commence on the Effective Date and shall continue until the latest of (a) the fifth (5^{th}) anniversary of the Effective Date, (b) the Budget Expiration Date, and (c) the Tail Expiration Date, if any, unless this Agreement is earlier terminated in accordance with this ARTICLE 12, in which event the Term shall end on the effective date of such termination.

12.2 Termination for Material Breach. Upon and subject to the terms and conditions of this Section 12.2, this Agreement shall be terminable by a Party in its entirety upon notice to the other Party if such other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged material breach (and specifically referencing the provisions of this Agreement alleged to have been materially breached), and the termination that is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such alleged material breach within such ninety (90) day period. Notwithstanding the foregoing, in the case of breach of a payment obligation not subject to a bona fide dispute hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be forty-five (45) days. For purposes of this Section 12.2, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above), material breach by a Party as determined by binding arbitration consistent with the provisions of Section 13.1.

12.3 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, the other Party (a) files in any court or agency pursuant to any Laws, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) proposes a written agreement of composition or extension of its debts, (c) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within sixty (60) days after the filing thereof, (d) proposes, or becomes a party to, any dissolution or liquidation, or (e) makes an assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for

purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including any Patent Rights in any country of a Party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the U.S. Bankruptcy Code, and any similar Laws in any other country in the Territory.

12.4 Termination for Breach of the IO License and Collaboration Agreement. Notwithstanding anything to the contrary herein, (a) Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Sanofi, if Regeneron has terminated the IO License and Collaboration Agreement, in its entirety, pursuant to Section 19.3, or Section 19.4 of the IO License and Collaboration Agreement, and (b) Sanofi shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Regeneron, if Sanofi has terminated the IO License and Collaboration Agreement, in its entirety, pursuant to Section 19.3 or Section 19.4 of the IO License and Collaboration Agreement.

12.5 Effect of Termination by Sanofi for Breach. Notwithstanding anything herein to the contrary, in the event that Sanofi terminates this Agreement pursuant to Sections 12.2, in addition to the provisions of Section 12.7 and Section 12.9, the following shall apply:

(a) Sanofi shall be granted a non-exclusive, non-transferable, fully paid-up, royalty-free, worldwide license, without the right to sublicense, for a period that shall expire eight (8) years from the Effective Date, to the Mice and the underlying Regeneron Intellectual Property for Sanofi and its Affiliates to use to identify, discover and develop MTCs as IO Antibodies;

(b) Regeneron shall perform a timely and expeditious technology transfer as required by Sanofi to pursue its rights under Section 12.5(a), subject to the execution of a material transfer agreement containing non-financial terms and conditions related to the use of the Mice consistent with Regeneron's commercial license agreements for the Mice;

(c) the licenses granted to Regeneron under this Agreement shall automatically terminate;

(d) Sanofi shall be granted a co-exclusive (with Regeneron and its Affiliates), fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense, under the Regeneron Target IP existing at the effective time of termination solely for use to develop and commercialize IO Discovery Program Antibodies that are the subject of the IO Discovery Program as of the effective time of termination (and for no other uses); and

(e) Sanofi shall have no further funding obligations under ARTICLE 4.

12.6 Effect of Termination by Regeneron for Breach. Notwithstanding anything herein to the contrary, in the event that Regeneron terminates this Agreement pursuant to Sections 12.2, in addition to the provisions of Section 12.7 and Section 12.9, the following shall apply:

(a) the licenses granted to Sanofi under this Agreement shall automatically terminate; and

(b) Regeneron shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense, under the Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize IO Discovery Program Antibodies that are the subject of the IO Discovery Program as of the effective time of termination (and for no other uses).

12.7 Survival of Obligations. Subject to Section 12.5, Section 12.6, and Section 12.10, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate and this Agreement shall cease to be of further force or effect; provided, that:

(a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including the payment of any non-cancelable Program Costs incurred as part of the IO Discovery Program (even if such costs and expenses arise following termination or expiration, as the case may be); provided, that Sanofi shall not be obligated to pay or reimburse Regeneron for any such Program Costs in the event Sanofi terminates this Agreement pursuant to Section 12.2;

(b) the obligations of the Parties with respect to the protection and nondisclosure of the other Party's Confidential Information in accordance with ARTICLE 9, as well as other provisions that by their nature are intended to survive any such expiration or termination (including Section 2.8 (except as set forth in Section 12.6), Section 4.2(e), Section 5.2(g), Section 5.5, Section 5.7, Section 6.1(e), Section 6.2(b), Section 6.2(c), Section 6.2(d) (as it relates to Joint Patent Rights) and Section 7.2, ARTICLE 10, this ARTICLE 12, and ARTICLE 13), shall survive and continue to be enforceable;

(c) without limiting Section 12.10, neither the early termination of this Agreement by either Party nor the expiration of this Agreement shall relieve Regeneron of any of its royalty obligations under ARTICLE 4 with respect to any IO Royalty Product, for which royalties remain payable to Sanofi under this Agreement, and such royalty provisions of ARTICLE 4 shall survive;

(d) with respect to a Tail Early Opt-In Antibody (if any), the provisions of this Agreement shall survive until the delivery by Regeneron to Sanofi of a Tail POC Report or a Tail Early Opt-In Termination Notice, as applicable; and

(e) the expiration or termination of this Agreement, and the terms and conditions of this ARTICLE 12 shall be without prejudice to any rights or remedies a Party may have for breach of this Agreement.

12.8 Return of Confidential Information. Subject to either Party's licenses that survive termination or expiration of this Agreement, Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Subject to the terms of the IO License and Collaboration Agreement (with respect to IO Licensed Products), upon the expiration or earlier termination of this Agreement, or upon written request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof); provided, that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement. An officer of the Receiving Party also shall certify in writing that it has satisfied its obligations under this Section 12.8 within ten (10) days of a written request by the Disclosing Party.

12.9 Special Damages. If Regeneron terminates this Agreement pursuant to Section 12.2, then, without limiting any other amount payable by Sanofi to Regeneron under this Agreement under Laws or pursuant to any contractual remedies available to Regeneron, Sanofi shall pay Regeneron, within sixty (60) days of the termination of this Agreement, an amount equal to the balance of the IO Discovery Budget (or Tail Period Budget, if any) that has not as of the effective date of termination been paid by Sanofi to Regeneron hereunder.

12.10 Termination by Sanofi At Will. Sanofi shall be entitled to terminate this Agreement at any time (except following a material breach of this Agreement by Sanofi pursuant to Section 12.2) without cause upon three (3) months' written notice to Regeneron. If Sanofi terminates the Agreement under this Section 12.10, then Sanofi shall pay to Regeneron within five (5) days of its notice of termination, an amount equal to the balance of the IO Discovery Budget (and Tail Period Budget, if any) that has not as of the effective date of termination been paid by Sanofi to Regeneron hereunder. In the event of such termination, in addition to the provisions of Section 12.7, Regeneron shall be granted a non-exclusive, non-transferable, royalty-bearing (in accordance with Section 4.4) worldwide license with the right to sublicense under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize IO Discovery Program Antibodies targeting IO Discovery Program Target Profiles in existence and included in the IO Discovery Program at the effective time of termination.

ARTICLE 13
DISPUTE RESOLUTION

13.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

13.2 Arbitrable Matters.

(a) Overview. In the event of a dispute between the Parties regarding any of the following matters (each, an "Arbitrable Matter") (i) the results of an audit under Section 7.2(d), and (ii) whether a breach constitutes a "material breach" as described in Section 12.2, the matter shall be resolved pursuant to this Section 13.2.

(b) Arbitration Procedures. Each Arbitrable Matter that is not an Expert Panel Dispute shall be resolved by binding arbitration by one (1) arbitrator who shall be an independent expert in the pharmaceutical or biotechnology industry mutually acceptable to the Parties. The Parties shall use their best efforts to mutually agree upon one (1) arbitrator; provided, that if the Parties have not done so within ten (10) days after initiation of arbitration by a Party hereunder, or such longer period of time as the Parties have agreed to in writing, then such arbitrator shall be an independent expert as described in the preceding sentence selected by the New York office of the American Arbitration Association. Such arbitration shall be limited to casting the deciding vote with respect to the Arbitrable Matter as more fully described in Section 13.2(c) and Section 13.2(d). In connection therewith, each Party shall submit to the arbitrator in writing its position on and desired resolution of such Arbitrable Matter. Such submission shall be made within ten (10) days of the selection or appointment of the arbitrator, and the arbitrator shall rule on the Arbitrable Matter within ten (10) days of receipt of the written submissions by both Parties. The arbitrator shall select one of the Parties' positions as his or her decision, and shall not have authority to render any substantive decision other than to so select the position of either Regeneron or Sanofi. Except as provided in the preceding sentence, such arbitration shall be conducted in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association. The arbitrator's ruling shall be final and binding upon the Parties. The costs of any arbitration conducted pursuant to this Section 13.2 shall be borne equally (50%/50%) by the Parties. The Parties shall use diligent efforts to cause the completion of any such arbitration within sixty (60) days following a request by any Party for such arbitration.

(c) Material Breach Under Section 12.2. The issue that shall be submitted to the arbitrator shall be whether the breach committed by a Party meets the requirements for a material breach under Section 12.2.

(d) Audit Disputes. The issue that shall be submitted to the arbitrator shall be the results of an audit as described under Section 7.2(d).

13.3 Expert Panel Disputes .

(a) Overview. In the event of an Expert Panel Dispute between the Parties, the Parties shall use all reasonable efforts to resolve any such Expert Panel Dispute by good faith negotiation and discussion. In the event that the Parties are unable to resolve any such Expert Panel Dispute within ten (10) Business Days of receipt by a Party of notice of such Expert Panel Dispute, either Party may submit the Expert Panel Dispute to the Executive Officers for resolution, specifying the nature of the Expert Panel Dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive

Officers shall diligently and in good faith attempt to resolve the referred Expert Panel Dispute within ten (10) Business Days of receiving such written notification. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve any such Expert Panel Dispute, the Parties shall refer such Expert Panel Dispute to an Expert Panel for resolution in accordance with Section 13.3(b).

(b) Expert Panel.

(i) In the event of any Expert Panel Dispute that cannot be resolved by the Executive Officers pursuant to Section 13.3(a), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 13.3(b). The specific issue to be decided by the Expert Panel with respect to (A) any Budget Dispute shall be limited to [***] each proposed budget submitted by a Party pursuant to Section 13.3(b)(iv), (B) any [***] shall be limited to [***], (c) with respect to a [***] shall be limited to whether or not [***], and (d) with respect to a Post-POC Plan Dispute shall be limited to a determination of [***], based on [***].

(ii) Within fifteen (15) Business Days of such notice, each Party shall appoint to the Expert Panel an individual who (A) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue, (B) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (C) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (A) through (C) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.

(iii) Within fifteen (15) Business Days of the appointment of the second (2nd) expert, the two (2) appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third (3rd) expert, then upon the written request of either Party, each Party-appointed expert shall, within five (5) Business Days of such request, nominate one expert candidate and the American Arbitration Association shall, within five (5) Business Days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.

(iv) In the case of a Budget Dispute, within ten (10) Business Days of the appointment of the third (3rd) expert, each Party shall submit to the Expert Panel in

writing its proposed version of the Disputed Budget. The specific issue that shall be submitted to the Expert Panel shall be limited to [***] budgets that are submitted. In connection with reaching its decision, the Expert Panel may order the Parties to produce any documents or other information that are relevant to the Expert Panel's decision. The Expert Panel shall select from the Parties' proposed budgets the one that [***], and shall not have authority to render any substantive decision other than to so select the proposed budget of either Regeneron or Sanofi. The budget selected by the Expert Panel shall be the final Tail Period Budget and binding on the Parties unless and until such budget is later amended by the mutual agreement of the Parties in accordance with Section 2.6 and this Agreement. Such decision shall be rendered by the Expert Panel no later than ten (10) Business Days after receipt by the Expert Panel of the Parties' respective proposed budgets.

(v) In the case of a [***] Dispute, within ten (10) Business Days of the appointment of the third (3rd) expert, each Party shall submit to the Expert Panel in writing its position as to [***]. The specific issue that shall be submitted to the Expert Panel shall be limited to [***]. In connection with reaching its decision, the Expert Panel may order the Parties to produce any documents or other information that are relevant to the Expert Panel's decision. The Expert Panel shall determine [***], and shall not have authority to render any substantive decision other than to so [***]. The [***] selected by the Expert Panel shall be the [***] that is deemed to be [***] and such selection shall be binding on the Parties. Such decision shall be rendered by the Expert Panel no later than ten (10) Business Days after receipt by the Expert Panel of the Parties' respective proposals.

(vi) In the case of a [***] Dispute, within ten (10) Business Days of the appointment of the third (3rd) expert, each Party shall submit to the Expert Panel in writing its position with respect to whether the proposed [***] that is the subject of such dispute is or is not [***], and each Party may include any documentation or other information that such Party determines may be relevant to the Expert Panel's decision; provided, that neither Party shall have the right to submit further documentation or other information to the Expert Panel after the expiration of such ten- (10-) Business Day period. The specific issue that shall be submitted to the Expert Panel shall be limited to whether or not such [***] is or is not [***]. The Expert Panel shall determine whether or not such [***] is or is not [***], and shall not have authority to render any other substantive decision. The Expert Panel's determination shall be final and binding on the Parties. Such decision shall be rendered by the Expert Panel no later than ten (10) Business Days after receipt by the Expert Panel of the Parties' respective positions.

(vii) In the case of a Post-POC Plan Dispute, within ten (10) Business Days of the appointment of the third (3rd) expert, each Party shall submit to the Expert Panel in writing its proposed version of the Disputed Plan Components. The specific issue that shall be submitted to the Expert Panel shall be limited to a determination of which of the proposed Post-POC Development Plans is [***]. In connection with reaching its decision, the Expert Panel may order the Parties to produce any documents or

other information that are relevant to the Expert Panel's decision. The Expert Panel shall select the proposed Post-POC Development Plan that is [***], and the Expert Panel shall not have authority to render any substantive decision other than to so select the proposed Post-POC Development Plan of either Regeneron or Sanofi. The plan selected by the Expert Panel shall be the final Post-POC Development Plan unless and until such plan is later amended in accordance with the IO License and Collaboration Agreement. Such decision shall be rendered by the Expert Panel no later than ten (10) Business Days after receipt by the Expert Panel of the Parties' respective proposed Post-POC Development Plans.

(viii) Except as provided in clauses (iv), (v) or (vi) above, any arbitration conducted pursuant to this Section 13.3 shall be conducted in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association. The Expert Panel's ruling shall be final and binding upon the Parties. The costs of any arbitration conducted pursuant to this Section 13.3(b) shall be borne equally (50%/50%) by the Parties. The Parties shall use diligent efforts to cause the completion of any such arbitration within forty-five (45) Business Days following a request by any Party for such arbitration. In rendering the final decision the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

ARTICLE 14
MISCELLANEOUS

14.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Except as set forth in ARTICLE 13, each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts. Each Party further agrees that service of any process, summons, notice or document delivered by reputable international overnight courier service to its address set forth in Section 14.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

14.2 Waiver . Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver

shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

14.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 4 attached hereto and shall be (a) delivered personally, or (b) sent via a reputable international overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand or one (1) Business Day after it is sent via a reputable international overnight courier service. Either Party may change its address by giving notice to the other Party in the manner provided above.

14.4 Entire Agreement. This Agreement and the IO License and Collaboration Agreement contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersede all prior understandings and writings relating to the subject matter hereof and thereof; provided that in the event of any conflict or inconsistency between this Agreement, on the one hand, and the IO License and Collaboration Agreement, on the other hand, this Agreement shall control regarding the Parties' rights and obligations with respect to any IO Antibody, IO Discovery Program Antibody or Product Candidate prior to Sanofi's exercise of its Opt-In Rights with respect to such Product Candidate, and the IO License and Collaboration Agreement shall control regarding the Parties' rights and obligations with respect to any IO Licensed Product from and after the time a Product Candidate or Tail Early Offer Antibody becomes an IO Licensed Product (except to the extent otherwise expressly provided in this Agreement). For the avoidance of doubt, the Existing Discovery Agreement and the Existing License and Collaboration Agreement shall remain in full force and effect in accordance with their respective terms and any variation between a provision of this Agreement and a corresponding or similar provision of the Existing Discovery Agreement or the Existing License and Collaboration Agreement shall not be considered in the interpretation of this Agreement, the Existing Discovery Agreement or the Existing License and Collaboration Agreement.

14.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

14.6 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided, that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

14.7 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to

the provisions of Section 9.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

14.8 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet a Party's obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

14.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 14.12.

14.10 Affiliates. Each Party may, and to the extent it is in the best interests of the IO Discovery Program shall, perform its obligations under this Agreement through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

14.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. This Agreement may be executed by exchange between the Parties of electronically transmitted signatures (via facsimile, PDF format via e-mail or other electronic means) and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

14.12 Third Party Beneficiaries. Except as provided below in this Section 14.12, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the

foregoing, ARTICLE 10 is intended to benefit, and to be enforceable by, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is only enforceable by the Parties.

14.13 Relationship of the Parties. Each Party shall bear its own costs and expenses incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided for in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

14.14 Limitation of Damages. EXCEPT AS SET FORTH IN SECTION 12.9, IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM THAT IS COVERED BY THE INDEMNIFICATION OBLIGATIONS IN ARTICLE 10.

14.15 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the performance of the IO Discovery Program to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

14.16 Construction.

(a) The use of words in the singular or plural, or with a particular gender, shall not limit the scope or exclude the application of any provision of this Agreement to such person or persons or circumstances as the context otherwise permits. The words "will" and "shall" shall have the same meaning and, unless the context otherwise requires, the use of the word "or" is used in the inclusive sense (and/or). The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term, irrespective of whether such term is used with "without

limitation" or "without limiting" throughout this Agreement. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

(b) The captions of this Agreement are for convenience or reference only and in no way define, describe, extend or limit the scope of intent of this Agreement or in the intent of any provision contained in this Agreement. Unless otherwise specified, (i) the references in this Agreement to any Article, Section, Schedule or Appendix means references to such Article, Section, Schedule or Appendix of this Agreement, (ii) references in any section to any clause are references to such clause of such section and (iii) unless the context otherwise requires, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

(c) Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement within a specified time period and notification of such approval or consent is not delivered within such time period, then, unless otherwise specified, the Party whose approval or consent is required shall be conclusively deemed to have withheld its approval or consent. This Agreement has been prepared jointly and the provisions contained herein shall not be construed or interpreted for or against any Party to this Agreement because such Party drafted or caused such Party's legal representative to draft any provision contained herein.

(d) In the event of any conflict between this Agreement and the Schedules, Exhibits or Appendices hereto, this Agreement shall prevail.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Immuno-Oncology Discovery and Development Agreement to be executed by their duly authorized representatives as of the day and year first above written.

SANOFI BIOTECHNOLOGY SAS

By:	/s/ Olivier Brandicourt
Name:	Olivier Brandicourt
Title:	Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By:	/s/ Leonard S. Schleifer
Name:	Leonard S. Schleifer, M.D., Ph.D.
Title:	President & CEO

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

SCHEDULE 1

[***]

SCHEDULE 2

Example IO Antibodies

[***]

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

SCHEDULE 3

Manufacturing Cost

[***]

SCHEDULE 4

Notices

If to Sanofi:

Sanofi Biotechnology SAS
54, rue La Boétie
75008 Paris
France
Attn: President

Copy (which shall not constitute notice) to:

Sanofi
54, rue La Boétie
75008 Paris
France
Attn: Executive Vice President and General Counsel

If to Regeneron:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President
Copy: General Counsel

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

SCHEDULE 5

Quarterly IOSC Update

[***]

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

SCHEDULE 6

Opt-In Report

[***]

EXHIBIT A

Form of Opt-In Notice

[Sanofi Letterhead]

[DATE]

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel Regeneron Pharmaceuticals, Inc.

Reference is hereby made to the Immuno-Oncology Discovery and Development Agreement (the "IO Discovery Agreement") by and between Sanofi Biotechnology SAS, a societe par actions simplifee, organized under the laws of France, having a principal place of business located at 54, rue La Boétie, 75008 Paris, France, and Regeneron Pharmaceuticals, Inc., a New York corporation with a principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Capitalized terms used herein shall have the defined meanings set forth in the IO Discovery Agreement.

Pursuant to Section [__] of the IO Discovery Agreement, Sanofi hereby provides this Opt-In Notice to Regeneron to license [INSERT PRODUCT CANDIDATE] under the IO License and Collaboration Agreement. Sanofi has determined, in its reasonable opinion, that the Parties [are][OR][are not] required by applicable Law to file an HSR Filing with respect to the transactions contemplated by the IO License and Collaboration Agreement with respect to [INSERT PRODUCT CANDIDATE]. Effective immediately, [subject to Section 6.1(a) of the IO License and Collaboration Agreement,][INSERT PRODUCT CANDIDATE] shall be considered an IO Licensed Product.

SANOFI BIOTECHNOLOGY SAS

By: _____
Name:
Title:

Exhibit 10.2

IMMUNO-ONCOLOGY LICENSE AND COLLABORATION AGREEMENT

By and Between

SANOFI BIOTECHNOLOGY SAS

and

REGENERON PHARMACEUTICALS, INC.

Dated as of July 1, 2015

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY. SUCH OMITTED PORTIONS, WHICH ARE MARKED WITH BRACKETS AND THREE ASTERISKS [***], HAVE BEEN SEPARATELY FILED WITH THE COMMISSION.

TABLE OF CONTENTS

IMMUNO-ONCOLOGY LICENSE AND COLLABORATION AGREEMENT

THIS IMMUNO-ONCOLOGY LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), dated as of July 1, 2015 (the "Effective Date"), and executed as of July 27, 2015 (the "Execution Date"), is by and between Sanofi Biotechnology SAS ("Sanofi"), a societe par actions simplifee, organized under the laws of France, having a principal place of business at 54, rue La Boétie, 75008 Paris, France, an indirect wholly owned subsidiary of Sanofi, a company organized under the laws of France with its principal headquarters at 54, rue La Boétie, 75008 Paris, France, and Regeneron Pharmaceuticals, Inc., a company organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, concurrently with the execution and delivery of this Agreement, the Parties have entered into an Immuno-Oncology Discovery and Development Agreement (as amended from time-to-time, the "IO Discovery Agreement");

WHEREAS, Sanofi, Regeneron and their respective Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory (each as defined below); and

WHEREAS, Regeneron and Sanofi desire to continue to collaborate on the Development, Manufacture and Commercialization of IO Licensed Products (each as defined below) in the Field in the Territory (each as defined below) upon the terms and conditions set forth herein (the "Collaboration"), including Regeneron granting to Sanofi the co-exclusive (with Regeneron) rights granted to Sanofi hereunder during the applicable Term (as defined below) upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Accounting Standards" shall mean, with respect to either Party, GAAP or IFRS, in each case, as generally and consistently applied throughout the Party's organization. Each Party shall promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained.

1.2 "Acquired Competing Product" shall mean a product the rights to which are acquired by a Party or one or more of its Affiliates that is a Competing Product to an IO Licensed Product, unless such acquired product is an "Acquired IO Antibody" as defined in the IO Discovery Agreement. For clarity, any "Acquired IO Antibody" (as defined in the IO Discovery Agreement) shall be subject to Section 2.5(e) of the IO Discovery Agreement and not Section 2.6(b) of this Agreement.

1.3 "Additional Major Market Country" shall mean, in any Contract Year, any country in the Territory, other than the Major Market Countries referred to in clause (a) of the definition thereof, in which Net Sales in the immediately preceding Contract Year were [***] or more of aggregate Net Sales in the Territory in the immediately preceding Contract Year. Such designation shall remain effective from and after January 1 of such Contract Year and each Contract Year thereafter as long as Net Sales in such country in the immediately preceding Contract Year are [***] or more of aggregate Net Sales in the Territory in such Contract Year. Notwithstanding the foregoing, the Parties shall have the right to mutually agree that a country that meets or exceeds the [***] aggregate Net Sales threshold in a given Contract Year shall not be an Additional Major Market Country if such country is not expected to meet or exceed such [***] aggregate Net Sales threshold on an ongoing basis.

1.4 "Additional Trial Costs" means, with respect to any Additional Trial, the aggregate amount of the reasonable and verifiable Out-of-Pocket Costs, Clinical Supply Costs and applicable FTE costs incurred by or on behalf of the Post-POC Other Party in connection with the conduct of such Additional Trial that are consistent with the budgets provided to the Post-POC Principal Party in respect thereof pursuant to Section 5.5(a).

1.5 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such first Person. For purposes of this definition, a Person shall be deemed to "control" another Person if such first Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to "control" another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect

ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside of the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of Sanofi's Affiliates be deemed Affiliates of Regeneron or any of Regeneron's Affiliates, nor shall Regeneron or any of Regeneron's Affiliates be deemed Affiliates of Sanofi or any of Sanofi's Affiliates.

1.6 "Ancillary Agreements" shall mean the IO Discovery Agreement, the Existing Discovery Agreement, the Existing License and Collaboration Agreement, and any supply agreement entered into by the Parties in connection with any of the foregoing.

1.7 "Ancillary Collaboration Agreements" shall mean the IO Discovery Agreement, the Existing Discovery Agreement and the Existing License and Collaboration Agreement.

1.8 "Antibody" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.9 "Anticipated First Commercial Sale" shall mean, with respect to an IO Licensed Product and, if the context specifies, with respect to one or more countries in the Territory, the date agreed upon by the IOSC in advance as the expected date of First Commercial Sale of such IO Licensed Product in such country(ies) in the Territory, if specified, or otherwise, in any country in the Territory.

1.10 "Approval" shall mean, with respect to a product (including an IO Licensed Product), any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the development (including Development of an IO Licensed Product), manufacture (including Manufacture of an IO Licensed Product) or commercialization (including Commercialization of an IO Licensed Product) of such product in the Field in a regulatory jurisdiction in the Territory, and shall include, any approval, registration, license or authorization granted in connection with any Registration Filing.

1.11 "Bi-Specific/Multi-Specific" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.12 "BLA" shall mean, with respect to each IO Licensed Product, a biologics license application filed with respect to such IO Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

1.13 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States or Paris, France are authorized or required by Law to remain closed.

1.14 [***]

1.15 "Clinical Supply Cost" shall mean (a) the Out-of-Pocket Cost for purchasing or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements for activities contemplated under the applicable Development Plan, (b) the Out-of-Pocket Cost for purchasing or the Manufacturing Cost to Manufacture, comparator agent, combination agent, or placebo requirements for activities contemplated under the applicable Development Plan, (c) the Out-of-Pocket Cost or the Manufacturing Cost for filling, packaging, labeling and delivery of such Clinical Supply Requirements, comparator agent, combination agent or placebo, as the case may be, for activities contemplated under the applicable Development Plan and (d) any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements. To the extent that Manufacturing Cost for comparator agent, combination agent or placebo includes any markup over Manufacturing Cost to the benefit of one of the Parties or its Affiliates, such markup shall be deducted in the calculation of Clinical Supply Cost.

1.16 "Clinical Supply Requirements" shall mean, with respect to an IO Licensed Product, the quantities of such IO Licensed Product that are required by a Party or the Parties for Development in the Field under this Agreement, including the conduct of research, pre-clinical studies and clinical trials in connection with a Development Plan and quantities of such IO Licensed Product that are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.

1.17 "Co-Commercialize," "Co-Commercialization" or "Co-Commercializing" shall mean the act of Co-Promoting in a Co-Commercialization Country.

1.18 "Co-Commercialization Country" shall mean (a) the United States and (b) each country in the ROW Territory in which Regeneron has exercised its option to Co-Promote an IO Licensed Product pursuant to Section 6.4(a) until such time as Regeneron discontinues Co-Commercializing all IO Licensed Products in such country pursuant to Section 6.4(c).

1.19 "COGS" shall mean, with respect to an IO Licensed Product for a Quarter, the cost (calculated in accordance with the Accounting Standards of the Lead Commercialization Party) of Manufacturing the IO Licensed Product sold in the Field in the Territory in the Quarter.

1.20 "Commercial Overhead Charge" shall mean, on a country-by-country and IO Licensed Product-by-IO Licensed Product basis in the Territory, beginning six (6) months prior to the Anticipated First Commercial Sale in the applicable country, an amount (determined by the JFC and approved by the IOSC at least twelve (12) months prior to the Anticipated First Commercial Sale in the country) to cover Sanofi's or Regeneron's, as applicable, internal costs of [***] and other administrative costs, in each case, to the extent attributable to the

Commercialization of the applicable IO Licensed Product in the Field in such country, such amount to be updated by the JFC and approved by the IOSC prior to January 1 of each following Contract Year. For the avoidance of doubt, "Commercial Overhead Charge" shall not include any amounts included in Field Force Cost, Medical Non-Approval Costs, Other Shared Expenses or Shared Commercial Expenses.

1.21 "Commercial Supply Cost" shall mean the Out-of-Pocket Cost for purchasing or the Manufacturing Cost for the Manufacture of Commercial Supply Requirements, including, scale-up after First Commercial Sale and any filling, packaging and labeling costs therefor, and any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.

1.22 "Commercial Supply Requirements" shall mean, with respect to each IO Licensed Product, quantities of Finished Product as are required to fulfill requirements for commercial sales, Non-Approval Trials and product sampling with respect to such IO Licensed Product in the Field in the Territory.

1.23 "Commercialize," "Commercialization" or "Commercializing" shall mean, with respect to an IO Licensed Product, any and all activities directed to marketing, promoting (including, if applicable, Co-Promoting), detailing, distributing, importing, offering for sale, having sold or selling such IO Licensed Product in the Field in the Territory, including market research, obtaining Pricing Approvals, pre-launch marketing [***], marketing and educational activities, post-Approval pharmacovigilance excluding pharmacovigilance for clinical trials other than Non-Approval Trials, sampling and Non-Approval Trials in the Territory. For clarity, the terms "Commercialize," "Commercialization" and "Commercializing" are used herein with respect to IO Licensed Products while the terms "commercialize," "commercialization" and "commercializing" are used herein with corresponding meanings with respect to other products.

1.24 "Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a market-by-market and IO Licensed Product-by-IO Licensed Product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the IO Licensed Product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the profit sharing nor other payments made or required to be made hereunder shall be a factor weighed (that is, a Party may not apply lesser resources or efforts in support of an IO Licensed Product because it must share profits from sales of such IO Licensed Product or make any other payments hereunder).

1.25 "Committee" shall mean any of the IOSC, JDC, JCC, JMC, JFC, any CRCC under this Agreement, and any other committee established by the Parties or by the Committees referenced above under this Agreement, each as described in ARTICLE III (together with Working Groups and other committees contemplated herein or established in accordance with this Agreement).

1.26 "Competing Product" shall mean, with respect to an IO Licensed Product, [***]

1.27 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by each Party (based on information reported under Section 5.4(e) and Section 9.6) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Commercial Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter, (c) Other Shared Expenses incurred by each Party for such Quarter, and (d) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.

1.28 "Contract Sales Force" shall mean sales representatives employed by a Third Party.

1.29 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2015, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall end on the effective date of any termination or expiration of this Agreement.

1.30 "Control" or "Controlled" means, with respect to any item of New Information or Party Information, material, regulatory documentation, Know-How, Patents or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise, to assign, or grant a license, sublicense, right of reference or other right to or under such New Information or Party Information, material, regulatory documentation, Know-How, Patents or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.31 "Co-Promote," "Co-Promotion" or "Co-Promoting" shall mean the joint marketing and promotion of IO Licensed Product(s) by the Parties (or their respective Affiliates) under the same trademark in a Co-Commercialization Country pursuant to the applicable Commercialization Plan(s).

1.32 "Country/Region Commercialization Budget" shall mean the budget for a particular Contract Year developed by the JCC and approved by the IOSC for the applicable Country/Region Commercialization Plan.

1.33 "Country/Region Commercialization Committee", or "CRCC", shall mean the committee established by the JCC for each Reporting Country/Region pursuant to Section 3.5.

1.34 "Country/Region Commercialization Plan" shall mean, for each Reporting Country/Region, the three (3) year rolling plan for Commercializing IO Licensed Products in the Field in such country or Region and the related Country/Region Commercialization Budget and a non-binding budget forecast for the next two (2) Contract Years, approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Without limitation, each Country/Region Commercialization Plan shall set forth, for each IO Licensed Product in the applicable Reporting Country/Region, the information, plans and forecasts set forth in Section 6.2(d).

1.35 "Detail" shall mean, with respect to each IO Licensed Product in the Field, a selling presentation for such product by a representative of each Party's sales force, or another employee of each Party who may be deemed to be part of the Commercialization effort for such IO Licensed Product (e.g., such as a key account manager, etc.).

1.36 "Develop," "Development" or "Developing" shall mean (a) with respect to REGN2810, the following activities undertaken or performed from and after the Effective Date, and (b) with respect to all other IO Licensed Products, the following activities undertaken or performed after such IO Licensed Product first becomes an IO Licensed Product hereunder: (i) activities relating to research, pre-clinical and clinical drug development of such IO Licensed Product in the Field, including, test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation and submission of Registration Filings but excluding activities necessary to obtain a Pricing Approval, reimbursement or listing on health care providers' and payers' formularies, (ii) [***], (iii) the development of companion diagnostics for use with such IO Licensed Product, and (iv) any other research and development activities with respect to such IO Licensed Product in the Field, including, activities to support the discovery of biomarkers and activities to support new product formulations, delivery technologies or new indications in the Field, either before or after the First Commercial Sale. For clarity, the terms "Develop," "Development" and "Developing" are used herein with respect to IO Licensed Products while the terms "develop," "development" and "developing" are used herein with corresponding meanings with respect to other products.

1.37 "Development Costs" shall mean (x) costs and expenses incurred by a Party for REGN2810, from and after the Effective Date directly in connection with the Development of REGN2810 in the Field in accordance with this Agreement and the REGN2810 Global Development Plan, (y) costs and expenses (including any Program Costs) incurred by a Party for each other IO Licensed Product that was not a Tail Early Opt-In Antibody, from and after the first (1st) day of the month in which the Opt-In Notice for such IO Licensed Product is received by Regeneron pursuant to Article 5 of the IO Discovery Agreement, and (z) costs and expenses (including any Program Costs) incurred by a Party for each other IO Licensed Product that was a Tail Early Opt-In Antibody, from and after the first (1st) day of the month in which the Tail POC Report for such IO Licensed Product is delivered by Regeneron pursuant to Article 5 of

the IO Discovery Agreement, in each case ((x), (y) and (z)) directly in connection with (i) the development of such IO Licensed Product under the IO Discovery Program in accordance with the IO Discovery Agreement, or (ii) the Development of such IO Licensed Product in the Field in accordance with this Agreement and the applicable Development Plan, including:

(a) all Out-of-Pocket Costs, including, fees and expenses associated with obtaining Registration Filings and Marketing Approvals necessary for the Development and Commercialization of IO Licensed Products in the Field under this Agreement;

(b) Development FTE Costs;

(c) Clinical Supply Costs;

(d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation (other than validation batches which are sold), (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, the transfer of process and Manufacturing technology and analytical methods, scale-up up to First Commercial Sale, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);

(e) any license fees and other payments under Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements or the Development of IO Licensed Products in the Field under the Plans for the Territory subject to Section 13.3(d) and Section 13.3(e) in this Agreement; and

(f) any other costs or expenses specifically identified and included in the applicable Development Plan or expressly included as Development Costs under this Agreement.

“Development Costs” shall include any costs and expenses (to the extent consistent with the foregoing definition) that this Agreement or the IO Discovery Agreement provides are to be shared or reimbursed as Development Costs.

1.38 “Development FTE Cost” shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the product of (a) the number of FTEs required for such Development activities as set forth in the approved Development Plan and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs.

1.39 "Development FTE Rate" shall mean [***] in the Contract Year ending December 31, 2015 and annually thereafter by the sum of (a) the average of the percentage increases or decreases, if any, in the U.S. CPI and the ROW CPI for the twelve (12) months ending June 30 of the Contract Year prior to the Contract Year for which the adjustment is being made, [***] the Parties shall meet to consider a revision to the Development FTE Rate. The Development FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs, information systems and allocated costs, such as, for example, allocated overhead costs. The Parties may agree to a separate FTE rate for contractors performing Development activities under this Agreement.

1.40 "Development Plan" shall mean a Global Development Plan or a Post-POC Development Plan, as the context requires.

1.41 "Dollars" or "$" shall mean United States Dollars.

1.42 "EMA" shall mean the European Medicines Agency or any successor agency thereto.

1.43 "Ex-Collaboration Product" shall mean any product that (a) is owned or controlled by Regeneron or Sanofi or any of their respective Affiliates and (b) is not an IO Discovery Program Antibody, an Existing Collaboration Product or an IO Licensed Product; provided, that "Ex-Collaboration Product" shall include (i) any "Excluded Candidates" and any "Refused Candidates" under the IO Discovery Agreement, (ii) any "Opt-Out Product" or "Terminated Licensed Product", each as defined in and under the Existing License and Collaboration Agreement, (iii) any Terminated IO Product under this Agreement, or (iv) any "Excluded Candidates" or "Refused Candidates" under the Existing Discovery Agreement.

1.44 "Excluded Candidate" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.45 "Excluded Target Profile" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.46 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Sanofi, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.47 "Existing Agreements" shall mean the Existing Discovery Agreement and the Existing License and Collaboration Agreement.

1.48 "Existing Collaboration Product" shall mean (a) a Licensed Product under the Existing License and Collaboration Agreement, or (b) any Antibody that (i) is the subject of development under the Existing Discovery Agreement and (ii) is not an IO Antibody, a Multi-Indication Antibody or a "Refused Candidate" under and as defined in the Existing Discovery Agreement.

1.49 "Existing Discovery Agreement" shall mean the Amended and Restated Discovery and Preclinical Development Agreement, between Sanofi, as successor-in-interest to Aventis Pharmaceuticals, Inc., and Regeneron Pharmaceuticals, Inc., dated as of November 10, 2009, as the same may be amended from time-to-time.

1.50 "Existing License and Collaboration Agreement" shall mean the Amended and Restated License and Collaboration Agreement, between Sanofi, as successor-in-interest to Aventis Pharmaceuticals Inc. and sanofi-aventis Amerique du Nord and Regeneron, dated as of November 10, 2009, as the same may be amended from time-to-time.

1.51 "Expert Panel Dispute" shall mean any Budget Dispute or Financial Dispute.

1.52 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.53 "Field" shall mean the treatment, prevention, palliation or diagnosis of any disease.

1.54 "Field Force Cost" shall mean, for IO Licensed Product(s) in each country in the Territory, beginning on the date agreed upon by the IOSC ([***]) the product of (a) the number of detailing personnel (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan), [***], and (b) the applicable Field Force FTE Rate. The calculation of the number of detailing personnel in (a) above will be based on the number and position of Details required to meet the sales forecast for the applicable IO Licensed Product(s) in the Field in the country as converted into [***] will be based on the FTE effort required to fulfill the deployment plans for the applicable IO Licensed Product(s) in the Field in the country as agreed by the JCC, and, in each case, shall allow for the reporting and auditing of such information in accordance with this Agreement, all as set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan. For the avoidance of doubt, the activities of contract personnel, including Contract Sales Force, shall be charged as Out-of-Pocket Costs; provided that in lieu of charging the activities of Contract Sales Force personnel as Out-of-Pocket Costs, the Parties may agree to a separate FTE rate for Contract Sales Force personnel performing such activities under this Agreement on a Region-by-Region or one or more Major Market Countries basis; provided further that any such separate FTE rate shall in no event exceed the applicable Field Force FTE Rate for sales representatives in the applicable Region or Major Market Country.

1.55 "Field Force FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the applicable personnel), the rates agreed upon in local currency by the Parties at least twenty-four (24) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, for each category of field force personnel based upon the fully burdened cost of [***], of pharmaceutical companies in the Field in the applicable country, and including an [***], such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior

calendar year. The Field Force FTE Rates shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs, information systems and allocated costs, such as, for example, allocated overhead costs.

1.56 "Finished Product" shall mean an IO Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.

1.57 "First Commercial Sale" shall mean, with respect to an IO Licensed Product in a country in the Territory, the first (1st) commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

1.58 "Formulated Bulk Product" shall mean IO Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.59 "FTE" shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes of Development shall be [***] hours per year.

1.60 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.

1.61 "Global Commercialization Budget" shall mean the budget(s) for a particular Contract Year approved by the IOSC with input from the JCC for the applicable Global Commercialization Plan.

1.62 "Global Commercialization Plan" shall have the meaning set forth in Section 6.2(a).

1.63 "Global Development Budget" shall mean the budget(s) for a particular Contract Year (a) delivered to the IOSC pursuant to Section 5.3(b), or (b) submitted to and approved by the IOSC pursuant to Section 5.4(d), as applicable, for the applicable Global Development Plan. For clarity, the REGN2810 Global Development Budget is a Global Development Budget.

1.64 "Global Development Plan" shall mean, with respect to an IO Licensed Product, a three (3) year rolling plan for the worldwide Development of such IO Licensed Product prepared by the Post-POC Principal Party and, on an annual basis, (a) delivered to the IOSC pursuant to Section 5.3(a), or (b) submitted to and approved by the IOSC pursuant to Section 5.4(a), as applicable, including the related Global Development Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from

time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, a Global Development Plan will not include Non-Approval Trials. For clarity, the REGN2810 Global Development Plan is a Global Development Plan.

1.65 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMA or the ICH, or other country regulatory agencies, as applicable.

1.66 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.67 "HSR Act" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. §18a), as amended.

1.68 "HSR Filing" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.69 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.70 "IFRS" shall mean International Financial Reporting Standards of the International Accounting Standards Board.

1.71 "Immunoconjugate" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.72 "IND" shall mean, with respect to each IO Licensed Product in the Field, an Investigational New Drug Application filed with the FDA with respect to such IO Licensed Product pursuant to 21 C.F.R. § 312 before the commencement of clinical trials involving such IO Licensed Product, including all amendments and supplements to such application or any equivalent filing with any Regulatory Authority outside the United States.

1.73 "Indication" shall mean any disease, state or condition.

1.74 "IO Antibody" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.75 "IO Discovery Program Antibody" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.76 "IO Discovery Program" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.77 "IO Licensed Products" shall mean (a) any IO Discovery Program Antibody for which Sanofi has exercised its Opt-In Rights in accordance with Article 5 of the IO Discovery Agreement, (b) any Acquired Competing Product that is included in the Collaboration pursuant to Section 2.6(b), and (c) REGN2810. For clarity, any IO Discovery Program Antibodies for which Sanofi has not exercised its Opt-In Right shall not be an IO Licensed Product even if such IO Discovery Program Antibody targets the same IO Licensed Target Profile as an IO Licensed Product.

1.78 "IO Licensed Target Profile" shall mean, with respect to any point in time during the Term, any IO Target Profile that is the target of an IO Licensed Product at such time.

1.79 "IO Target Profile" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.80 "Joint Intellectual Property" shall mean Joint Patent Rights and Joint Inventions.

1.81 "Joint Patent Rights" shall mean Patents that cover or claim a Joint Invention.

1.82 "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information, including marketing and supply information (whether or not patentable or otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's or such Party's Affiliates' Patents or Patent applications.

1.83 "Launch Preparation Expenses" shall mean, with respect to an IO Licensed Product, on a country-by-country basis in the Territory, with respect to each IO Licensed Product, all Commercialization expenses to support such IO Licensed Product in the Field [***].

1.84 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions or ordinances of any Governmental Authority.

1.85 "Lead Commercialization Party" shall mean, with respect to an IO Licensed Product in a country, the Party that is allocated principal responsibility for the Commercialization of such IO Licensed Product for such country pursuant to Section 6.1.

1.86 "Lead Regulatory Party" shall mean, with respect to an IO Licensed Product, the Party that is allocated principal responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for IO Licensed Products in the Field under this Agreement, and for related regulatory duties, pursuant to Section 7.1(a).

1.87 "Legal Dispute" shall mean any dispute, controversy or claim related to compliance with this Agreement or the IO Discovery Agreement or the validity, breach, termination or interpretation of this Agreement or the IO Discovery Agreement.

1.88 "License" shall mean any license or other agreement to acquire rights from a Third Party, which license or other agreement has been entered into pursuant to Section 2.11 of the IO Discovery Agreement or that is approved by the IOSC for the Development, Manufacture or Commercialization of any IO Licensed Product in the Field under this Agreement.

1.89 "Licensed Product" shall have the meaning ascribed to such term in the Existing License and Collaboration Agreement.

1.90 "Major Market Country" shall mean any of the following: [***].

1.91 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be. For clarity, the terms "Manufacture" and "Manufacturing" are used herein with respect to IO Licensed Products while the terms "manufacture" and "manufacturing" are used herein with corresponding meanings with respect to other products.

1.92 "Manufacturing Plan" shall mean the Manufacturing plan as prepared by the JMC as described in Section 8.5.

1.93 "Marketing Approval" shall mean an Approval required for the marketing and sale of any product in the Field in a country in the Territory, but excluding any IND or separate Pricing Approval.

1.94 "Marketing Guidelines" shall mean the U.S. Marketing Guidelines, the ROW Marketing Guidelines, and, to the extent not inconsistent with the foregoing, the Global Marketing Guidelines.

1.95 "Medical Non-Approval Cost" shall mean, for Licensed Product(s) in each country in the Territory, beginning on the date agreed upon by the IOSC ([***]) the product of (a) the number of office-based people supporting (i) the coordination of Non-Approval Trials, (ii) the maintenance of Approvals, and (iii) Pricing Approvals (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan) and (b) the applicable Medical Non-Approval FTE Rate. The calculation of the number of people in (a) above will be designed to ensure the proper reporting and auditing of such information in accordance with this Agreement. For the avoidance of doubt, the activities of contract personnel shall be charged as an Out-of-Pocket Cost.

1.96 "Medical Non-Approval FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of

the medical affairs professional), a rate agreed upon in local currency by the Parties at least twenty-four (24) months prior to the Anticipated First Commercial Sale in such Region or Major Market Country, as applicable, based upon the fully burdened cost of [***], such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Non-Approval FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.97 "Multi-Indication Antibody" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.98 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of IO Licensed Products in the Field in the Territory by or on behalf of a Party or its Affiliates or Sublicensees to Third Parties, less the following deductions, determined in accordance with such Party's Accounting Standards, consistently applied:

(a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such IO Licensed Products;

(b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;

(c) chargebacks and other amounts paid on sale or dispensing of IO Licensed Products;

(d) Third Party cash rebates and chargebacks related to sales of IO Licensed Products, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) compulsory refunds, credits, rebates and co-pay assistance directly related to the sale of IO Licensed Products, accrued, paid or deducted pursuant to agreements (including, managed care agreements) or governmental regulations;

(g) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering IO Licensed Products that are separately identified on the invoice or other documentation;

(h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of IO Licensed Products, which are separately identified on the invoice or other documentation; and

(i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such IO Licensed Product falling within

categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

Net Sales in currency other than Dollars shall be translated into Dollars according to the provisions of Section 9.10. Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but that are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of an IO Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if such Party or its Affiliate or Sublicensee sells such IO Licensed Products in the form of a combination product containing any IO Licensed Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the First Commercial Sale of such Combination Product, the Parties shall agree on the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Bi-Specifics/Multi-Specifics shall not be deemed Combination Products.

Solely for the purposes of Section 2.6(c) of this Agreement, the term "IO Licensed Product" as used in the definition of Net Sales shall also refer to Special Termination Products.

1.99 "New Information" shall mean any and all ideas, inventions, information, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public that arise or are conceived or developed during the Term under this Agreement by (a) either Party or its Affiliates or (b) the Parties or their Affiliates jointly, in each case ((a) and (b)) to the extent specifically related to any IO Licensed Product in the Field. "New Information" under this Agreement shall include any "New Information" under, and as defined in, the Existing License and Collaboration Agreement to the extent specifically related to any IO Licensed Product in the Field.

1.100 "Non-Approval Trials" shall mean any post-marketing surveys, registries and clinical trials post-first Marketing Approval not intended to gain additional labeled Indications, but excluding any post-first Marketing Approval clinical trials required by Regulatory Authorities to maintain Marketing Approvals of existing labeled Indication(s).

1.101 "Non-IO Indication" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.102 "Non-PD-1 Licensed Product" shall mean any IO Licensed Product that is not a PD-1 Licensed Product.

1.103 "Oncology Field" shall mean the treatment, prevention, or palliation of any cancer or oncological disease or condition.

1.104 "Opt-In Notice" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.105 "Opt-In Right" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.106 "Other Product" shall mean (a) any Proprietary Product, (b) any product of a Third Party (for clarity, whether or not such product is an IO Antibody), and (c) any product that is in the public domain.

1.107 "Other Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 7.6, 12.1(a), 12.2(e), 12.3(b), 13.1(b), 13.1(c), 13.1(d), 13.3(b), 13.3(d) (except to the extent allocated between the Parties as a "Development Cost"), and 17.1(c).

1.108 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the paying Party's Accounting Standards) by either Party or its Affiliates in connection with activities under this Agreement.

1.109 "Party Information" shall mean, with respect to a Party, all ideas, inventions, information, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information (whether or not patentable or protectable as a trade secret) not generally known to the public (in each case, other than New Information) that are disclosed or made available under this Agreement by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates under this Agreement. With respect to each Party, Party Information does not include New Information. "Party Information" under this Agreement shall include any "Party Information" under, and as defined in, the Existing License and Collaboration Agreement.

1.110 "Patent Cooperation Treaty" or "PCT" means the Patent Cooperation Treaty, opened for signature June 19, 1970, 28 U.S.T. 7645.

1.111 "Patent Rights" shall mean unexpired Patents.

1.112 "Patents" shall mean (a) all national, regional and international patents and patent applications, including, provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including, divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including, utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including, revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including, so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.113 "PD-1" shall mean the receptor known as Programmed Cell Death protein 1.

1.114 "PD-1 Licensed Product" shall mean an IO Licensed Product that is an IO Antibody that targets PD-1 and that is not a Bi-Specific/Multi-Specific. For clarity, REGN2810 is a PD-1 Licensed Product.

1.115 [***]

1.116 "Person" shall mean and include an individual, a partnership, a joint a venture, a limited liability company, a corporation, a firm, a trust, an unincorporated organization and a government or other department or agency thereof.

1.117 "Phase III Trial" shall mean a clinical trial that is intended to gather further evidence of safety and efficacy of a product as a monotherapy or in combination with one or more other products (and to help evaluate its overall risks and benefits) for a particular Indication or Indications and is intended to support Marketing Approval for such product for such Indication or Indications in one or more countries or that would otherwise satisfy the requirements of 21 C.F.R. § 312.21(c) (or its equivalent under the Laws of any country in the Territory other than the United States).

1.118 "Plan" shall mean any Country/Region Commercialization Plan, U.S. Commercialization Plan, ROW Commercialization Plan, Global Commercialization Plan, Global Development Plan (including the REGN2810 Global Development Plan), Post-POC Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of any IO Licensed Product in the Field under this Agreement.

1.119 "Positive Phase III Trial Results" shall mean a Phase III Trial of an IO Licensed Product that meets its primary end-point as defined in the study protocol for such Phase III Trial, and the safety profile supports continued clinical testing of such IO Licensed Product in the applicable Indication or filing of an application for Marketing Approval for such IO Licensed Product.

1.120 "Post-POC Development Plan" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.121 "Post-POC Other Party" shall mean, with respect to an IO Licensed Product, the Party that is not the Post-POC Principal Party for such IO Licensed Product.

1.122 "Post-POC Principal Party" shall mean, with respect to an IO Licensed Product, the Party that is allocated principal responsibility for the Development of such IO Licensed Product pursuant to Section 5.2.

1.123 "Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for an IO Licensed Product that can be charged to

consumers or that will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise

1.124 "Product Candidate" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.125 "Product Trademark" shall mean, with respect to each IO Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC for use on such IO Licensed Product in one or more countries in the Territory and accompanying logos, slogans, trade names, trade dress or other indicia of origin, in each case as selected by the JCC in accordance with Section 11.2.

1.126 "Program Costs" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.127 "Promotional Materials" shall mean, with respect to each IO Licensed Product, promotional, advertising, communication and educational materials relating to such IO Licensed Product for use in connection with the marketing, promotion and sale of such IO Licensed Product in the Field in the Territory, and the content thereof, and shall include, promotional literature, product support materials and promotional giveaways.

1.128 "Proprietary Product" shall mean (a) an Existing Collaboration Product, and (b) an Ex-Collaboration Product.

1.129 "Prosecuting Party" shall mean Sanofi with respect to the filing, prosecution and maintenance of a Joint Patent Right that claims or covers a Competing Product that is Controlled by Sanofi and included in the Collaboration pursuant to Section 2.6(b) (or the Manufacture or use thereof) (and no other IO Licensed Product), and Regeneron in the case of all other Joint Patent Rights.

1.130 "Quarter" or "Quarterly" shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1 during the Term, except that the first (1st) Quarter shall commence on the Effective Date and shall end on September 30, 2015 and the last Quarter shall end on the last day of the Term.

1.131 "Refused Candidate" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.132 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and the Regeneron Know-How.

1.133 "Regeneron Know-How" shall mean all Know-How that is Controlled as of the Effective Date and at any time during the Term by Regeneron or any of its Affiliates (other than by operation of the license and other grants in ARTICLE IV) and relates to an IO Licensed Product and is necessary or useful for the Development, Manufacture or Commercialization of

an IO Licensed Product in the Field, excluding any Joint Inventions and any Know-How that is disclosed or claimed by the Regeneron Patent Rights. For clarity, Regeneron Know-How shall include New Information of Regeneron.

1.134 "Regeneron Patent Rights" shall mean those Patents Controlled as of the Effective Date or hereafter during the Term by Regeneron or any of its Affiliates (other than by operation of the license in ARTICLE IV and other than the Joint Patent Rights) that include at least one (1) Valid Claim that, absent a license from Regeneron or any of its Affiliates, would be infringed by the development (including Development), manufacture (including Manufacture), use, sale or offer for sale (including Commercialization), or import of any IO Licensed Product in the Field by Sanofi.

1.135 "Region" shall mean (a) the United States, and (b) such countries or group of countries in the ROW Territory as determined by the JCC.

1.136 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, any testing, marketing authorization application, supplementary application or variation thereof, IND, BLA, or any equivalent applications in any country.

1.137 "REGN2810" shall mean Regeneron's hinge-stabilized fully human monoclonal antibody of IgG4 isotope that targets PD-1, and which [***] (referred to therein as antibody clone H4H7798N). For clarity, "REGN2810" is not a Bi-Specific/Multi-Specific or Immunoconjugate.

1.138 "REGN2810 Budget Amount" shall mean six hundred and fifty million Dollars ($650,000,000), or such other amount as mutually agreed on by the Parties in writing.

1.139 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any IO Licensed Product in the Field under this Agreement. The term "Regulatory Authority" includes, the FDA, the EMA and the Japanese Ministry of Health, Labour and Welfare.

1.140 "Reporting Country/Region" shall mean (a) each Major Market Country, and (b) each other country or Region as determined by the JCC pursuant to Section 3.5.

1.141 "Rest of World Territory" or "ROW Territory" shall mean all countries in the Territory other than the United States.

1.142 "ROW Commercialization Budget" shall mean the budget(s) for a particular Contract Year developed by the JCC and approved by the IOSC for the applicable ROW Commercialization Plan.

1.143 "ROW Commercialization Plan" shall mean, with respect to an IO Licensed Product, the three (3) year rolling plan developed by the JCC and approved by the

IOSC for Commercializing such IO Licensed Product in the ROW Territory, including the related ROW Commercialization Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Without limitation, each ROW Commercialization Plan shall set forth (if not otherwise set forth in the applicable Country/Region Commercialization Plan(s)) for an IO Licensed Product in the ROW Territory, the information, plans and forecasts set forth in Section 6.2(c).

1.144 "ROW CPI" shall mean the "EU15 CPI" (or its successor equivalent index), which is published monthly and available via *The Bloomberg Professional*, as published by Bloomberg L.P.

1.145 "Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.

1.146 "Sanofi Know-How" shall mean all Know-How that is Controlled as of the Effective Date and at any time during the Term by Sanofi or its Affiliates (other than by operation of the license and other grants in ARTICLE IV) and relates to an IO Licensed Product and is necessary or useful for the Development, Manufacture or Commercialization of an IO Licensed Product in the Field, excluding any Joint Inventions and any Know-How that is disclosed or claimed by the Sanofi Patent Rights. For clarity, Sanofi Know-How shall include New Information of Sanofi.

1.147 "Sanofi Patent Rights" shall mean those Patents Controlled as of the Effective Date or hereafter during the Term by Sanofi or any of its Affiliates (other than by operation of the license in ARTICLE IV and other than the Joint Patent Rights) that include at least one (1) Valid Claim that, absent a license from Sanofi or any of its Affiliates, would be infringed by the development (including Development), manufacture (including Manufacture), use, sale or offer for sale (including Commercialization), or import of any IO Licensed Product in the Field by Regeneron.

1.148 "Shared Commercial Expenses" shall mean the sum of the following items, in each case to the extent directly attributable to Commercialization of IO Licensed Products in the Field in the Territory in accordance with an approved Country/Region Commercialization Plan or Global Commercialization Plan:

(a) the Lead Commercialization Party shall be permitted to take an allowance of [***] to cover the cost of distribution, freight, insurance and warehousing, related to the sale of IO Licensed Products in the Field in the Territory, less any amount deducted from Net Sales pursuant to clause (g) of the definition of Net Sales;

(b) bad debt incurred by the Lead Commercialization Party and its Affiliates attributable to IO Licensed Products in the Field sold in the Territory;

(c) Field Force Cost;

(d) Medical Non-Approval Cost;

(e) Out-of-Pocket Costs related to (i) the marketing, advertising or promotion of IO Licensed Products in the Field in the Territory (including, pricing activities, commercial pharmacovigilance, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for IO Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for IO Licensed Products in the Field in the Territory;

(f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of IO Licensed Products in the Field in the Territory (including, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion relate to both IO Licensed Products and other products developed or commercialized by a Party or its Affiliates as agreed upon in an approved Global Commercialization Plan or Country/Region Commercialization Plan;

(g) Out-of-Pocket Costs related to Non-Approval Trials and health economic outcomes research for IO Licensed Products in the Field in the Territory, including, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not included in Commercial Supply Cost;

(h) Out-of-Pocket Costs related to Pricing Approvals and the maintenance of all Approvals directly related to the Commercialization of IO Licensed Products in the Field in the Territory;

(i) Commercial Overhead Charge;

(j) Out-of-Pocket Costs related to regulatory affairs activities, other than activities to secure Registration Filing of indications and line extensions; and

(k) any other costs or expenses directly related to the Commercialization of an IO Licensed Product and not included in clauses (a) through (j) above;

in each case (a) through (k) (inclusive), to the extent incurred after First Commercial Sale of such IO Licensed Product; and

(l) Launch Preparation Expenses;

The foregoing shall not include any costs that have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will be fairly allocated to the IO Licensed Products in the Field in the Territory (to the extent that any Shared Commercial Expense is attributable, in part, to products or activities other than the IO Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

1.149 "Special Termination Product" shall mean an IO Licensed Product as to which this Agreement has been terminated in accordance with Section 19.2(a)(i) or Section 19.2(b)(i).

1.150 "Sublicensee" shall mean a Third Party or an Affiliate to whom Regeneron or Sanofi will have granted a license or sublicense under such Party's rights pursuant to Section 4.4 to Commercialize IO Licensed Products in the Field in the Territory. For the avoidance of doubt, a "Sublicensee" will include a Third Party to whom a Party will have granted the right to distribute IO Licensed Products in the Field wherein such distributor pays to such Party a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of IO Licensed Products by such distributor, irrespective of whether a license or sublicense is granted under Section 4.4.

1.151 "Tail Early Opt-In Antibody" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.152 "Tail POC Report" shall have the meaning ascribed to such term in the IO Discovery Agreement.

1.153 "Terminated IO Product" shall mean an IO Licensed Product as to which this Agreement has been terminated in accordance with its terms in accordance with ARTICLE XIX, and shall include any Special Termination Product.

1.154 "Termination Notice Period" shall mean the Sanofi Termination Notice Period or the Regeneron Termination Notice Period, as applicable.

1.155 "Territory" shall mean all the countries and territories of the world.

1.156 "Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

1.157 "Third Party [***]" shall mean any IO Antibody that is owned or controlled by a Third Party that targets [***] and is not a Bi-Specific/Multi-Specific.

1.158 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.159 "U.S. Commercialization Budget" shall mean the budget(s) for a particular Contract Year developed by the JCC and approved by the IOSC for the applicable U.S. Commercialization Plan.

1.160 "U.S. Commercialization Plan" shall mean, with respect to an IO Licensed Product, the three (3) year rolling plan developed by the JCC and approved by the IOSC for Commercializing such IO Licensed Product in the U.S., including the related U.S. Commercialization Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this

Agreement. Without limitation, each U.S. Commercialization Plan shall set forth for an IO Licensed Product, the information, plans and forecasts set forth in Section 6.2(b).

1.161 "U.S. CPI" shall mean the Consumer Price Index – All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.162 "Valid Claim" shall mean (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) that has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and that has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a Patent application, which claim has been pending less than five (5) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued Patent (from and after which time the same shall be deemed a Valid Claim subject to paragraph (a) above).

1.163 Additional Definitions. Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE
Acquiring Party	2.6(b)
Additional Trial	5.5
Aggregate Profits	Schedule 2
Agreement	Preamble
Alliance Manager	3.12
Budget Dispute	3.11(c)(iii)
[***]	5.6(g)(ii)
Collaboration	Preamble
Collaboration Purpose	3.1(b)
Combination Product	1.91
Combination Therapy	5.6(a)
Commercialization Plan	6.2
Competing Combination Study	5.6(g)
Controlling Party	5.6(d)
Co-Promote Commitment Level	6.4(e)
Cost	Schedule 1
Damages	17.1(a)
Default Interest Rate	9.11
Development Compensation Payment	Schedule 2
Development Cost True-Up	Schedule 2
Disputed Budget	3.11(c)(iii)
Effective Date	Preamble

DEFINITION	SECTION/SCHEDULE
Excluded Know-How Rights	12.1(e)
Excluded Rights	4.3
Execution Date	Preamble
Expert Panel	10.4(b)(i)
Financial Dispute	3.11(c)(iii)
Force Majeure	ARTICLE XVIII
Global Commercialization Plan	6.2(a)
Global Marketing Guidelines	3.4(b)(viii)
Governance Disputes	10.2
Indemnified Party	17.2
HSR Clearance Notice	6.1(a)
Indemnifying Party	17.2
IO Development Balance	Schedule 2
IO Development Balance Costs	Schedule 2
IO Discovery Agreement	Preamble
IOSC	3.1(a)
JCC	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JMC	3.1(a)
Joint Invention	12.1(b)
Lead Litigation Party	13.1(c)
Manufacturing Cost	Schedule 1
Manufacturing Notice	8.3(a)
Modified Clause	20.6
Non-Acquiring Party	2.6(b)
Non-Proprietary Combination Therapy	5.6(f)
Other Shared Revenue	Schedule 2
OverPaying Party	13.3(e)
Party(ies)	Preamble
PD-1 Matter	3.11(a)
PD-1 Milestone	9.3
PD-1 Milestone Payment	9.3
PD-1 Sales	9.3
Profit Split	Schedule 2
Profit Split True-Up	Schedule 2
Profits	Schedule 2
Publishing Party	16.3
Quarterly True-Up	Schedule 2
Regeneron	Preamble
Regeneron Budget Dispute	3.11(c)(i)
Regeneron Indemnitees	17.1(a)

DEFINITION	SECTION/SCHEDULE
Regeneron Profits	Schedule 2
Regeneron Sole Inventions	12.1(a)
Regeneron Termination Notice Period	19.2(b)
REGN2810 Global Development Plan	5.3(a)
ROW Marketing Guidelines	3.4(b)(ix)
Royalty Term	9.4
Sanofi	Preamble
Sanofi Budget Dispute	3.11(c)(ii)
Sanofi Indemnitees	17.1(b)
Sanofi Profits	Schedule 2
Sanofi Sole Inventions	12.1(a)
Sanofi Termination Notice Period	19.2(a)
Shared Facility	Schedule 1
Sole Developer	2.6(c)
Sole Inventions	12.1(a)
Target Labeling	7.2(d)
Term	19.1(a)
Third Party Acquisition	2.6(b)
Third Party Claim	17.1(a)
Unresolved Matter	3.11(b)
U.S. Marketing Guidelines	3.4(b)(vii)
VelocImmune Royalties	13.3(e)
Working Group	3.1(a)

ARTICLE II
COLLABORATION

2.1 Scope of Collaboration. Upon and subject to terms and conditions of this Agreement, the Parties will cooperate in good faith to Develop, Manufacture and Commercialize IO Licensed Products in the Field in the Territory in such a manner so as to optimize the commercial potential of each IO Licensed Product. The Parties shall establish various Committees as set forth in ARTICLE III of this Agreement to oversee and coordinate the Development, Manufacture and Commercialization of IO Licensed Products in the Field in the Territory, and each Party shall, subject to the terms and conditions set forth in ARTICLE XVI, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as reasonably requested by the other Party or as may be reasonably required for the Parties to operate effectively and efficiently under and in accordance with the terms and conditions of this Agreement.

2.2 Compliance With Law. Both Sanofi and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement that violates, or which it believes, in good faith, may violate, any applicable Law.

2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish all information in its possession and control (or in its control and accessible by it consistent with its regular business practices) required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Licenses to which it is a party and to notify the other Party of any terms or conditions in any such License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement, including any sublicense under a License referenced in subsection (a) above, to which it is a party and that is related to the Collaboration, including any obligations to pay royalties, fees or other amounts due thereunder. Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, neither Party may terminate or amend any License or any other material agreement entered into pursuant to a Plan if such termination or amendment would impose any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of any IO Licensed Product in the Field in the Territory.

2.5 Commercially Reasonable Efforts; Plans. Subject to the terms of this Agreement, each Party (and its Affiliates) shall use Commercially Reasonable Efforts to fulfill all responsibilities assigned to it under this Agreement and any then-applicable Plans. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Plans approved, which may be amended from time to time as circumstances may require, each in accordance with this Agreement.

2.6 Limitation on Exercise of Rights Outside of Collaboration.

(a) Non-Compete. Without limitation of and in addition and subject to Section 2.5 of the IO Discovery Agreement, during the Term, except as set forth in Section 5.5 or Section 5.6 or otherwise in this Agreement or Section 2.5 or Section 5.5 of the IO Discovery Agreement, neither Party nor any of its Affiliates, either alone, or with or through any Third Party, shall develop or commercialize any Competing Product.

(b) Company Acquisitions. Notwithstanding Section 2.6(a), if as the result of an acquisition (i) by a Third Party, or (ii) of a Third Party or a business or division of a

Third Party (each such acquisition ((i) or (ii)), a "Third Party Acquisition") by or of a Party or one or more of its Affiliates (the "Acquiring Party"), the Acquiring Party acquires rights to a product that is an Acquired Competing Product to an IO Licensed Product, the Acquiring Party shall, within [***] after the closing of such Third Party Acquisition, present a proposal to the other Party (the "Non-Acquiring Party") to include such Acquired Competing Product in the Collaboration based on the terms of this Agreement. As part of such presentation, the Acquiring Party shall provide the Non-Acquiring Party with all information with respect to such Acquired Competing Product reasonably available to the Acquiring Party and material to a decision by the Non-Acquiring Party as to whether to approve the inclusion of such Acquired Competing Product in the Collaboration, and to the extent in the Acquiring Party's possession and control (or in the Acquiring Party's control and accessible by the Acquiring Party consistent with the Acquiring Party's regular business practices), any such information reasonably requested by the Non-Acquiring Party. The Non-Acquiring Party shall, on or before the date which is [***] after the receipt of such presentation, decide whether to approve the inclusion of such Acquired Competing Product in the Collaboration under the terms of this Agreement. If the Non-Acquiring Party timely approves the inclusion of such Acquired Competing Product in the Collaboration, then effective as of the closing of such Third Party Acquisition the Acquired Competing Product shall automatically be included in the Collaboration as an IO Licensed Product hereunder; provided that such Acquired Competing Product shall not be included within the Collaboration unless and until [***]. If the Non-Acquiring Party does not approve such inclusion, the Acquiring Party shall, within [***] after such decision of the Non-Acquiring Party, commit in writing to the Non-Acquiring Party, to either (x) [***], or (y) [***] (2) the Term of this Agreement with respect to the applicable IO Licensed Product, or (3) [***]. The Acquiring Party shall not be precluded under this Section 2.6 from conducting any activities (either directly, or with or through any Third Party) with respect to such Acquired Competing Product during such [***] period.

(c) Special Termination Products. Notwithstanding Section 2.6(a), in the case of any Special Termination Product, the non-terminating Party (the "Sole Developer") shall have the right to Develop, Manufacture and Commercialize such Special Termination Product outside of the Collaboration, subject to this Section 2.6(c). If a Special Termination Product is Commercialized by Regeneron as the Sole Developer (either directly, or with or through an Affiliate or Third Party) in accordance with this Section 2.6(c), then Regeneron shall pay to Sanofi, within sixty (60) days following the end of each Quarter during the applicable Royalty Term, a royalty payment of [***] on the aggregate Net Sales of such Special Termination Product. For clarity, (i) Regeneron shall not owe any royalty payments to Sanofi under this Section 2.6(c) with respect to any product that is a "Licensed Product" or an "Opt-Out Product" under the Existing License and Collaboration Agreement or an "IO Royalty Product" under the IO Discovery Agreement and (ii) Sanofi shall not owe any royalty payments to Regeneron under this Section 2.6(c) with respect to any Special Termination Product.

ARTICLE III
INFORMATION EXCHANGE AND UPDATES; MANAGEMENT

3.1 Committees and Management .

(a) The Parties agree to establish, as provided and for the purposes specified herein, each of the following committees: an Immuno-Oncology Steering Committee (the "IOSC"), a Joint Development Committee ("JDC"), a Joint Commercialization Committee (the "JCC"), CRCCs to the extent provided in Section 3.5, and such other commercialization sub-committees as the JCC shall deem to be appropriate, a Joint Manufacturing Committee ("JMC"), a Joint Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The IOSC, JMC and JFC shall be established within thirty (30) days after the Execution Date. The JDC shall be established within thirty (30) days following the first (1st) exercise by Sanofi of its Opt-In Rights pursuant to Article 5 of the IO Discovery Agreement. The JCC shall be established at least two (2) years prior to the anticipated filing date for Marketing Approval for the first (1st) IO Licensed Product in the Territory. It is understood that the Parties may wish to establish multiple Committees reporting to the IOSC, JDC, and JCC with responsibility for different IO Licensed Products. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the IOSC for Committees established in the future and not described herein) and may be further designated by the IOSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines. Subject to the terms of this ARTICLE III, (i) any one or more Committees established pursuant to this Agreement may have the same members appointed by each Party, and such members may meet to simultaneously discuss matters within the jurisdiction of such Committees, and (ii) a Party may appoint a member of one Committee to one or more other Committees notwithstanding whether the other Party appoints the same members to any such Committees.

(b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the IO Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 Immuno-Oncology Steering Committee.

(a) Formation, Composition and Membership. The IOSC shall have overall responsibility for the oversight of the Collaboration. The purpose of the IOSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program for each IO Licensed Product, including the Manufacture of IO Licensed Products in the Field for use in activities under the Plans and for the Commercialization of IO Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the

provisions of Section 3.11 below on which such Committees are unable to reach consensus. The IOSC shall be composed of at least three (3) senior representatives (so long as each Party has an equal number of representatives) appointed by each of Regeneron and Sanofi. The IOSC established under this Agreement may have the same members as the IOSC established under the IO Discovery Agreement, and such members may meet to simultaneously discuss matters within the jurisdiction of the IOSC under this Agreement and the IOSC under the IO License and Collaboration Agreement, respectively. Unless otherwise agreed by the Parties, at all times during which there is an IO Licensed Product being Developed under this Agreement, one of Sanofi's representatives on the IOSC must be Sanofi's President of Research and Development, or equivalent senior-most executive responsible for research and development, and one of Regeneron's representatives on the IOSC must be Regeneron's President of Research and Development, or equivalent senior-most executive responsible for research and development.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the IOSC shall in particular (i) annually review and approve the Global Development Plan(s), Manufacturing Plan(s), Global Commercialization Plan(s), U.S. Commercialization Plan(s), ROW Commercialization Plan(s), and Country/Region Commercialization Plan(s); (ii) discuss the REGN2810 Global Development Plan and REGN2810 Global Development Budget, including any material amendments thereto, and review and discuss the then-current progress and results of the Development activities thereunder; (iii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then-effective Plans; (iv) reconcile any inconsistencies between or among any of the U.S. Commercialization Plan(s), the ROW Commercialization Plan(s), the Country/Region Commercialization Plan(s) and the Global Commercialization Plan for each IO Licensed Product; (v) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point of communication for seeking consensus regarding key global strategy, Plan and budget issues; (vi) review and discuss the results and data from any Additional Trial and any clinical trial of a Combination Therapy; (vii) without limiting the rights or obligations of the Parties under Section 5.5 or Section 5.6, review and approve clinical trials of Combination Therapies; (viii) approve Licenses or other agreements to acquire rights from a Third Party that are necessary or useful for the Development, Manufacture or Commercialization of any IO Licensed Product in the Field under this Agreement, (ix) subject to Section 3.1(b), review and discuss the roles and responsibilities of the Committees and Working Groups and any proposals of the Parties or any such Committees or Working Groups related thereto, and establish Committees, Working Groups and sub-committees of the IOSC, as the IOSC deems appropriate; (x) approve the Anticipated First Commercial Sale of an IO Licensed Product in the Territory and in one or more countries of the Territory, as applicable; and (xi) consider and act upon such other matters as are specifically assigned to the IOSC under this Agreement or otherwise agreed by the Parties.

3.3 Joint Development Committee.

(a) Composition and Purpose. The purpose of the JDC shall be (i) to advise the IOSC on the strategy for the worldwide Development of each IO Licensed Product in

the Field; (ii) to develop (or oversee the development of), review and annually amend and present to the IOSC for approval the Global Development Plan(s) (and related Global Development Budget(s)) for IO Licensed Products other than REGN2810, and (iii) to oversee the implementation of the Global Development Plan(s) and the Development operational aspects of the Collaboration (other than with respect to REGN2810). The JDC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). The JDC will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi.

(b) Specific Responsibilities. In particular, the JDC shall be responsible for the following activities with respect to the IO Licensed Products (other than REGN2810):

(i) advising the IOSC on the overall global Development strategy for each Licensed Product in the Field;

(ii) developing (or overseeing the development of), and updating at least annually, the Global Development Plan(s) (and related Global Development Budget(s)) for IO Licensed Products, as described in Section 5.4, for final approval by the IOSC;

(iii) reviewing and overseeing the implementation of, and compliance with, the Global Development Plan(s) (including the Global Development Budget(s)) for IO Licensed Products;

(iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;

(v) overseeing clinical and regulatory matters pertaining to IO Licensed Products in the Field arising from the Plans, and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of IO Licensed Products in the Field as contemplated under the Global Development Plan(s) and for Non-Approval Trials;

(vi) reviewing and approving proposed Target Labeling for IO Licensed Products and reviewing and, to the extent set forth herein, approving proposed changes to product labeling with respect to such IO Licensed Products in the Field in accordance with Section 7.2;

(vii) developing a target profile for each IO Licensed Product;

(viii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of IO Licensed Products in the Field;

(ix) formulating a life-cycle management strategy for IO Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;

(x) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the IO Licensed Products in the Field;

(xi) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan(s); and

(xii) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the IOSC.

3.4 Joint Commercialization Committee.

(a) Composition and Purpose. The purpose of the JCC shall be to develop and oversee the strategy for the Commercialization of IO Licensed Products in the Field in the Territory, and to oversee the implementation of the Commercialization Plans and the Commercialization operational aspects of the Collaboration on a country-by-country basis. The JCC shall be composed of at least two (2) senior executives of each Party having expertise and authority with respect to commercialization of products; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) JCC Responsibilities. In particular, the JCC shall be responsible for the following activities, which shall in each case be consistent with the applicable Commercialization Plans:

(i) developing and proposing to the IOSC the global strategy for the Commercialization of each IO Licensed Product in the Field in the Territory;

(ii) establishing the Regions and Reporting Country/Regions and establishing a Country/Region Commercialization Committee for each such Reporting Country/Region pursuant to Section 3.5;

(iii) [***] (A) developing (or overseeing the development of) and updating no less frequently than [***], the U.S. Commercialization Plan(s) and related U.S. Commercialization Budget(s) for final approval by the IOSC, (B) developing (or overseeing the development of) and updating no less frequently than [***], the ROW Commercialization Plan(s) and related ROW Commercialization Budget(s) for final approval by the IOSC; and (C)

establishing, to the extent provided in Section 3.5, Country/Region Commercialization Committees to establish Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any amendments thereto and carry out the other activities described in Section 3.5;

(iv) defining target groups to be covered by overall marketing efforts in the applicable country, including [***];

(v) establishing the trade dress for each IO Licensed Product, consistent with the guidelines established by the JCC, in the applicable Major Market Country;

(vi) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan(s) for review by the JMC and approval by the IOSC;

(vii) for each IO Licensed Product, developing and updating, as necessary, the promotional guidelines for branding, positioning, core messages and Promotional Material messages and IO Licensed Product pricing and rebate/discount guidelines; guidelines for determining the percentage of sales force compensation linked to sales of such IO Licensed Product in the U.S. (collectively, the items referred to in this paragraph (vii) shall be referred to as the "U.S. Marketing Guidelines") as part of the U.S. Commercialization Plan;

(viii) for each IO Licensed Product, developing and updating, as necessary, global promotional guidelines for branding, positioning, core messages and Promotional Material messages (collectively, the items referred to in this paragraph (viii) shall be referred to as the "Global Marketing Guidelines"), provided that any inconsistency between the U.S. Marketing Guidelines and the Global Marketing Guidelines shall be resolved in favor of the U.S. Marketing Guidelines and any inconsistency between the ROW Marketing Guidelines and the Global Marketing Guidelines shall be resolved in favor of the ROW Marketing Guidelines;

(ix) for each IO Licensed Product, on a country-by-country basis for the Major Market Countries in the ROW Territory, developing and updating, as necessary, the ROW Territory promotional guidelines for branding, positioning, core messages and Promotional Material messages and IO Licensed Product pricing and rebate/discount guidelines; guidelines for determining the percentage of sales force compensation linked to sales of such IO Licensed Product in such country in the ROW Territory (collectively, the items referred to in this paragraph (ix) shall be referred to as the "ROW Marketing Guidelines") as part of the ROW Commercialization Plan;

(x) reviewing and overseeing compliance with the U.S. Commercialization Plan (including the related U.S. Commercialization Budget),

ROW Commercialization Plan (including the related ROW Commercialization Budget), and the Global Commercialization Plan (including the related Global Commercialization Budget) for each IO Licensed Product, including ensuring that the country specific launch plans are consistent with the applicable Marketing Guidelines, and reviewing and validating latest annual estimates for the current Contract Year compared to the U.S. Commercialization Budget, ROW Commercialization Budget, Global Commercialization Budget and Country/Region Commercialization Budgets;

(xi) establishing or validating the number and position of Details required to meet market and sales forecasts and their conversion into the equivalent number of FTEs for performance of such Details according to applicable weighting factors, based upon sales force and market practices on a country-by-country basis, consistent, however, with the applicable Marketing Guidelines;

(xii) for each IO Licensed Product selecting a Product Trademark in accordance with Section 11.2 and giving guidance on trade dress for such IO Licensed Product;

(xiii) determining the launch date for each IO Licensed Product on a country-by-country basis in the Territory;

(xiv) reviewing and approving [***] and similar policies for each IO Licensed Product in the applicable Major Market Country, which shall be consistent with the applicable Marketing Guidelines;

(xv) preparing short-term and long-term sales forecasts for each IO Licensed Product on a country-by-country basis for Major Market Countries and reviewing such forecasts for the remaining countries;

(xvi) [***] (B) overseeing the [***], and (C) determining which such [***] and whether any [***] should be referred to the JDC (or, with respect to REGN2810, the IOSC) for consideration for inclusion in the applicable Global Development Plan;

(xvii) validating the contents, design and layout of packaging for each IO Licensed Product in the Field;

(xviii) validating plans and policies regarding journal and other publications with respect to each IO Licensed Product in the Field in concert with the JDC (or, with respect to REGN2810, the IOSC);

(xix) formulating a life-cycle management strategy for each IO Licensed Product in the Field and evaluating new opportunities for new

indications, formulations, delivery systems and improvements in concert with the JDC (or, with respect to REGN2810, the IOSC);

(xx) preparing the Global Commercialization Plan and Global Commercialization Budget;

(xxi) matters relating to the non-Lead Commercialization Party's Co-Promote Commitment Level with respect to an IO Licensed Product in a Co-Commercialization Country, including consenting to changes therein; and

(xxii) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement or by the IOSC, JDC, JFC, or JMC.

3.5 Reporting Country/Regions; Country/Region Commercialization Committees. The JCC will establish the Regions and Reporting Country/Regions, and for each Reporting Country/Region, as determined by the JCC, the JCC will establish a Country/Region Commercialization Committee as and when determined by the JCC; provided that each country in the Territory shall be included in a Reporting Country/Region. The Country/Region Commercialization Committees will be responsible for establishing the Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) (for clarity, the U.S. Commercialization Plan shall be the Country/Region Commercialization Plan for the U.S., and the U.S. Commercialization Budget shall be the Country/Region Commercialization Budget for the U.S.) and any amendments thereto with respect to the applicable Reporting Countries/Region(s). The Country/Region Commercialization Committees will also serve as a forum to consider and discuss and, if so empowered by the JCC, decide, in a more detailed and focused manner with respect to the applicable Reporting Countries/Region(s), and make suggestions or recommendations to the JCC with respect to, the matters referred to in Section 3.4, as applicable, including the implementation of decisions with respect thereto made by the JCC as contemplated by this Section 3.5.

3.6 Joint Finance Committee. The JFC shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including (a) sharing information regarding the REGN2810 Global Development Budget, including any material amendments thereto, and discussing the reports delivered pursuant to Section 5.3(b), (b) such specific responsibilities set forth in ARTICLE IX and (c) such other responsibilities determined by the IOSC. The JFC also shall respond to inquiries from the IOSC, the JDC, the JMC, and the JCC, as needed.

3.7 Joint Manufacturing Committee. Working with the IOSC, the JDC, the JCC, and the JFC, as appropriate, the Joint Manufacturing Committee shall be responsible for overseeing process development and Manufacturing activities, including preparing and updating the Manufacturing Plan for approval by the IOSC and carrying out such other responsibilities set forth in ARTICLE VIII, process and technology selection, process improvements and related intellectual property filing strategy and obtaining a common process for Manufacturing, recalls, market withdrawals, and any other corrective actions related to any IO Licensed Product in the

Territory, and for any other matters specifically assigned to the JMC by the IOSC. For process development activities, the Joint Manufacturing Committee shall consult the appropriate expert functions within both Parties or their Affiliates as appropriate.

3.8 Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Sanofi, with each representative having the requisite experience and seniority to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of such Committee. Each Party may replace its Committee members upon written notice to the other Party; provided, that such replacement has the foregoing requisite experience and seniority; and provided, further, that the Committee composition meets the requirements of this ARTICLE III. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi, and each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of each meeting and prepare and issue final minutes within thirty (30) days thereafter.

3.9 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than once every Quarter during the Term, commencing from and after the time such Committee is established as provided herein unless the co-chairpersons agree otherwise; provided that until such time as a second (2nd) Product Candidate becomes an IO Licensed Product under the terms of this Agreement and the IO Discovery Agreement (i.e., there is an IO Licensed Product other than REGN2810), the JMC shall only meet on an as-needed basis. All Committee meetings may be conducted by telephone, video-conference or in person as determined by mutual agreement of the co-chairpersons; provided, that each Committee shall meet in person at least once each calendar year, unless the Parties mutually agree to meet by alternative means. Unless otherwise agreed by the Parties, all in-person meetings of a Committee shall be held on an alternating basis between Regeneron's facilities and Sanofi's facilities. Further, in addition to the regularly scheduled quarterly meetings, a Committee shall meet upon the reasonable request of the co-chairpersons or either Party's co-chairperson, as applicable. A reasonable number of other representatives of a Party may attend any Committee meeting as non-voting observers (provided, that such additional representatives are under obligations of confidentiality and non-use applicable to the confidential information of the other Party that are at least as stringent as those set forth in ARTICLE XVI). In addition, other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of any IO Licensed Product in the Field (under obligations of confidentiality) may be invited by the Committee co-chairpersons to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice. Any alternative agreement of the Parties or the applicable co-chairpersons with respect to Committee meetings under this Section 3.9 shall be in writing.

3.10 Decision-Making; Authority. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. The Committees shall review and discuss the matters before it in good faith such that the perspectives of each Party's representatives on such Committee are given due consideration. Notwithstanding anything in this ARTICLE III to the contrary (but, for clarity, without limitation to ARTICLE VIII), in no event shall the Post-POC Other Party with respect to an IO Licensed Product be allocated any responsibility for any Development, Manufacturing or regulatory activity with respect to such IO Licensed Product without its prior consent, which may not be unreasonably withheld, conditioned or delayed.

3.11 Resolution of Committee Matters.

(a) Generally. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible, provided that, in the case of any matter that cannot be resolved by the JDC, the JCC, any CRCC, the JMC, the JFC or other relevant Committee established hereunder, at the written request of either Party, such matter shall promptly, and in any event within [***] (or [***] in the event of an urgent matter) after such request, be referred to the IOSC with a written request for resolution. With respect to [***], the relevant Committee shall review and discuss such matters before it in good faith; however, [***].

(b) Unresolved Matters. The IOSC shall review and discuss the matters before it in good faith such that the perspectives of each Party's representatives on the IOSC are given due consideration. In the event that the IOSC is, after a period of [***] from the date a matter is submitted in writing to it for resolution pursuant to Section 3.11(a), unable to make a decision due to a lack of consensus between the representatives of Regeneron on such Committee, on the one hand, and of Sanofi, on the other hand (any such matter, an "Unresolved Matter"), then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within ten (10) Business Days (or, in the case of a Legal Dispute, thirty (30) days) of receiving such written notification, failing which, unless such matter is an Expert Panel Dispute (in which case it shall be resolved in accordance with Section 3.11(c) and Section 10.4) or a Legal Dispute (in which case it shall be resolved in accordance with Section 10.3), either Regeneron's Executive Officer or Sanofi's Executive Officer shall, except as otherwise expressly set forth in this Agreement, have final decision-making authority with respect to such Unresolved Matter as follows:

(i) except as set forth in Section 5.4(a), the [***] shall have final decision-making authority with respect to Unresolved Matters pertaining to [***];

(ii) [***] shall have final-decision-making authority with respect to any Unresolved Matter pertaining to [***];

(iii) [***] shall have final decision-making authority with respect to any Unresolved Matter pertaining to [***]; and

(iv) [***] shall have final decision-making authority with respect to any Unresolved Matter pertaining to [***];

provided that:

(A) in no event may Regeneron or Sanofi exercise its final decision-making authority in a manner that would be reasonably likely to have a material negative impact on the Commercialization of (I) any IO Licensed Products anywhere in the Territory, or (II) such IO Licensed Product in any country in the Territory in which such Party exercising final decision-making authority is not the Lead Commercialization Party with respect to such IO Licensed Product; and

(B) neither Party shall have final decision-making authority with respect to any Unresolved Matter that (1) constitutes a Legal Dispute or an Expert Panel Dispute or (2) [***]. Any such Unresolved Matter as described in the foregoing clauses (x) or (y) may only be resolved by the mutual agreement of the Parties. Any Unresolved Matter constituting an Expert Panel Dispute shall be referred to binding arbitration pursuant to Section 3.11(c) and Section 10.4. Any Unresolved Matter constituting a Legal Dispute shall be resolved as provided in Section 10.3.

(c) Expert Panel Disputes.

(i) Regeneron may challenge any (A) Global Development Budget for an IO Licensed Product for which Sanofi is the Post-POC Principal Party, (B) Global Commercialization Budget, (C) U.S. Commercialization Budget for an IO Licensed Product for which Sanofi is the Lead Commercialization Party, or (D) ROW Commercialization Budget, [***] (a "Regeneron Budget Dispute").

(ii) Sanofi may challenge any (A) Global Development Budget for an IO Licensed Product for which Regeneron is the Post-POC Principal Party, (B) Global Commercialization Budget, or (C) the U.S. Commercialization Budget for an IO Licensed Product for which Regeneron is the Lead Commercialization Party in the U.S., [***] (a "Sanofi Budget Dispute").

(iii) In the event that the IOSC is, after a period of ten (10) Business Days from the date a matter is submitted to it for resolution pursuant to Section 3.11(a), unable to make a decision due to a lack of consensus between the representatives of Regeneron on such Committee, on the one hand, and of Sanofi,

on the other hand, with respect to (A) (1) any Regeneron Budget Dispute or Sanofi Budget Dispute, or (2) any [***] (in each case ((1) and (2)), a "Budget Dispute," and the relevant budget being referred to as the "Disputed Budget") or (B) any other matter before the JFC regarding accounting, financial (including reporting and controls), or funds flow matters under this Agreement, including any dispute relating to a Consolidated Payment Report of a Party for a Quarter or any payment due thereunder and any dispute relating to calculating the IO Development Balance, but, for clarity, not including any matter relating to the conduct or inclusion of any matter in any Plan, even if such dispute may affect the budget for any such Plan, or any Legal Dispute (a "Financial Dispute"), then such matter shall be referred to the Expert Panel Disputes resolution procedures set forth in Section 10.4; provided, that any such dispute resolved by an independent audit pursuant to Section 14.2 shall not be considered an "Expert Panel Dispute" hereunder for purposes of ARTICLE X.

(iv) Interim Budgets. Pending resolution by the Executive Officers of any Budget Dispute (other than a Budget Dispute relating to REGN2810) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the IO Licensed Products in the Field in the Territory pursuant to this Agreement; provided that [***]. Unless the Parties otherwise agree in writing, the most recent Committee-approved Plan(s) shall be extended, and projected forward, as necessary, pending approval by the Executive Officers of any interim budget(s) and Plan(s) referred to in this Section 3.11(c)(iv).

3.12 Alliance Management. Each of Sanofi and Regeneron shall appoint a senior representative who possesses a general understanding of research, clinical, regulatory, manufacturing and commercialization issues to act as its Alliance Manager ("Alliance Manager"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for being the primary point of communication for seeking consensus both internally within the respective Party's organization and with the other Party's organization and for the sharing of information and responding to information requests between Committee meetings.

3.13 Obligations of the Parties. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein. To the extent a Party performs any of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement which restricts or prohibits a Party from taking any specified action.

3.14 Exchange of Information. Each of Regeneron and Sanofi, will provide regular and fulsome updates to the other Party, through the IOSC or the applicable Committee, with respect to all activities undertaken by or on behalf of such Party under the Collaboration. Without limiting the foregoing, during the Term, each of Regeneron and Sanofi will promptly notify the other Party of any material information regarding the research, Development, Manufacturing or Commercialization of IO Licensed Products, including any material correspondence with a Governmental Authority, and each Party shall provide the other Party with such information regarding the Collaboration that the other Party may reasonably request.

ARTICLE IV
LICENSE GRANTS

4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, Section 4.6) and any License to which Regeneron or any of its Affiliates is a party, Regeneron hereby grants to Sanofi the nontransferable (except as permitted by Section 20.8), royalty-free, fully paid up, co-exclusive (with Regeneron and its Affiliates) right and license, with the right to grant sublicenses in accordance with Section 4.4, under the Regeneron Intellectual Property and Regeneron's interest in the Joint Intellectual Property, to make, have made, use, develop, import, sell and offer to sell (including to promote and, in the Co-Commercialization Countries, to Co-Commercialize) IO Licensed Products for use in the Field in the Territory.

4.2 Sanofi License Grants . Subject to the terms and conditions of this Agreement and any License to which Sanofi or any of its Affiliates is a party, Sanofi hereby grants to Regeneron the nontransferable (except as permitted by Section 20.8), royalty-free, fully paid up, co-exclusive (with Sanofi and its Affiliates) right and license, with the right to grant sublicenses in accordance with Section 4.4, under the Sanofi Intellectual Property and Sanofi's interest in the Joint Intellectual Property, to make, have made, use, develop, import, sell and offer to sell (including to promote and, in the Co-Commercialization Countries, to Co-Commercialize) IO Licensed Products for use in the Field in the Territory.

4.3 Newly Created Intellectual Property. In addition to the other licenses granted under this ARTICLE IV and subject to the other terms and conditions of this Agreement, to the extent permitted under any relevant Third Party agreement, each Party grants to the other Party and its Affiliates the perpetual, royalty-free, fully paid-up, non-exclusive, worldwide right and license, with the right to grant sublicenses, to use and practice for any and all purposes: all intellectual property (including, Know-How, Patents and Patent applications and copyrights), other than Know-How jointly owned pursuant to Section 12.1(e) and other than Excluded Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans. As used above, the term "Excluded Rights" shall mean any Patents or Know-How claiming or covering composition (including any formulation) of an IO Licensed Product, including, for the avoidance of doubt, any manufacturing or cell line related intellectual property. For the avoidance of doubt, nothing in this Section 4.3 shall be construed to grant either Party any license to Patents or Know-How of

the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.

4.4 Sublicensing. Unless otherwise restricted by any License, Sanofi will have the right to sublicense any of its rights under Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld, conditioned or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Sanofi may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. Unless otherwise restricted by any License, Regeneron will have the right to sublicense any of its rights under Section 4.2 with the prior written consent of Sanofi, such consent not to be unreasonably withheld, conditioned or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Sanofi's consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, the confidentiality and non-use obligations set forth in ARTICLE XVI, and will include, an obligation of such Sublicensee to account for and report its sales of IO Licensed Products to the Party granting such sublicense on the same basis as if such sales were Net Sales by such Party granting such sublicense. For the avoidance of doubt, each Party shall be entitled to receive its share of the applicable Profit Split based on Net Sales of IO Licensed Products sold by any Sublicensee of either Party under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement that has or is reasonably likely to have an adverse effect on either Party or any of its Affiliates or any Party's intellectual property, then the harmed Party may cause the other Party or its Affiliate to exercise, and the other Party or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and the other Party, at the option of the other Party, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Each Party will forward to the other Party a complete copy of each applicable fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.

4.5 No Implied License. Except as expressly provided in this ARTICLE IV or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.

4.6 Retained Rights.

(a) Regeneron Retained Rights. With respect to the licenses granted under this ARTICLE IV, and for the avoidance of doubt, Regeneron expressly reserves for itself

and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, the right to Manufacture, to have Manufactured and to Commercialize IO Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the further avoidance of doubt, Regeneron retains all rights in Regeneron Intellectual Property, Regeneron's interest in the Joint Inventions and IO Licensed Products not expressly licensed hereunder, including the right to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the IO Licensed Products in the Field.

(b) Sanofi Retained Rights. With respect to the licenses granted under this ARTICLE IV, and for the avoidance of doubt, Sanofi expressly reserves for itself and its Affiliates and Third Party licensees under the Sanofi Intellectual Property and Sanofi's interest in the Joint Inventions, the right to Manufacture, to have Manufactured, and to Commercialize IO Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Sanofi retains all rights in Sanofi Intellectual Property, Sanofi's interest in the Joint Inventions and IO Licensed Products not expressly licensed hereunder, including, the right to exploit Sanofi Intellectual Property and Sanofi's interest in Joint Inventions for purposes unrelated to the IO Licensed Products in the Field.

ARTICLE V
DEVELOPMENT ACTIVITIES

5.1 Development of IO Licensed Products. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to IO Licensed Products in the Field pursuant to the applicable Development Plans under the general direction and oversight of the IOSC. Each Party shall use Commercially Reasonable Efforts to Develop IO Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, Good Practices.

5.2 Post-POC Principal Party. The Post-POC Principal Party with respect to an IO Licensed Product shall have principal responsibility for formulating and carrying out the Development activities for such IO Licensed Product under the applicable Development Plan(s). Unless and to the extent otherwise agreed by the Parties with respect to a particular IO Licensed Product, (a) Regeneron shall be the Post-POC Principal Party with respect to any PD-1 Licensed Product, including REGN2810, (b) Sanofi shall [***], (c) the Party that [***] and (d) thereafter, the Parties shall alternate, on a Non-PD-1 Licensed Product-by-Non-PD-1 Licensed Product basis. For clarity, unless the Parties mutually agree otherwise, the Post-POC Principal Party with respect to an IO Licensed Product shall be the Post-POC Principal Party with respect to all other IO Licensed Products targeting the same IO Licensed Target Profile as such first (1st) IO Licensed Product, and designation of a Party as the Post-POC Principal Party with respect to an IO Licensed Product because it targets the same IO Licensed Target Profile as another IO Licensed Product for which it is the Post-POC Principal Party shall not affect the assignment of Product Candidates between the Parties as set forth in the preceding sentence.

5.3 REGN2810 Global Development Plan and REGN2810 Global Development Budget.

(a) REGN2810 Global Development Plan. Within ninety (90) days after the Execution Date, Regeneron will prepare and deliver to the IOSC a Global Development Plan for REGN2810 (the "REGN2810 Global Development Plan"). The REGN2810 Global Development Plan will set forth, in a reasonable level of detail, a plan for Development of REGN2810 in the Oncology Field over at least three (3) Contract Years, and will include strategies and timelines for Developing and obtaining Approvals for REGN2810 in the Oncology Field in the Territory. Regeneron will have the right to amend the REGN2810 Global Development Plan in its sole discretion; provided that the REGN2810 Global Development Plan shall at all times be consistent with the Collaboration Purpose and any such amendment shall be presented to the IOSC at the next IOSC meeting. Regeneron will promptly present any material amendments to the REGN2810 Global Development Plan to the IOSC for review and discussion for so long as REGN2810 is an IO Licensed Product.

(b) REGN2810 Global Development Budget. Regeneron shall prepare the Global Development Budget for REGN2810 (the "REGN2810 Global Development Budget") as part of the initial REGN2810 Global Development Plan (of which such REGN2810 Global Development Budget is a part) and submit such REGN2810 Global Development Budget to the IOSC simultaneously with submission of the initial REGN2810 Global Development Plan pursuant to Section 5.3(a) for review and discussion by the IOSC. For clarity, the REGN2810 Global Development Budget and any amendments thereto are part of the REGN2810 Global Development Plan. Subject to Section 3.11(c)(iii) and Section 10.4, the REGN2810 Global Development Budget may not provide for aggregate expenditure of Development Costs in excess of the REGN2810 Budget Amount (and Sanofi shall not be obligated to reimburse Development Costs in excess of the REGN2810 Budget Amount) unless the Parties mutually agree in writing; provided that, for clarity, the foregoing shall not operate to restrict Regeneron from incurring additional Development Costs in excess of the REGN2810 Budget Amount at its sole cost and expense; provided, further, that any such additional cost and expense shall not be counted against any Global Development Budget (including the REGN2810 Global Development Budget) or added to the IO Development Balance. Subject to the immediately preceding sentence, Regeneron shall have the right to amend the REGN2810 Global Development Budget at any time without the approval of the IOSC, provided that Regeneron shall provide the IOSC with any amended REGN2810 Global Development Plan and, if applicable, any amended REGN2810 Global Development Budget, within thirty (30) days after making any material change thereto. Regeneron shall deliver to Sanofi, no later than August 31, 2015, a good faith forecast of the anticipated Development Costs to be incurred for REGN2810 for the last two quarters of the current Contract Year and the two subsequent Contract Years.

5.4 Global Development Plans and Global Development Budgets.

(a) Global Development Plans. With respect to all IO Licensed Products (other than REGN2810), within three (3) months after the time such IO Licensed Product first (1st) becomes an IO Licensed Product in accordance with the terms of the IO

Discovery Agreement and this Agreement, the JDC shall prepare and present a Global Development Plan for such IO Licensed Product to the IOSC for review and approval. Prior to the delivery of the first (1st) Global Development Plan for any such IO Licensed Product by the JDC, the Parties shall Develop the IO Licensed Product in accordance with the applicable Post-POC Development Plan. In connection with their preparation, review and approval, as applicable, of the initial Global Development Plan for an IO Licensed Product (other than REGN2810), the JDC and IOSC shall consider the Post-POC Development Plan in good faith, and unless otherwise agreed in writing by the Parties, the Global Development Plan for an IO Licensed Product (other than REGN2810) shall be consistent with the Post-POC Development Plan for such IO Licensed Product in all material respects. For clarity, this Section 5.4(a) is not intended to limit Section 5.4(c).

(b) Contents of Global Development Plans. Each Global Development Plan for an IO Licensed Product other than REGN2810 will set forth the plan for Development of such IO Licensed Product in the Field (including, for clarity, with respect to any Non-IO Indication) over at least three (3) Contract Years, and will include (x) strategies and timelines for Developing and obtaining Approvals for such IO Licensed Product in the Field in the Territory, (y) subject to the last sentence of Section 3.10, the allocation of responsibilities for Development activities between the Parties with respect to such IO Licensed Product and (z) any other information reasonably requested by a Party and agreed by the JDC and IOSC. Each Global Development Plan and any amendment thereto shall be consistent with the Collaboration Purpose.

(c) Amendments to the Global Development Plans. An amended Global Development Plan for each IO Licensed Product (other than REGN2810) will be presented by the JDC to the IOSC for review and approval at least two (2) months prior to the end of each Contract Year. Each such Global Development Plan will be reviewed and amended or approved by the JDC not less frequently than once every six (6) months for the ensuing three (3) year period. Amendments to a Global Development Plan may be made under this Section 5.4(c) to reflect results achieved and other changed circumstances with respect to the applicable IO Licensed Product; unless otherwise agreed by the Parties, no amendments to a Global Development Plan shall be made in the absence of such changes. All amendments to a Global Development Plan shall be consistent with the Collaboration Purpose.

(d) Global Development Budgets. Each Global Development Plan for an IO Licensed Product (other than REGN2810) shall include a related Global Development Budget. The JDC shall prepare the Global Development Budget as part of the initial Global Development Plan for such IO Licensed Product (of which such Global Development Budget is a part) and submit such Global Development Budget to the IOSC for review and approval simultaneously with submission of the initial Global Development Plan for such IO Licensed Product pursuant to Section 5.4(a). Each Global Development Budget with respect to an IO Licensed Product shall provide for a commercially reasonable amount of funding for the Development of such IO Licensed Product in accordance with this Agreement. The JDC shall have the right to submit amendments for such Global Development Budget to the IOSC for

review and approval. Subject to Section 3.11(c)(iii) and Section 10.4, no Global Development Budget or any amendment thereto shall be effective without the approval of the IOSC.

(e) Development Reports. Within forty-five (45) days after the end of each Quarter, Regeneron and Sanofi shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with (i) each Global Development Plan together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter and shall be in such form, format and of such level of detail as approved by the JFC, and (ii) any Additional Trials or clinical trials of Combination Therapies conducted by or on behalf of such Party. At the next IOSC meeting held following such forty-five (45) day period, the IOSC will approve the final Development Costs which will be used in calculating the IO Development Balance.

5.5 Additional Trials.

(a) Additional Trials. Subject to Section 5.6, if the Post-POC Other Party with respect to an IO Licensed Product presents a proposal to the IOSC to undertake any additional clinical trial of (i) such IO Licensed Product or (ii) a Non-Proprietary Combination Therapy involving such IO Licensed Product (but, for clarity, except for (ii), not any other Combination Therapy, which shall be governed by Section 5.6), in each case that is not contemplated in the applicable Global Development Plan and the IOSC fails to approve the proposal for the inclusion of such clinical trial(s) under the applicable Global Development Plan within the timeframe established by the IOSC pursuant to this Section 5.5, then the Post-POC Other Party may, at its option and at its sole cost and expense, subject to this Section 5.5(a), conduct such additional clinical trial(s) of such IO Licensed Product, Combination Therapy with another IO Licensed Product or Non-Proprietary Combination Therapy (but, for clarity, except for the foregoing, not any other Combination Therapy, which shall be governed by Section 5.6) outside the scope of the applicable Development Plan (any such clinical trial, an "Additional Trial"); provided, that [***]. The Post-POC Other Party shall also provide to the Post-POC Principal Party any drug safety data from such additional clinical trials in accordance with Section 7.4. Separate from the determination of whether to include such clinical trial(s) in the relevant Development Plan, the Post-POC Principal Party may disapprove the conduct of an Additional Trial outside the relevant Development Plan, or any such protocols or clinical trial designs, or any amendments thereto, for [***]. If the Post-POC Principal Party disapproves the conduct of any proposed Additional Trial outside of the applicable Global Development Plan (or any amendment to the plan therefor) in accordance with this Section 5.5, the Post-POC Other Party may not proceed with the proposed Additional Trial (or amend the plan therefor). If the Post-POC Other Party disputes such disapproval, such dispute shall be referred to the Executive Officers for resolution. If the Executive Officers are not able to resolve such dispute, then such dispute shall be [***].

(b) Results. In the event that either Party conducts any Additional Trials, all results, Know-How and Patent Rights generated in or arising from any such Additional Trial shall be subject to the grants of rights pursuant to ARTICLE IV of this Agreement.

Publication of any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 5.5 shall be subject to ARTICLE XVI.

(c) Funding. If the Post-POC Principal Party approves an Additional Trial, such Additional Trial shall be funded at the Post-POC Other Party's sole cost and expense, which cost and expense shall not, subject to Section 9.2(d), be counted against any Global Development Budget or added to the IO Development Balance.

(d) Review of Additional Trial Protocols. The IOSC will establish procedures for the expeditious review of clinical trial protocols for the IO Licensed Products submitted to the IOSC by the Post-POC Other Party pursuant to this Section 5.5, including (a) timelines and deadlines for approving such clinical trial protocols and (b) pre-approval authorizations for Non-Approval Trials.

5.6 Combination Therapies.

(a) Generally. The IOSC shall discuss whether to include in the Global Development Plan for an IO Licensed Product the Development of such IO Licensed Product for use with other IO Licensed Products, other IO Discovery Program Antibodies, or Other Products (each, a "Combination Therapy"), including Proprietary Products and Other Products that are owned or controlled by a Third Party or that are in the public domain. Subject to this Section 5.6, each Party shall have the right to propose to the IOSC Other Products for co-development with IO Licensed Products under the applicable Development Plan.

(b) Combinations with IO Discovery Program Antibodies. Proposed combinations of any IO Licensed Product with an IO Discovery Program Antibody shall be governed by Section 2.10(b)(i) of the IO Discovery Agreement.

(c) Combinations with other IO Licensed Products. In the event that either Party proposes a Combination Therapy of an IO Licensed Product with another IO Licensed Product (including any PD-1 Licensed Products), the [***] shall be the Post-POC Principal Party with respect to the Development of such Combination Therapy. For clarity, nothing in this Section 5.6(c) shall impact (i) the rights of a Party as the Post-POC Principal Party with respect to an IO Licensed Product (other than with respect to the Development of such Combination Therapy), including with respect to other Development of such IO Licensed Product or with respect to being the Lead Commercialization Party for such IO Licensed Product, or (ii) the Lead Commercialization Party's rights in respect of such IO Licensed Product, in each case, as set forth in this Agreement.

(d) Combinations with Proprietary Products. Except with respect to PD-1 Licensed Products as provided in Section 5.6(e), no development of a Combination Therapy of an IO Licensed Product with a Proprietary Product may be incorporated into a Global Development Plan for an IO Licensed Product without the [***]; provided that [***]. The Parties acknowledge and agree that [***]. The "Controlling Party" with respect to a Proprietary Product shall be determined as follows: (A) if such product is an Existing Collaboration Product,

then [***] shall be the Controlling Party (subject to the terms of such Ancillary Collaboration Agreement), and (B) if such Proprietary Product is an Ex-Collaboration Product, [***] shall be the Controlling Party. For clarity, references hereunder to the Party that is or is not the Controlling Party (including to the non-Controlling Party) with respect to a Proprietary Product shall refer [***].

(i) Existing Collaboration Products.

(A) If the Parties agree to the development of a Combination Therapy of an IO Licensed Product with an Existing Collaboration Product, unless otherwise agreed by the Parties, the development of such Combination Therapy shall be conducted [***]. Unless the Parties otherwise agree and notwithstanding anything to the contrary in the Existing Agreements, [***] percent ([***]%) of the costs and expenses associated with developing the proposed Existing Collaboration Product in combination with the proposed IO Licensed Product, including the cost of clinical supply of the Existing Collaboration Product, which shall be provided by the Controlling Party to the developing party pursuant to the terms of the applicable Existing Agreement at Manufacturing Cost, shall be [***], and the other [***] percent ([***]%) of such costs and expenses shall be [***].

(B) If the Parties do not agree to the development of a Combination Therapy of an IO Licensed Product with an Existing Collaboration Product proposed by the Controlling Party of the Existing Collaboration Product, and [***] shall have the right to [***].

(C) If the Parties do not agree to the development of a Combination Therapy of an IO Licensed Product with an Existing Collaboration Product proposed by the Party that is not the Controlling Party of the Existing Collaboration Product, and [***] notwithstanding anything to the contrary in the Existing Agreements, [***] shall have the right to [***].

(D) For clarity, nothing in this Section 5.6(d)(i) is intended or shall be construed to limit the rights of the Post-POC Principal Party of the relevant IO Licensed Product to develop any other Combination Therapies of such IO Licensed Product with Other Products that are not Proprietary Products.

(ii) Ex-Collaboration Products.

(A) If the Parties agree to the development of a Combination Therapy of an IO Licensed Product with an Ex-Collaboration Product, unless otherwise agreed by the Parties, the development of such Combination Therapy shall be conducted [***], and [***] shall be responsible for [***] percent ([***]%) of the costs and expenses incurred in connection therewith

(which for clarity [***], including the cost of clinical supply, which shall be [***].

(B) If the Parties do not agree to the development of a Combination Therapy of an IO Licensed Product with an Ex-Collaboration Product proposed by the Controlling Party of the Ex-Collaboration Product, and [***] shall be free to [***].

(C) For clarity, nothing in this Section 5.6(d)(ii) is intended or shall be construed to limit the rights of the Post-POC Principal Party of the relevant IO Licensed Product to develop any other Combination Therapies of such IO Licensed Product with Other Products that are not Ex-Collaboration Products.

(e) Combinations with PD-1 Licensed Products. Subject to any rights of Sanofi with respect to Ex-Collaboration Products for which Sanofi is the Controlling Party, Regeneron shall have the right to develop and commercialize, in its sole discretion, any PD-1 Licensed Product in combination with (i) Ex-Collaboration Products, or (ii) Other Products owned or controlled by a Third Party or in the public domain that are not Antibodies and that do not target any IO Licensed Target Profile, in each case ((i) and (ii)) inside (i.e., under the applicable Plans and budgets) or outside the Collaboration; [***]. Any license fees, royalties or milestone payments received from any such Third Party under such a collaboration agreement in respect of such Combination Therapy of a PD-1 Licensed Product in combination with an Other Product owned or controlled by such Third Party in a Quarter shall be [***]. Any license fees, royalties or milestone payments owed to any such Third Party shall be [***].

(f) Non-Proprietary Combination Therapies. Except as provided in Section 5.6(e), any Combination Therapy that does not involve a Proprietary Product (e.g., an Other Product owned or controlled by a Third Party or that is in the public domain) or a Competing Product (any such Combination Therapy, a "Non-Proprietary Combination Therapy") shall not be subject to Section 5.6(d) and such Non-Proprietary Combination Therapy may be Developed by the Post-POC Principal Party for the IO Licensed Product that is part of such Non-Proprietary Combination Therapy, and [***] percent ([***]%) of the costs and expenses associated with the development of any such Non-Proprietary Combination Therapy shall be [***]. Any license fees, royalties or milestone payments received from any such Third Party under such a collaboration agreement in respect of such Non-Proprietary Combination Therapy in a Quarter shall be [***]. Any license fees, royalties, or milestone payments owed to any such Third Party shall be [***].

(g) Competing Combination Therapies.

(i) Competing Combination Studies. Notwithstanding anything in Section 2.6 or this Section 5.6 to the contrary, each Party and its respective Affiliates shall be entitled to (A) initiate, sponsor or conduct a clinical study or (B) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in any clinical study, initiated, sponsored or conducted

by any Third Party, in each of the foregoing cases with respect to the combination of any Ex-Collaboration Product of such Party (or its Affiliate's), together with any Competing Product that [***] a "Competing Combination Study"), unless (1) [***], or (2) [***]. For any Competing Combination Study permitted by this Section 5.6(g)(i), the applicable Party proposing to participate in a Competing Combination Study shall notify the other Party at least [***] prior to initiating such Competing Combination Study, such notice to include a brief synopsis of the protocol and a description of the Party's (or its Affiliate's) role(s) and responsibilities in connection with the Competing Combination Study. Further, for any Competing Combination Study permitted by this Section 5.6(g)(i), the Party conducting such study shall promptly provide the other Party with available results of such Competing Combination Study to the extent such disclosure is not prohibited by Law or contract. Each Party or its Affiliates shall be entitled to use data from Competing Combination Studies permitted by this Section 5.6(f)(i) to promote the combination of an Ex-Collaboration Product together with the applicable Competing Product, unless an IO Licensed Product has been granted a Marketing Approval in the applicable country for use in combination with such Ex-Collaboration Product, in the same Indication(s). Notwithstanding any other provision of this Section 5.6(g)(i), neither a Party nor its respective Affiliates shall receive any compensation or other payments (either in cash or in kind) based on the development or commercialization of a Competing Product. Neither Party will intentionally delay the commencement, enrollment or completion of a clinical study of an IO Licensed Product under any Development Plan hereunder as a result of any ongoing or pending Competing Combination Study permitted by this Section 5.6(g)(i). For the avoidance of doubt, neither Party nor its respective Affiliates shall use or disclose any Party Information or New Information subject to the confidentiality provisions of ARTICLE XVI in connection with any of the activities described in this Section 5.6(g)(i).

(ii) [***]. Notwithstanding anything in Section 2.6 or this Section 5.6 to the contrary, Sanofi and its Affiliates shall be entitled to (A) initiate, sponsor or conduct a clinical study or (B) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in any clinical study, initiated, sponsored or conducted by any Third Party, in each of the foregoing cases with respect to the combination of any Third Party [***] with any [***] (any such clinical study, a "[***]") (1) if such Third Party [***] has [***], and (2) [***]. For clarity, Sanofi shall have the right to continue any [***] properly commenced in accordance with the foregoing sentence whether or not the conditions set forth in clause (1) or (2) continue to be true for the duration of such [***]. For any [***] permitted by this Section 5.6(g)(ii), Sanofi shall notify Regeneron prior to initiating such [***], such notice to include, to the extent such disclosure is not prohibited by Law or contract, a brief synopsis of the protocol and a description of Sanofi's (or its Affiliate's) role(s) and responsibilities in connection with such [***]. Notwithstanding the foregoing, Sanofi shall not intentionally delay the commencement, enrollment or completion of a clinical

study of an IO Licensed Product under any Development Plan hereunder as a result of any ongoing or pending [***] permitted by this Section 5.6(g)(ii). For the avoidance of doubt, neither Sanofi nor its Affiliates shall use or disclose any Party Information or New Information subject to the confidentiality provisions of ARTICLE XVI in connection with any of the activities described in this Section 5.6(g)(ii). If Sanofi participates in any [***] permitted by this Section 5.6(g)(ii), Sanofi shall be permitted to further develop, manufacture and commercialize such [***] for use in combination with the applicable Third Party [***] either directly, or with or through any Affiliate or Third Party, notwithstanding anything to the contrary contained herein (but subject to the limitations on Sanofi's exercise of rights outside of the Collaboration with respect to developing or commercializing Competing Products).

ARTICLE VI
COMMERCIALIZATION

6.1 Commercialization of IO Licensed Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to IO Licensed Products in the Field in the Territory under the direction and oversight of the JCC. The following provisions shall apply with respect to such Commercialization activities:

(a) Commercialization of IO Licensed Products in the U.S. With respect to each IO Licensed Product, the Post-POC Principal Party for such IO Licensed Product shall be the Lead Commercialization Party for such IO Licensed Product in the U.S. Regeneron shall be the Lead Commercialization Party for all PD-1 Licensed Products in the U.S., subject to the last sentence of this Section 6.1(a). The Lead Commercialization Party with respect to an IO Licensed Product in the U.S. shall use Commercially Reasonable Efforts to Commercialize such IO Licensed Product in the Field in the U.S., and carry out the Commercialization activities with respect to such IO Licensed Product in the U.S. in accordance with the U.S. Commercialization Plan and, to the extent applicable, the Global Commercialization Plan in a timely manner and conduct all such activities in compliance with applicable Laws. Except as otherwise provided in this Agreement, such Lead Commercialization Party shall bear all costs and expenses in connection with the Commercialization of such IO Licensed Product in the Field in the U.S. Such Lead Commercialization Party or its Affiliate shall invoice and book all sales of such IO Licensed Product in the Field in the U.S. and shall appropriately record all such sales in accordance with such Party's Accounting Standards. Such Lead Commercialization Party or its Affiliate shall also be responsible for the distribution of such IO Licensed Product in the U.S. and for paying all governmental rebates which are due or owing with respect to such IO Licensed Product in the U.S. If Sanofi is the Post-POC Principal Party for an IO Licensed Product in the U.S. and has made an HSR Filing pursuant to Section 5.7 of the IO Discovery Agreement with respect thereto, then in the U.S., Regeneron shall be the Lead Commercial Party with respect to such IO Licensed Product until such time as Regeneron receives from Sanofi a written notice that the applicable waiting period under the HSR Act has expired or been terminated (the "HSR Clearance Notice") (for clarity, upon delivery of such HSR Clearance Notice, Sanofi shall become the Lead Commercial Party with respect to such IO Licensed Product); provided that if

Regeneron does not receive such HSR Clearance Notice within one hundred and eighty (180) days of the HSR Filing date, then Regeneron shall remain the Lead Commercialization Party for such IO Licensed Product in the U.S. unless the Parties otherwise agree in writing.

(b) Commercialization of IO Licensed Products in the ROW Territory. Sanofi shall be the Lead Commercialization Party with respect to the Commercialization of IO Licensed Products in the Field in the ROW Territory. Sanofi shall use Commercially Reasonable Efforts to Commercialize IO Licensed Products in the Field in the ROW Territory, and carry out the Commercialization activities with respect to the ROW Territory in accordance with the ROW Commercialization Plan, the applicable Country/Region Commercialization Plans and, to the extent applicable, the Global Commercialization Plan in a timely manner and conduct all such activities in compliance with applicable Laws. Except as otherwise provided in this Agreement, Sanofi shall bear all costs and expenses in connection with the Commercialization of IO Licensed Products in the Field in the ROW Territory. Sanofi or its Affiliate shall invoice and book all sales of IO Licensed Products in the Field in the ROW Territory and shall appropriately record all such sales in accordance with Sanofi's Accounting Standards. For clarity, neither Regeneron nor any of its Affiliates shall book sales for any IO Licensed Product in the ROW Territory. Sanofi or its Affiliate shall also be responsible for the distribution of IO Licensed Products in the Field in the ROW Territory and for paying all governmental rebates that are due or owing with respect to IO Licensed Products in the Field in the ROW Territory.

6.2 Commercialization Plan(s). With respect to each IO Licensed Product, the Parties shall prepare, as described in this Section 6.2, a U.S. Commercialization Plan, ROW Commercialization Plan, and (x) to the extent provided by Section 6.2(a), a Global Commercialization Plan, and (y) to the extent provided by Section 6.2(d), one or more Country/Region Commercialization Plans (collectively, the "Commercialization Plans") in accordance with this Section 6.2. Each Commercialization Plan and all amendments thereto will be consistent with the Collaboration Purpose. To the extent agreed to by the Parties, acting through the JCC, any one or more of the Commercialization Plans may be combined into a single Commercialization Plan.

(a) Global Commercialization Plan. With respect to each IO Licensed Product, the JCC shall prepare a global plan setting forth those Commercialization activities for such IO Licensed Product that the Parties mutually agree are global in nature (any such plan, a "Global Commercialization Plan"), including a Global Commercialization Budget therefor. The Global Commercialization Plan shall be submitted to the IOSC for review and approval at least two (2) years before the Anticipated First Commercial Sale anywhere in the Territory of the applicable IO Licensed Product or as otherwise mutually agreed by the Parties. Such Global Commercialization Plan for each subsequent Contract Year shall be amended by the JCC and approved by the IOSC at least two (2) months prior to the end of the then-current Contract Year.

(b) U.S. Commercialization Plan. With respect to each IO Licensed Product, the Lead Commercialization Party shall prepare, at the direction of the JCC and with assistance and input from the other Party, the U.S. Commercialization Plan for such IO Licensed Product, including the U.S. Commercialization Budget therefor. The U.S. Commercialization

Plan shall be presented to the IOSC for review and approval [***]. Such U.S. Commercialization Plan for each subsequent Contract Year shall be amended by the JCC and approved by the IOSC at least two (2) months prior to the end of the then current Contract Year. Each U.S. Commercialization Plan for an IO Licensed Product will be consistent with the Global Development Plan and the Global Commercialization Plan for such IO Licensed Product. The U.S. Commercialization Plan with respect to each IO Licensed Product shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale in the U.S., to enable the JCC and the IOSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

(i) the overall global strategy for Commercializing such IO Licensed Product in the Field in the U.S., including target product profiles, branding, positioning, promotional materials and core messages for such IO Licensed Product;

(ii) [***];

(iii) the related U.S. Commercialization Budget;

(iv) anticipated launch date for such IO Licensed Product in the U.S.;

(v) market and sales forecasts for such IO Licensed Product in the Field in the U.S. in a form to be agreed between the Parties;

(vi) strategies for the detailing and promotion of such IO Licensed Product in the Field in the U.S.;

(vii) anticipated major advertising, public relations and patient advocacy programs for such IO Licensed Product in the Field in the U.S.;

(viii) Non-Approval Trials in the U.S.;

(iv) all other U.S. Marketing Guidelines; and

(x) if the Parties are Co-Promoting an IO Licensed Product in the U.S., the U.S. Commercialization Plan shall include more detailed information on the coordination of detailing and promotional efforts, including the estimated number of detailing FTEs for each Party (based on the number and position of Details required to meet the market and sales forecasts) and the specific allocation of Co-Promotion efforts between the Parties.

(c) ROW Commercialization Plan. With respect to each IO Licensed Product, the Lead Commercialization Party shall prepare, at the direction of the JCC and with assistance and input from the other Party, the ROW Commercialization Plan for such IO Licensed Product, including the ROW Commercialization Budget therefor. The ROW Commercialization Plan shall be presented to the IOSC for review and approval [***]. Such

ROW Commercialization Plan for each subsequent Contract Year shall be amended by the JCC and approved by the IOSC at least two (2) months prior to the end of the then current Contract Year. Each ROW Commercialization Plan for an IO Licensed Product will be consistent with Global Development Plan and the Global Commercialization Plan for such IO Licensed Product. The ROW Commercialization Plan with respect to each IO Licensed Product shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale in the ROW Territory, to enable the JCC and the IOSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

(i) the overall global strategy for Commercializing such IO Licensed Product in the Field in the ROW Territory, including target product profiles, branding, positioning, promotional materials and core messages for such IO Licensed Product;

(ii) [***];

(iii) the related ROW Commercialization Budget;

(iv) anticipated launch date for such IO Licensed Product in the ROW Territory;

(v) market and sales forecasts for such IO Licensed Product in the Field in the ROW Territory in a form to be agreed between the Parties;

(vi) strategies for the detailing and promotion of such IO Licensed Product in the Field in the ROW Territory;

(vii) anticipated major advertising, public relations and patient advocacy programs for such IO Licensed Product in the Field in the ROW Territory;

(viii) Non-Approval Trials in each Major Market in the ROW Territory; and

(ix) all other ROW Marketing Guidelines.

(d) Country/Region Commercialization Plans. Each Country/Region Commercialization Plan for an IO Licensed Product, and all amendments thereto, will be consistent with the Global Commercialization Plan, the U.S. Commercialization Plan, or the ROW Commercialization Plan, as applicable, for such IO Licensed Product and the Collaboration Purpose. It is anticipated that each Country/Region Commercialization Plan and the Country/Region Commercialization Budget for each IO Licensed Product for each Reporting Country/Region in the ROW Territory will be prepared by the applicable Country/Region Commercialization Committee and submitted to the JCC and the IOSC for approval [***]. Such Country/Region Commercialization Plan for each subsequent Contract Year shall be amended by the applicable Country/Region Commercialization Committee, and approved by the JCC and the

IOSC, at least two (2) months prior to the end of the then current Contract Year. Each Country/Region Commercialization Plan with respect to each IO Licensed Product shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including, subject to the ROW Commercialization Plan and, if applicable, the Global Commercialization Plan for such IO Licensed Product, the overall strategy for Commercializing such IO Licensed Product, pricing strategies, market and sales forecasts, and estimated FTE and Shared Commercial Expenses. The U.S. Commercialization Plan shall be deemed to be the Country/Region Commercialization Plan with respect to the U.S. In those countries where the Parties are Co-Promoting an IO Licensed Product, such Country/Region Commercialization Plans (including, if applicable, the U.S. Commercialization Plan) shall include more detailed information on the coordination of detailing and promotional efforts, including the estimated number of detailing FTEs for each Party (based on the number and position of Details required to meet the market and sales forecasts) and the specific allocation of Co-Promotion efforts between the Parties.

6.3 Commercialization Efforts; Sharing of Commercial Information.

(a) The Parties (through their respective Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize IO Licensed Products in the Field in the Territory in accordance with the applicable Commercialization Plans and the applicable Marketing Guidelines. Without limiting the generality of the foregoing, (i) Sanofi, with respect to (A) all IO Licensed Products in the ROW Territory, (B) the IO Licensed Products for which Sanofi is the Lead Commercialization Party in the U.S., and (C) the IO Licensed Products for which Sanofi is the Co-Promoting Party in the U.S., and (ii) Regeneron, with respect to (A) the IO Licensed Products for which Regeneron is the Lead Commercialization Party in the U.S. and (B) the IO Licensed Products for which Regeneron is the Co-Promoting Party in the applicable Co-Commercialization Countries, will, as necessary, (x) build, train and apply a field force necessary to Commercialize such IO Licensed Products in the Field in accordance with the applicable Commercialization Plans and all applicable Laws, and (y) cause its respective sales representatives in such countries to provide the FTE effort and to detail such IO Licensed Products in the Field in accordance with the approved Commercialization Plans and all applicable Laws.

(b) Each Party will provide the other Party with full access to material information directly relating to the Commercialization of each IO Licensed Product in the Field, including, information relating to anticipated launch dates, key market metrics, market research, and sales. Without limiting the foregoing, beginning in the Quarter of the First Commercial Sale in each Major Market Country, the Lead Commercialization Party will provide to the other Party, and with respect to each Co-Commercialization Country, the Co-Promoting Party will provide to the Lead Commercialization Party, on a quarterly basis, with reports of the activity within its field force in each such Major Market Country, which will include reasonable data from reports created by Sanofi or Regeneron for its internal management purposes.

(c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the IO Licensed Products in the Field, IO Licensed Product quality complaints and similar information.

(d) No Party may initiate or support any Non-Approval Trial for an IO Licensed Product in the Field in the Territory without the prior approval of the IOSC.

6.4 Co-Commercialization of IO Licensed Products.

(a) Exercise of Co-Promotion Option by the non-Lead Commercialization Party. In the event that the Party that is not the Lead Commercialization Party with respect to an IO Licensed Product in any country in the Territory desires to Co-Promote such IO Licensed Product in such country, then such Party shall notify the Lead Commercialization Party of (i) its preliminary indication of intent regarding such Co-Promotion of such IO Licensed Product in such country [***] and (ii) its final decision regarding whether to Co-Promote such IO Licensed Product in such country [***]. If such non-Lead Commercialization Party does not timely notify the Lead Commercialization Party of its preliminary indication or of its final decision within the periods set forth in clause (i) or (ii) above, as applicable, such non-Lead Commercialization Party shall not be entitled to exercise its option to Co-Promote such IO Licensed Product in such country until on or after [***].

(b) Co-Commercialization. The Lead Commercialization Party and the Co-Promoting Party (through their respective Affiliates where appropriate) shall Co-Commercialize IO Licensed Products under the applicable Product Trademarks in each Co-Commercialization Country for which the Co-Promoting Party has exercised its Co-Promotion Option for such IO Licensed Product pursuant to Section 6.4(a) in accordance with the then-current and applicable Commercialization Plans. Each Party shall use, or shall cause its local Affiliates to use, Commercially Reasonable Efforts to Co-Commercialize each IO Licensed Product with respect to which the non-Lead Commercialization Party has exercised its Co-Promotion Rights in the applicable Co-Commercialization Countries, and carry out the activities assigned to it in the applicable Commercialization Plans. Each Party shall ensure that its Co-Commercialization activities conform to the parameters in the applicable approved Commercialization Plans.

(c) Decision to Discontinue Co-Commercialization. In the event that the Co-Promoting Party decides it no longer wishes to Co-Commercialize an IO Licensed Product in a particular Co-Commercialization Country in the Territory or that it does not wish to [***] for Co-Commercialization of such IO Licensed Product in any such Co-Commercialization Country in the Territory, and only if the Co-Promoting Party has Co-Commercialized such IO Licensed Product and [***] in such Co-Commercialization Country from the date it commences Co-Promoting such IO Licensed Product in such Co-Commercialization Country, the Co-Promoting Party may cease all Co-Commercialization activities with respect to such IO Licensed Product in such Co-Commercialization Country upon [***] prior written notice to the JCC, the applicable Country/Region Commercialization Committee and to the Lead Commercialization Party for such IO Licensed Product in such Co-Commercialization Country. Once the Co-Promoting Party exercises its right to cease Co-Commercializing a particular IO Licensed

Product in a Co-Commercialization Country, the Co-Promoting Party will cease to be a Co-Promoting Party with respect to such IO Licensed Product in such country, and such non-Lead Commercialization Party will not again be able to exercise its right pursuant to Section 6.4(a) to Co-Commercialize such IO Licensed Product in such country.

(d) Field Force Coordination. The JCC or the applicable Committee shall coordinate the Co-Promotion of each IO Licensed Product for which the non-Lead Commercialization Party exercises its Co-Promotion Rights by (i) the Lead Commercialization Party and its local Affiliates and their respective field forces, on the one hand, and (ii) the Co-Promoting Party and its local Affiliates and their respective field forces, on the other hand. The Parties will cooperate in the conduct of such activities with respect to scheduling, geographical allocation, and professional or other customer targeting in in accordance with the applicable Commercialization Plan(s). Without limiting the generality of the foregoing, in each Co-Commercialization Country the Parties will share and, to the extent appropriate, cooperate to implement consistent policies and procedures with respect to the manner in which details and other sales visits are conducted.

(e) FTE Efforts. Upon the exercise of its election pursuant to Section 6.4(a) to Co-Promote an IO Licensed Product in a country, the Co-Promoting Party will provide to the Lead Commercialization Party a binding notice of the FTE effort that the Co-Promoting Party commits to deliver in Co-Promoting such IO Licensed Product in such country during the first (1st) Contract Year for which the Co-Promoting Party exercised its right to Co-Promote (the "Co-Promote Commitment Level"). If the Co-Promoting Party elects to Co-Promote an IO Licensed Product in a country, in no event shall the Co-Promote Commitment Level be [***] of the total anticipated FTE effort by both Parties (taken together) in Co-Promoting such IO Licensed Product in such Co-Commercialization Country, unless otherwise agreed by the Parties. Such FTE effort shall be based upon the forecasted number and position of Details required to meet the market and sales forecasts for such IO Licensed Product in such Co-Commercialization Country in such Contract Year, and their conversion (by the JCC or applicable Country/Region Commercialization Committee) into the equivalent number of detailing FTEs according to applicable weighting factors, based upon the sales force and marketing practices in such Co-Commercialization Country. After the first (1st) Contract Year for which the Co-Promoting Party has exercised its right to Co-Promote an IO Licensed Product in a country, the Parties shall annually review and, if mutually agreed by the Parties, amend the Co-Promote Commitment Level for such IO Licensed Product in such country. In no event shall the Co-Promote Commitment Level in Co-Promoting such IO Licensed Product in such Co-Commercialization Country [***] of the anticipated total FTE effort by both Parties in Co-Promoting such IO Licensed Product in such Co-Commercialization Country or such other maximum percentage agreed by the Parties. The Co-Promoting Party's binding notice referred to above in this Section (e) shall be accompanied by a plan (which shall be developed by the Co-Promoting Party in cooperation with the Lead Commercialization Party and shall be intended to coordinate and integrate the Parties' respective FTE efforts and detailing activities) for ensuring that the Co-Promoting Party will have in place a field force of qualified sales representatives to satisfy the Co-Promote Commitment Level. In each Co-Commercialization Country, the non-Lead

Commercialization Party shall perform the anticipated total FTE effort above the Co-Promote Commitment Level.

(f) Training. The Parties will coordinate sales force training efforts in Co-Commercialization Countries and will share training materials (and conduct joint training, where appropriate) to facilitate joint sales force training efforts.

(g) Samples. With respect to IO Licensed Products for which the non-Lead Commercialization Party exercises its Co-Promotion Rights in the Co-Commercialization Countries, the Lead Commercialization Party shall provide the Co-Promoting Party with IO Licensed Product samples for use in such Co-Commercialization Countries as required in the applicable Commercialization Plan(s). The Lead Commercialization Party and, if applicable, the Co-Promoting Party (and each of their respective Affiliates) shall use samples strictly in accordance with the then-applicable approved Commercialization Plan(s) and shall store and distribute samples in compliance with applicable Laws. Each Party (and its local Affiliates) will maintain those records required by all applicable Laws and shall allow representatives of the other Party to inspect such records and storage facilities for the IO Licensed Product samples on request.

6.5 IO Licensed Product Pricing and Pricing Approvals in the Territory. Without limitation of the responsibility and authority of the Committees with respect to pricing matters as provided herein, [***]; provided that all such pricing decisions (including rebates or discounts) shall be made in a manner (a) intended to optimize the economic value of the IO Licensed Products in the applicable Territory, (b) consistent with the Collaboration Purpose and (c) in conformance with the applicable Marketing Guidelines. The Co-Promoting Party with respect to an IO Licensed Product shall have the right to [***]. Without limiting the foregoing, the non-Lead Commercialization Party in a country in the Territory shall have the right to [***].

6.6 Sales and IO Licensed Product Distribution in the Territory; Other Responsibilities.

(a) The Lead Commercialization Party (or its Affiliate) for an IO Licensed Product in a country in the Territory shall invoice and book, and appropriately record, all sales of such IO Licensed Product in such country. The Lead Commercialization Party (or its Affiliate) for an IO Licensed Product in a country in the Territory also shall be responsible for (i) the distribution of such IO Licensed Product in such country and for paying all governmental rebates which are due and owing with respect to such IO Licensed Product in such country, (ii) handling all returns of such IO Licensed Product sold under this Agreement in such country and (iii) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to such IO Licensed Product in such country.

(b) Sanofi, with respect to (i) all IO Licensed Products in the ROW Territory, (ii) the IO Licensed Products for which Sanofi is the Lead Commercialization Party in the U.S., and (iii) the IO Licensed Products for which Sanofi is the Co-Promoting Party in the U.S. (through its local Affiliates where appropriate), and Regeneron, with respect to (x) the IO Licensed Products for which Regeneron is the Lead Commercialization Party in the U.S. and (y)

the IO Licensed Products for which Regeneron is the Co-Promoting Party in the applicable Co-Commercialization Countries, shall each maintain records relating to their respective FTEs for such IO Licensed Products in the Field in such countries in a manner sufficient to permit the determination of Field Force Costs and Medical Non-Approval Costs and the incentive compensation requirements set forth in the applicable Marketing Guidelines.

6.7 Contract Sales Force. Each Party shall be entitled to engage a Contract Sales Force for up to [***] percent ([***]%) of such Party's sales force utilized for any IO Licensed Product to discharge its annual FTE effort with respect to Commercialization of such IO Licensed Product, provided that (a) in the event that a Co-Promoting Party discontinues Co-Commercialization of an IO Licensed Product in a particular Co-Commercialization Country in the Territory pursuant to Section 6.4(c), then the Lead Commercialization Party shall be entitled to engage a Contract Sales Force for more than [***] percent ([***]%) for such IO Licensed Product in such country; (b) that in the event that the Co-Promoting Party does not satisfy its Co-Promote Commitment Level with respect to any IO Licensed Product in any Co-Commercialization Country, then the Lead Commercialization Party shall be entitled to engage a Contract Sales Force for more than [***] percent ([***]%) for such IO Licensed Product in such Co-Commercialization Country. If a Party (or its local Affiliate) retains a Contract Sales Force, that Party (or its local Affiliate) will be responsible for (i) all costs and expenses associated with retaining such Contract Sales Force above approved Field Force Costs included in the applicable Country/Region Commercialization Budget for its sales force (except to the extent that a Contract Sales Force is maintained by the Lead Commercialization Party with respect to an IO Licensed Product in any Co-Commercialization Country because the Co-Promoting Party discontinues or fails to [***], in which event such costs and expenses shall [***], (ii) the Contract Sales Force's compliance with this Agreement, including, the training and monitoring of such Contract Sales Force and ensuring compliance with all applicable Laws, and (iii) ensuring that sales representatives in such Contract Sales Force have minimum skill levels customary for sales representatives in major pharmaceutical companies in such country in the relevant therapeutic area.

6.8 Promotional Materials .

(a) Except as provided in and subject to Section 6.8(b), (i) the Lead Commercialization Party with respect to an IO Licensed Product in the U.S. will be responsible, consistent with the U.S. Marketing Guidelines, the U.S. Commercialization Plan, and, if applicable, the Global Commercialization Plan for such IO Licensed Product, and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b)(vii), and (ii) Sanofi will be responsible, consistent with the ROW Marketing Guidelines, and the applicable ROW Commercialization Plan, Country/Region Commercialization Plan, and Global Commercialization Plan, and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b)(vii), in each case (i) and (ii), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the U.S. or the ROW Territory, as applicable, except where the non-Commercialization Party shall perform such responsibilities in a country in the Territory as the Lead Regulatory Party. Upon request, each Party will have the

right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by the other Party for use in the Territory.

(b) The Parties and their Affiliates shall only use the Promotional Materials and only conduct marketing and promotional activities for the IO Licensed Products which, in each case, are approved by the JCC or the applicable Country/Region Commercialization Committee if so delegated by the JCC for the applicable Major Market Country. The Lead Commercialization Party with respect to an IO Licensed Product for which the other Party has exercised its Co-Promotion Rights in a Co-Commercialization Country shall ensure that the Co-Promoting Party's sales representatives are provided with reasonable quantities of Promotional Materials for such IO Licensed Product for use in such Co-Commercialization Country consistent with the Co-Promote Commitment Level for such IO Licensed Product in accordance with the approved Commercialization Plan(s). All Promotional Materials generated for a Co-Commercialization Country shall be maintained in confidence and shall not be disclosed or distributed to Third Parties, until such time as they have been reviewed and approved as set forth in this Section.

(c) The Lead Commercialization Party with respect to an IO Licensed Product in a country in the Territory shall own all rights to all Promotional Materials with respect to such IO Licensed Product in such country, including all copyrights thereto.

6.9 Promotional Claims/Compliance. Neither Party nor any of its Affiliates shall make any medical or promotional claims for any IO Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any IO Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.

6.10 Restriction on Bundling in the Territory. If a Party or its Affiliates or Sublicensees sell an IO Licensed Product in the Field in its Territory to a customer who also purchases other products or services from any such entity, such Party agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any IO Licensed Product as part of any multiple product offering or discount or price the IO Licensed Products in a manner that (a) is reasonably likely to disadvantage an IO Licensed Product in order to benefit sales or prices of other products offered for sale by such Party or its Affiliates to such customer, (b) is inconsistent with the Collaboration Purpose or (c) would result in pricing and discounting inconsistent with the applicable Marketing Guidelines.

6.11 Inventory Management. The Lead Commercialization Party with respect to an IO Licensed Product in a country in the Territory shall use Commercially Reasonable Efforts to manage inventory of such IO Licensed Product on hand at wholesalers and Sublicensees in such country so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.12 Medical and Consumer Inquiries. The JCC shall establish guidelines to handle medical questions or inquiries from consumers relative to IO Licensed Products in the Territory.

6.13 Market Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize an IO Licensed Product in the Field in such country and (b) no generic equivalent of an IO Licensed Product in the Field may be marketed in such country.

6.14 Post Marketing Clinical Trials. Subject to the provisions of this Agreement, the Parties shall comply with any clinical trials obligations with respect to a Marketing Approval with respect to any IO Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

ARTICLE VII
CLINICAL AND REGULATORY AFFAIRS

7.1 Ownership of Approvals and Registration Filings.

(a) Unless otherwise agreed to by the Parties, which may be agreed on a country-by-country basis, the Post-POC Principal Party with respect to an IO Licensed Product shall be the Lead Regulatory Party with respect to such IO Licensed Product and shall [***]. If a Party does not have an Affiliate in a given country and such Party would otherwise be the Lead Regulatory Party for that country, then, at the request of such Party, the other Party may instead perform the functions of the Lead Regulatory Party for that country.

(b) The Lead Regulatory Party shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available [***] to and for the benefit of the other Party.

(c) The non-Lead Regulatory Party shall provide such assistance with respect to regulatory matters as is reasonably requested by the Lead Regulatory Party and consistent with the terms of this Agreement.

7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate applicable regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to each IO Licensed Product in the Field in each jurisdiction as to which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this ARTICLE VII. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially

Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for each IO Licensed Product in the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.

(b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture or Commercialization of the IO Licensed Products in the Field in the Territory, including, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities and (ii) to comply with Laws in connection with the Development, Manufacture or Commercialization of the IO Licensed Products in the Field anywhere in the Territory. The Parties shall provide to each other prompt written notice of any Approval of an IO Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and regulatory filings for IO Licensed Products in the Field in the Territory.

(c) The Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities pertaining to the Development or Commercialization of an IO Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including, all annual and periodic safety reports for IO Licensed Products in the Field), and consistent with applicable Laws, to have up to two (2) representatives from the other Party attend and actively participate in all material, pre-scheduled meetings, telephone conferences or discussions with Regulatory Authorities to the extent such material meetings, telephone conferences or discussions pertain to the Development or Commercialization of any IO Licensed Product in the Field. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

(d) For each IO Licensed Product, the JDC shall develop and the IOSC shall approve proposed target IO Licensed Product labeling ("Target Labeling") for use in the Territory.

7.3 Regulatory Events. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified

below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority, that:

(a) raises any material concerns regarding the safety or efficacy of any IO Licensed Product in the Field;

(b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of an IO Licensed Product in the Field under the Plans; provided, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or

(c) is reasonably likely to lead to a recall or market withdrawal of any IO Licensed Product in the Field anywhere in the Territory.

Information that shall be disclosed pursuant to this Section 7.3 shall include, but not be limited to the following matters with respect to IO Licensed Products:

(i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;

(ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the extent involving matters described in clauses (a), (b) or (c) of this Section 7.3;

(iii) receipt of a warning letter issued by a Regulatory Authority;

(iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and

(v) receipt of product complaints concerning actual or suspected IO Licensed Product tampering, contamination, or mix-up (e.g., wrong ingredients).

7.4 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning pharmacovigilance and risk management plans and product complaint reporting in all countries in which any IO Licensed Product is being developed, manufactured, or commercialized anywhere in the Territory. Without limitation to the foregoing, the Parties shall execute a Safety Data Exchange Agreement setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse events/adverse drug reactions and IO Licensed Product

complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.

7.5 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to an IO Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of an IO Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the IO Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of IO Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection, to the extent that its receipt of notification from the Regulatory Authority so permits.

7.6 Recalls and Other Corrective Actions . Decisions with respect to any recall, market withdrawal or other corrective action related to any IO Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld, conditioned or delayed; provided, that nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of an IO Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

ARTICLE VIII
MANUFACTURING AND SUPPLY

8.1 Manufacture and Supply of Clinical Supply Requirements of Formulated Bulk Product. Until such time as Commercial Supply Requirements are being Manufactured, Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements of IO Licensed Products in the

Field in the Territory in accordance with the Manufacturing Plan. Regeneron may [***]. If an entity other than Regeneron is to be used to Manufacture Formulated Bulk Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to Manufacture the applicable IO Licensed Product in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Party Manufacturers. The Formulated Bulk Product Manufactured by or on behalf of Regeneron for Clinical Supply Requirements will be included in Development Costs or Shared Commercial Expenses, if and as applicable in accordance with this Agreement, at the Manufacturing Cost calculated in accordance with Part I of Schedule 1. To the extent that Regeneron maintains manufacturing capacity available for the Manufacture of Clinical Supply Requirements, the costs and expenses of maintaining such capacity shall be included as a Development Cost to the extent it is not included as a Manufacturing Cost. For the avoidance of doubt, nothing in this Section 8.1 shall require Regeneron to expand its manufacturing capacity or use any manufacturing capacity acquired or constructed by Regeneron in the future to satisfy its obligations under this Section 8.1. [***], Sanofi shall, upon completion of the process transfer, make capacity at this facility available to provide Formulated Bulk Product for Phase III Trials of IO Licensed Products on Regeneron's behalf as set forth in the Manufacturing Plan in the event that the requirements for Formulated Bulk Product for Phase III Trials exceed Regeneron's capacity at its Manufacturing facilities.

8.2 Finished Product Supply of Clinical Supply Requirements. Regeneron will timely identify, and enter into an agreement with, a Third Party or Third Parties or Sanofi (or use its own facilities, if Regeneron has such capabilities) to perform the filling, packaging, labeling and testing of the Formulated Bulk Product and supply Finished Product for Clinical Supply Requirements for IO Licensed Products for use under this Agreement. If an entity other than Regeneron is to be used to perform filling, packaging, labeling or testing services related to Finished Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to perform such services in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Parties. Such Finished Product for Clinical Supply Requirements Manufactured on behalf of Regeneron will be included in Development Costs or Shared Commercial Expenses, if and as applicable in accordance with this Agreement at the Manufacturing Cost calculated in accordance with Part I of Schedule 1.

8.3 Manufacture and Supply of Commercial Supply Requirements.

(a) The Parties, through the JMC and IOSC, will determine whether a Party, or a Third Party on behalf of a Party, will be responsible for Manufacturing and supplying Commercial Supply Requirements of Formulated Bulk Product or Finished Product for each IO Licensed Product for use under this Agreement. The JMC shall use all reasonable efforts to make such determination no later than [***] prior to the Anticipated First Commercial Sale of each IO Licensed Product. [***]. Such a notice (a "Manufacturing Notice") shall be irrevocable and shall be treated as a firm commitment to supply such Formulated Bulk Product or Finished Product, as the case may be. Preference will be given to having a Party or both Parties, rather than Third Parties, Manufacture and supply Commercial Supply Requirements [***]. If both

Parties desire to Manufacture and supply such Commercial Supply Requirements, [***]. If one Party desires to Manufacture and supply [***]. If the Parties cannot agree on terms under which either or both Parties will Manufacture and supply Commercial Supply Requirements of an IO Licensed Product, the JMC shall arrange for a Third Party to Manufacture and supply such Commercial Supply Requirements.

(b) Once Manufacture of Commercial Supply Requirements of an IO Licensed Product begins, or is scheduled to begin, Manufacture of Clinical Supply Requirements of such IO Licensed Product shall be coordinated with Manufacture of Commercial Supply Requirements of such IO Licensed Product. Formulated Bulk Product and Finished Product Manufactured by or on behalf of a Party for Commercial Supply Requirements, and for Clinical Supply Requirements that are Manufactured in coordination with the Commercial Supply Requirements, will be billed at the Manufacturing Cost described in Part II of Schedule 1 as a Commercial Supply Cost and Clinical Supply Cost, respectively. If a Party has commercial scale capacity available in anticipation of beginning to Manufacture Commercial Supply Requirements, the JMC shall decide if such Party shall Manufacture any Clinical Supply Requirements even before it begins to Manufacture Commercial Supply Requirements.

(c) Any Third Party manufacturer of Commercial Supply Requirements or Clinical Supply Requirements will be required to enter into a separate confidentiality agreement with Regeneron prior to the transfer of the Manufacturing operations from Regeneron to such Third Party. All of Regeneron's costs and expenses associated with the transfer of the Manufacturing operations and related Know-How to the Third Party manufacturer (or Sanofi, to the extent that Sanofi Manufactures all or part of the Commercial Supply Requirements or Clinical Supply Requirements) will be billed as a Development Cost.

8.4 Supply Agreement. The Parties shall timely enter into one or more clinical supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements, which shall contain terms consistent with this Agreement. At least [***] of an IO Licensed Product, the Parties shall enter into separate commercial supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements and Commercial Supply Requirements after the First Commercial Sale, which shall contain terms consistent with this Agreement. Each supply agreement will include as an annex thereto a customary quality agreement containing terms and conditions regarding quality assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

8.5 Process Development and Manufacturing Plans. The Parties, through the JMC, will develop and amend as necessary, for each IO Licensed Product, a Manufacturing Plan. The JMC shall be responsible for deciding on process and technology selection, on process improvements and all related process development activities which impact Manufacturing. The JMC shall also be responsible for all decisions relating to Manufacturing Formulated Bulk Product for Clinical Supply Requirements of IO Licensed Products. Each Manufacturing Plan shall set forth the supply requirements of an IO Licensed Product over an ensuing period of

[***]. The Manufacturing Plan will include arrangements for the Manufacture of back-up Formulated Bulk Product for IO Licensed Product requirements at a Party or a Third Party back-up Manufacturing facility. The Manufacturing Plan (including each annual amendment thereto) shall be prepared by the JMC and approved by the IOSC at least two (2) months prior to the end of the then current Contract Year, except that the initial Manufacturing Plan covering at least initial expected Clinical Supply Requirements for an IO Licensed Product, to the extent not included in the Post-POC Development Plan, shall be approved by the IOSC within the initial Global Development Plan. The Parties shall design Manufacturing Plans to ensure an adequate supply of IO Licensed Product and shall use Commercially Reasonable Efforts to perform their responsibilities in accordance with the approved Manufacturing Plans.

8.6 Manufacturing Shortfall. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not, despite its using Commercially Reasonable Efforts, be able to supply the agreed upon demand forecast for the IO Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JMC and IOSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of IO Licensed Product (including the other Party) should be utilized.

8.7 Manufacturing Compliance. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this ARTICLE VIII or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the IO Licensed Products supplied under this Agreement or (b) the regulatory status of the IO Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party's facilities involved in the Manufacture of IO Licensed Products in the Field pursuant to this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Sanofi, if applicable) involved in the Manufacture of IO Licensed Products for use in the Field under this Agreement.

8.8 Amendments to the Existing License and Collaboration Agreement. To the extent that ARTICLE VIII of the Existing License and Collaboration Agreement is amended after the Execution Date, the Parties shall discuss in good faith whether any corresponding changes shall be made to ARTICLE VIII of this Agreement.

ARTICLE IX
PERIODIC REPORTS; PAYMENTS

9.1 Upfront Payment. Within ten (10) Business Days of Sanofi's receipt of an invoice from Regeneron (which invoice may be delivered electronically) following the

Execution Date, Sanofi shall pay to Regeneron a non-refundable, non-creditable amount of three hundred and seventy five million Dollars ($375,000,000).

9.2 Development Costs.

(a) IO Licensed Products for which Sanofi is the Post-POC Principal Party. Sanofi shall be responsible for paying one hundred percent (100%) of the total Development Costs for IO Licensed Products for which Sanofi is the Post-POC Principal Party, whether incurred by or on behalf of Sanofi, Regeneron or their respective Affiliates (provided that such Development Costs are incurred in accordance with the applicable Global Development Budget), and fifty percent (50%) of such expenses shall count as IO Development Balance Costs and be included in the IO Development Balance. Any such Development Costs incurred by or on behalf of Regeneron shall be added to the Development Cost True-Up. For clarity, no such Development Costs incurred by either Party shall be treated as Other Shared Expenses.

(b) IO Licensed Products for which Regeneron is the Post-POC Principal Party. The Parties shall share equally (50%/50%) in the total Development Costs for IO Licensed Products for which Regeneron is the Post-POC Principal Party (including, for clarity, REGN2810 and any other PD-1 Licensed Products), whether incurred by or on behalf of Sanofi, Regeneron or their respective Affiliates, and any such Development Costs shall be counted toward the Development Cost True-Up as set forth in Schedule 2; provided that none of such Development Costs shall count as IO Development Balance Costs or be included in the IO Development Balance. Unless otherwise agreed to by the Parties, the aggregate amount of all shared Development Costs with respect to an IO Licensed Product shall not exceed, at any time, the aggregate Global Development Budget for such IO Licensed Product.

(c) Non-IO Indication Expenses Prior to Opt-In. If, with respect to any Product Candidate under the IO Discovery Agreement for which Sanofi has exercised its Opt-In Rights pursuant to Article 5 of the IO Discovery Agreement, (i) Regeneron has incurred development costs and expenses (solely to the extent such costs and expenses are not reimbursed under the Existing Agreements) in respect of any Non-IO Indication for such Product Candidate, and (ii) [***], then, in either case (A) or (B), [***] of the development costs and expenses incurred by Regeneron in respect of such Non-IO Indication for such IO Licensed Product shall be added to the Development Cost True-Up in the Quarter in which the earlier of (1) and (2) occurs: [***]. [***] of such development costs and expenses incurred by Regeneron in respect of such Non-IO Indication expenses shall be included in the IO Development Balance (provided that, for clarity, none of such Non-IO Indication development costs or expenses referred to in clause (i) above shall count against any Global Development Budget hereunder or the “IO Discovery Budget” or “Tail Period Budget” under the IO Discovery Agreement).

(d) Additional Trial Costs. If and only if [***], then the applicable percentage (as determined pursuant to the last sentence of this Section 9.2(d)) of the Additional Trial Costs incurred directly in connection with the conduct of such Additional Trial shall be included in the Development Cost True-Up for the Post-POC Other Party in the Quarter in which the earlier of (A) and (B) occurs: [***]. The percentage of Additional Trial Costs shall be added to or subtracted from the Development Cost True-Up as follows: (x) if Regeneron is the Post-

POC Other Party, then an amount equal to [***] of the Additional Trial Costs shall be added to the Development Cost True-Up, and [***] of the Additional Trial Costs shall be added to the IO Development Balance (but, for clarity, no portion of such Additional Trial Costs shall be included in any Global Development Budget), and (y) if Sanofi is the Post-POC Other Party, then an amount equal to [***] of the Additional Trial Costs shall be subtracted from the Development Cost True-Up, and [***].

(e) Research Expenses. The Parties acknowledge that payments made by a Party pursuant to this Section 9.2 are being made as research and development expenses, as defined in Section 41 of the U.S. Internal Revenue Code.

9.3 PD-1 Milestone Payment. In addition to the other payments contemplated herein, Sanofi shall pay to Regeneron a one-time non-refundable, non-creditable milestone payment in the amount of three hundred and seventy five million Dollars ($375,000,000) (the "PD-1 Milestone Payment") in the event that, in any consecutive twelve- (12-) month period during the Term, PD-1 Sales are greater than or equal to two billion Dollars ($2,000,000,000) (the "PD-1 Milestone"). After the achievement of such PD-1 Milestone, Sanofi shall have ten (10) Business Days from the date of electronic receipt of an invoice therefor from Regeneron to pay the amount of the PD-1 Milestone Payment to Regeneron. For purposes of clarification, the PD-1 Milestone Payment shall be made only once and only upon the first (1st) occurrence of the PD-1 Milestone, and no amounts shall be due for subsequent or repeated achievements of such PD-1 Milestone in subsequent consecutive twelve- (12-) month periods. "PD-1 Sales" shall mean the sum of (a) aggregate Net Sales of all PD-1 Licensed Products in the Territory in any consecutive twelve- (12-) month period, plus (b) aggregate Net Sales of all Non-PD-1 Licensed Product that are sold for use in combination with any PD-1 Licensed Product in such consecutive twelve- (12-) month period. Notwithstanding anything in this Agreement to the contrary, if the payment due under this Section 9.3 becomes subject to withholding or similar tax that Sanofi would be required by Law to withhold or pay on behalf of Regeneron because of any assignment of this Agreement to an Affiliate of Sanofi, then Sanofi shall pay to Regeneron such additional amounts under this Section 9.3 so that Regeneron will receive three hundred and seventy five million Dollars ($375,000,000) net of any withholding or similar taxes.

9.4 Royalties. Any royalty amounts payable pursuant to Section 2.6(c) of this Agreement shall be paid to Sanofi for the period of time, as determined on a Special Termination Product-by-Special Termination Product and country-by-country basis, commencing on the first (1st) commercial sale of such Special Termination Product (or the effective date of the applicable termination, if later) and [***] (the "Royalty Term"). During the Royalty Term, Regeneron shall deliver to Sanofi with each royalty payment a report detailing in reasonable detail the information necessary to calculate the royalty payments due under this Section 9.4 for such Quarter, including the following information, specified on an Special Termination Product-by-Special Termination Product and country-by-country basis: (a) total gross invoiced amount from sales of each such Special Termination Product by Regeneron, its Affiliates and Sublicensees; (b) all relevant deductions from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable.

9.5 Sharing of Profits from IO Licensed Products. Commencing on the Effective Date and continuing during the Term, the Parties shall share the Profit Split as described in Schedule 2.

9.6 Periodic Reports. Sanofi and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Sections 5.3(b) and 5.4(e);

(b) Within five (5) days following the end of each month, commencing with the month in which First Commercial Sale occurs, each Party shall deliver electronically to the other Party a monthly detailed Net Sales report with monthly and year-to-date sales for each IO Licensed Product in the Field in the Territory by country in Dollars;

(c) Within twenty (20) days following the end of each Quarter, commencing with the Quarter in which First Commercial Sale occurs, each Party shall deliver electronically to the other Party a written report setting forth, on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each IO Licensed Product in local currency and in Dollars, (ii) IO Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross IO Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales;

(d) Within twenty (20) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses or Shared Commercial Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses or Shared Commercial Expenses incurred by such Party in such Quarter on a country-by-country and IO Licensed Product-by-IO Licensed Product basis, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;

(e) Within forty-five (45) days after the end of each Quarter, commencing with the Quarter in which the First Commercial Sale in a Reporting Country/Region occurs (or such earlier agreed upon Quarter, if appropriate), (i) with respect to each IO Licensed Product in the U.S., the Lead Commercialization Party for such IO Licensed Product shall provide to the other Party, (ii) with respect to each IO Licensed Product in each Reporting Country/Region in the ROW Territory, Sanofi shall provide to Regeneron, and (iii) with respect to each IO Licensed Product for each Co-Commercialization Country, the Co-Promoting Party with respect to such IO Licensed Product in such country shall provide to the Lead Commercialization Party for such IO Licensed Product in such country, in each case (i)-(iii) (inclusive), in electronic form, a report summarizing in reasonable detail the marketing, detailing, selling and promotional activities undertaken by such Party (or its Affiliates) during the previous Quarter in such Reporting Country/Region or Co-Commercialization Country; and

(f) Within sixty (60) days following the end of each Quarter, each Party shall deliver electronically to the other Party a Consolidated Payment Report in respect of

such Quarter, combining the information reported by each Party pursuant to this ARTICLE IX and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by this Section 9.6 (including showing the calculation of the Profit Split) and, if applicable, providing for the netting of such payments. In the event there is any dispute relating to a Consolidated Payment Report of a Party for a Quarter, such matter shall be submitted to the JFC for resolution. In the event that no resolution is reached by the JFC, the matter shall be escalated to the IOSC in accordance with Section 3.11(a) and, if necessary, to the Executive Officers in accordance with Section 3.11(c) and the Expert Panel in accordance with Section 10.4.

(g) All reports referred to in this Section 9.6 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JFC, the financial data in the reports will include calculations in local currency and Dollars.

9.7 Funds Flow. The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Sanofi is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report of each Party for a Quarter, it shall, subject to Section 9.14, make such payment to Regeneron within fifteen (15) days after the exchange between the Parties of their respective Consolidated Payment Reports pursuant to Section 9.6. If Regeneron is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report of each Party for a Quarter, it shall, subject to Section 9.14, make such payment to Sanofi within fifteen (15) days after the exchange between the Parties of their respective Consolidated Payment Reports pursuant to Section 9.6. For the avoidance of doubt, any cost or expense paid or reimbursed under this Agreement, the IO Discovery Agreement or the Existing Agreements shall be paid or reimbursed only once so as to avoid any “double counting,” regardless of whether such cost or expense is reflected in more than one plan or budget under this Agreement, the IO Discovery Agreement or the Existing Agreements.

9.8 Invoices and Documentation. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder. All payments otherwise due and owing under this Agreement shall be supported by, and, if any such payment is due hereunder within a specified time period, such specified time period shall not start running until receipt by the owing Party of, an invoice delivered (whether electronically or physically) to the Party owing such amount, except as provided in Section 9.1, in such form approved by the JFC.

9.9 Budgets and Forecasts. With respect to each plan delivered hereunder, the Party delivering such plan shall include a budget as part of such plan and such budget (and associated non-binding two (2) year budget forecast included in the applicable related plan), including each Global Development Budget, Global Commercialization Budget, U.S. Commercialization Budget, ROW Commercialization Budget, and Country/Region Commercialization Budget shall include a break-out of the expenditures by Quarter for the initial Contract Year of such budget and on an annual basis for the next two (2) Contract Years. By no

later than April 30 of each Contract Year, each Party will provide the other Party with a good faith estimate of a re-forecast of the projected expenditures, by Quarter, for the remaining portion of the initial Contract Year for each such budget.

9.10 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in Dollars. In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, such amounts shall be converted to Dollars using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into Dollars, using the spot rates (the "Mid Price Close" found on Thomson Reuters Eikon, or any other source as agreed to by the Parties) from the last Business Day of the month of the period to which the payment relates.

9.11 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to one month London Inter-Bank Offering Rate (LIBOR) Dollars, as quoted on Thomson Reuters Eikon (or any other source agreed to by the Parties) effective for the date on which the payment was due, [***] (such sum being referred to as the "Default Interest Rate").

9.12 Taxes. Except as set forth in Section 9.3, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party with respect to any payments to such other Party hereunder shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided that the withholding Party shall furnish the other Party with proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on the other Party's behalf the benefit of any available treaty on the avoidance of double taxation that applies to any payments hereunder to such other Party.

9.13 Adjustments to FTE Rates. Notwithstanding anything herein to the contrary, upon the request of either Party, the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Field Force FTE Rate, the Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.

9.14 Right to Offset Payments. Subject to Section 9.12, each Party shall have the right to offset any amount owed by the other Party to such first Party under or in connection with this Agreement [***], including pursuant to this ARTICLE IX or in connection with any breach against any payments owed by such first Party to such other Party under this Agreement; provided, however, that no such offset shall be permitted to the extent and for so long as such other Party is contesting in good faith its obligation to make any such payment to such first Party under the applicable dispute resolution procedures of this Agreement [***]. Such offsets shall be in addition to any other rights or remedies available under this Agreement and applicable Law.

9.15 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this ARTICLE IX, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be escalated to the IOSC in accordance with Section 3.11(a) and, if necessary, to the Executive Officers in accordance with Section 3.11(c) and the Expert Panel in accordance with Section 10.4. Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

ARTICLE X
DISPUTE RESOLUTION

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Resolution of Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in ARTICLE III ("Governance Disputes") shall be resolved pursuant to ARTICLE III and, to the extent such matters constitute an Expert Panel Dispute, Section 10.4, except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply.

10.3 Resolution of Legal Disputes. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts to resolve any Legal Dispute arising under this Agreement by good faith negotiation and discussion. In the event that the IOSC is unable to resolve any such Legal Dispute within the first (1st) ten (10) Business Day period set forth in Section 3.11(b), either Party may submit in writing the Legal Dispute to the Executive Officers for resolution, specifying the nature of the Legal Dispute with sufficient specificity to permit

adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred Legal Dispute within the thirty (30) day period set forth in Section 3.11(b). Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve any such Legal Dispute, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and the last sentence of Section 20.16(c).

10.4 Resolution of Expert Panel Disputes.

(a) The Parties shall use all reasonable efforts to resolve any Expert Panel Dispute arising under this Agreement by good faith negotiation and discussion. In the event that the Parties are unable to resolve any such Expert Panel Dispute within the ten (10) Business Day period set forth in Section 3.11(b), either Party may submit in writing the Expert Panel to the Executive Officers for resolution, specifying the nature of the Expert Panel Dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred Expert Panel Dispute within a ten (10) Business Day period. Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve any such Expert Panel Dispute, the Parties shall refer such Expert Panel Dispute to an Expert Panel for resolution in accordance with Section 10.4(b). Notwithstanding the foregoing sentence or Section 10.4(b), if such Expert Panel Dispute is a [***].

(b) Expert Panel for Expert Panel Disputes.

(i) In the event of any Expert Panel Dispute that cannot be resolved by the Executive Officers pursuant to Section 10.4(a) (other than a Legal Dispute), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4(b). Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position.

(ii) Within fifteen (15) Business Days of such notice, each Party shall appoint to the Expert Panel an individual who (A) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue, (B) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (C) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (A) through (C) above, disclosing any potential conflict or bias and

certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.

(iii) Within fifteen (15) Business Days of the appointment of the second (2nd) expert, the two (2) appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third (3rd) expert, then upon the written request of either Party, each Party-appointed expert shall, within five (5) Business Days of such request, nominate one expert candidate and the American Arbitration Association shall, within five (5) Business Days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.

(iv) With respect to any Budget Dispute, within ten (10) Business Days of the appointment of the third (3rd) expert, each Party shall submit to the Expert Panel in writing its proposed version of the Disputed Budget. The specific issue that shall be submitted to the Expert Panel shall be limited to [***]. In connection with reaching its decision, the Expert Panel may order the Parties to produce any documents or other information that are relevant to the Expert Panel's decision. The Expert Panel shall select from the Parties' proposed budgets the one that is [***], and shall not have authority to render any substantive decision other than to so select the proposed budget of either Regeneron or Sanofi. The budget selected by the Expert Panel shall be the final budget and binding on the Parties unless and until such budget is later amended in accordance with this Agreement. Such decision shall be rendered by the Expert Panel no later than ten (10) Business Days after receipt by the Expert Panel of the Parties' respective proposed budgets; provided, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

(v) With respect to any Financial Dispute, within seven (7) days of the appointment of the third (3rd) expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or information that are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the

hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third (3rd) expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution. In rendering the final decision, which shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions, the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

(vi) With respect to any matter submitted to the Expert Panel pursuant to clause (iv) or (v) above, the Expert Panel's ruling shall be final and binding upon the Parties and may be entered and enforced in any court having jurisdiction. Each Party shall bear its own costs and expenses incurred in connection with any arbitration conducted pursuant to this Section 10.4(b), except that the costs and expenses of any Expert Panel shall be borne equally (50%/50%) by the Parties. The Parties shall use diligent efforts to cause the completion of any such arbitration within forty-five (45) Business Days following a request by any Party for such arbitration. Except as provided in this Section 10.4(b), any arbitration conducted pursuant to this Section 10.4 shall be conducted in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association.

10.5 No Waiver. Nothing in this ARTICLE X or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

ARTICLE XI
TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. For each IO Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory, unless such

Product Trademark is prohibited by Law in any country in the Territory or the JCC determines that, consistent with the Collaboration Purpose, a different Product Trademark should be used in one or more particular countries or Regions to maximize the commercial potential of such IO Licensed Product; provided, that the Parties and the JCC shall endeavor in good faith to reach agreement on a single Product Trademark for use in the entire Territory. Once a Product Trademark has been selected by the JCC, the Parties shall enter into an agreement or, in the alternative, shall amend this Agreement as the Parties may agree, in order to address the Parties' respective rights and obligations with respect to such Product Trademark. Each IO Licensed Product in the Field shall be promoted and sold in the Territory under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, (a) the Lead Commercialization Party with respect to an IO Licensed Product in a country in the Territory(or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s) for such IO Licensed Products, together with all associated domain names and all goodwill related thereto in such country.

11.4 Prosecution and Maintenance of Product Trademark(s). The Lead Commercialization Party with respect to an IO Licensed Product in a country in the Territory will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) for such IO Licensed Products in such country. Notwithstanding the foregoing, in the event the Lead Commercialization Party elects not to prosecute or maintain any such Product Trademark(s) in any such country in the Territory, the Lead Commercialization Party shall provide reasonable prior written notice to the other Party of its intention not to prosecute or maintain any such Product Trademark in such country in the Territory, and the other Party shall have the right to do so on behalf of the Lead Commercialization Party for use with such IO Licensed Product, subject to consultation and cooperation with the Lead Commercialization Party. All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of Product Trademarks as provided in this Section 11.4 shall be shared by the Parties as part of Shared Commercial Expenses.

11.5 License to the Product Trademark(s). The Lead Commercialization Party with respect to an IO Licensed Product in a country in the Territory hereby grants to the other Party a co-exclusive license (non-exclusive only with respect to such other Party) to use the Product Trademark(s) for such IO Licensed Products solely for the purposes of the other Party's Development, Manufacturing, and, if applicable, Co-Promotion of such IO Licensed Products in such country, or other Commercialization activities with respect to such IO Licensed Products if such activities are agreed to by the Lead Commercialization Party or set forth in any Plans, subject to the terms and conditions of this Agreement. Consistent with Section 4.4 of this Agreement, neither Party shall license (or, as applicable, sublicense) rights to use, or otherwise transfer ownership of the Product Trademark(s) without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Each Party shall only utilize the Product Trademark(s) on approved Promotional Materials, on the IO Licensed Products as needed and on or other approved product-related materials for the IO Licensed

Products in the Field in the Territory for the purposes contemplated herein, and all use by a Party or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC that are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) in relation to a product that is an IO Licensed Product, or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5.

11.6 Use of Corporate Names. The Lead Commercialization Party (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include the non-Lead Commercialization Party's name with equal prominence on materials related to each IO Licensed Product in the Field (including, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such IO Licensed Product), unless to do so would be prohibited under applicable Laws; provided, in the case of multi-product materials that refer to an IO Licensed Product in the Field as well as other pharmaceutical products, the prominence of the non-Lead Commercialization Party's name shall be commensurate with the relative prominence of the IO Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable IO Licensed Product in the Field in the Territory during the Term and thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples, only for the time period and solely to the extent necessary to exhaust the existing inventory of IO Licensed Product (including packaging materials for such IO Licensed Product) and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld, conditioned or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

ARTICLE XII
NEWLY CREATED INVENTIONS AND KNOW-HOW

12.1 Ownership of Newly Created Intellectual Property.

(a) Each Party (and each Party's respective Affiliates) shall exclusively own all right, title and interest in and to any and all intellectual property (including, Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement Collaboration solely by such Party, its Affiliates or its or their Sublicensees (other than by the other Party or its Affiliates) ("Sole Inventions"). Sole

Inventions made solely by or on behalf of Sanofi, its Affiliates, or its or their Sublicensees (or than by Regeneron or its Affiliates) are referred to herein as "Sanofi Sole Inventions". Sole Inventions made solely by or on behalf of Regeneron, its Affiliates or its or their Sublicensees are referred to herein as "Regeneron Sole Inventions". The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's intellectual property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder. Any remuneration payable under applicable Law to an inventor and costs and expenses associated with determining such remuneration shall be treated as Other Shared Expenses.

(b) The Parties shall each own an equal, undivided half interest in any and all intellectual property (including, Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement during the Term jointly by or on behalf of Sanofi, its Affiliates or its or their Sublicensees, on the one hand, and Regeneron, its Affiliates or its or their Sublicensees, on the other hand ("Joint Inventions"). Each Party shall disclose to the other Party in writing and shall cause its Affiliates, and its and their Sublicensees to so disclose, the conception, discovery, invention or reduction to practice of any Joint Invention.

(c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party shall, and hereby does, irrevocably assign, and shall cause its Affiliates and its and their Sublicensees to assign, to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) Subject to the other terms and conditions of this Agreement (other than Section 12.1(a)), to the extent permitted under any relevant Third Party agreement, each Party agrees that all Know-How, other than Excluded Know-How Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the Effective Date directly in connection with the performance of the research and clinical activities approved by the IOSC, in each case, as included in the Global Development Plans shall be Joint Inventions. Each Party agrees to execute all necessary documentation to reflect the foregoing. As used above, the term "Excluded

Know-How Rights" shall mean any Know-How claiming or covering composition (including any formulation) of an IO Licensed Product, including, for the avoidance of doubt, any manufacturing or cell line related intellectual property. For further clarity, nothing in this Section 12.1(e) shall be construed to grant either Party any rights to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities and development activities approved by the IOSC, in each case, as included in Global Development Plans.

(f) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement, including the terms of ARTICLE IV, shall be governed as follows: each Party's interest in the Joint Inventions may be licensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement), and if such consent is required by operation of law, such consent is hereby granted; provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in ARTICLE IV, provided that each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 12.1(f) and the other terms of this Agreement that relate to the Joint Inventions; provided further that nothing in this ARTICLE XII shall relieve a Party or its Affiliates of their obligations under ARTICLE XVI with respect to New Information or confidential Party Information provided by or on behalf of the other Party or such other Party's Affiliates. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. The provisions governing Joint Inventions set forth in this Section 12.1(f) shall survive the expiration or termination of this Agreement.

12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Regeneron Patent Rights in the countries and regions in the Territory as determined in accordance with clause (ii) of this Section 12.2(a). Regeneron shall undertake such activities [***]. Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Regeneron Patent Rights: (i) Regeneron shall use Commercially Reasonable Efforts to provide to Sanofi for review and comment a substantially completed draft of any priority Patent application in the Territory at least thirty (30) days prior to the filing of any such priority Patent application by Regeneron and incorporate any reasonable comment from Sanofi within such thirty (30) day period unless

Regeneron reasonably believes that such comments will adversely affect the Patent application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Regeneron [***]; (iii) Regeneron shall provide Sanofi promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; and (iv) Regeneron shall consult with Sanofi a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Regeneron Patents in the Field (including substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent application, abandoning any Patent or not filing or perfecting the filing of any Patent application in any country). In the event that Regeneron desires to abandon any Regeneron Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Sanofi of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent Right with the applicable patent office) and Sanofi shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof, in Regeneron's name or Sanofi's name at Sanofi's sole discretion, unless, with respect to any such Patent applications that are unpublished, Regeneron notifies Sanofi that Regeneron would prefer to maintain the subject matter of such Patent application as a trade secret and Sanofi agrees in writing.

(b) Sanofi shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Sanofi Patent Rights in the countries and regions in the Territory as determined in accordance with clause (ii) of this Section 12.2(b). Sanofi shall undertake such activities [***]. Sanofi shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Sanofi shall have the following obligations with respect to the filing, prosecution and maintenance of Sanofi Patent Rights: (i) Sanofi shall use Commercially Reasonable Efforts to provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent application in the Territory at least thirty (30) days prior to the filing of any such priority Patent application by Sanofi and incorporate any reasonable comment from Regeneron unless Sanofi reasonably believes that such comments will adversely affect the Patent application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Sanofi shall [***]; (iii) Sanofi shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; and (iv) Sanofi shall consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Sanofi Patent Rights in the Field (including substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent application, abandoning any Patent or not filing or perfecting the filing of any Patent application in any country). In the event that Sanofi desires to abandon any Patent included in the Sanofi Patent Rights in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Sanofi Patent Right with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Sanofi's name, unless, with respect to any such Patent

applications that are unpublished, Sanofi notifies Regeneron that Sanofi would prefer to maintain the subject matter of such Patent application as a trade secret and Regeneron agrees in writing.

(c) The Parties shall consult with each other regarding the filing, prosecution and maintenance of any Joint Patent Rights, and responsibility for such activities shall be the obligation of the Prosecuting Party. The Prosecuting Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners [***]. The Prosecuting Party shall have the following obligations with respect to the filing, prosecution and maintenance of the Joint Patent Rights: (i) the Prosecuting Party shall use Commercially Reasonable Efforts to provide the non-Prosecuting Party with notice and a copy of a substantially completed draft of any priority Patent application at least thirty (30) days prior to the filing of any such priority Patent application by the Prosecuting Party and incorporate any reasonable comment provided by the non-Prosecuting Party within such thirty (30) day period (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) the Prosecuting Party shall notify the non-Prosecuting Party prior to the filing of a Patent application by the Prosecuting Party; (iii) the Prosecuting Party [***]; (iv) the Prosecuting Party shall provide the non-Prosecuting Party promptly with copies of all material communications received from or filed in patent offices with respect to such filings and the Parties shall use all reasonable efforts to reach agreement in a timely manner with respect to all material responses and amendments; and (v) the Prosecuting Party shall provide the non-Prosecuting Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Joint Patent Rights, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office (including substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent application, abandoning any Joint Patent Right or not filing or perfecting the filing of any Patent application in any country), with notice of such proposed action or inaction so that the non-Prosecuting Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Prosecuting Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Prosecuting Party to the Prosecuting Party describing such breach, or in the event that the Prosecuting Party fails to undertake the filing of a Patent application within the earlier of (i) ninety (90) days of a written request by the non-Prosecuting Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Prosecuting Party may assume the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Prosecuting Party for purposes hereof (and will undertake such filing, prosecutions and maintenance in such Party's name). Notwithstanding the foregoing, the Prosecuting Party may withdraw from or abandon any Joint Patent Rights on thirty (30) days' prior written notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent application with the applicable patent office), providing the non-Prosecuting Party the right to assume the prosecution or maintenance thereof in such non-Prosecuting Party's name and at such non-Prosecuting Party's cost and expense.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights pursuant to this Section 12.2, including, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The Parties shall cooperate to determine for which of the Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights to seek an extension of the term in the Territory.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be treated as Other Shared Expenses.

12.3 Interference, Opposition, and Other Administrative Patent Proceedings.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition, post-grant review, inter-partes review, derivation proceeding, supplemental examination, reissue or reexamination relating to Regeneron Patent Rights, Sanofi Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The Parties will reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms, provided that if such agreement cannot be reached promptly, such decisions will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue, post-grant review, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Sanofi Patent Rights or Joint Patent Rights in the Territory for use in the Field shall be treated as Other Shared Expenses.

ARTICLE XIII
INTELLECTUAL PROPERTY LITIGATION AND LICENSES

13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual, potential or suspected infringement of a Sanofi Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property right jointly owned or licensed under this Agreement, by a Third Party’s activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing

of this claim or assertion and shall provide such other Party with all available evidence supporting such known, potential or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the IOSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution or settlement of any such claim.

(b) With respect to any such actual, suspected or potential infringement by virtue of a generic or potential generic competitor's activities in the Field in the Territory, including any Abbreviated New Drug Application (as defined in the Federal Food, Drug, and Cosmetic Act) filing, Paragraph IV Certification, any regulatory filing based on Section 351(k) of the Public Health Service Act (42 U.S.C. 262) or Article 10(4) of the Directive 2001/83/EC or any other similar regulation promulgated by the FDA, EMA or by other applicable similar governmental regulatory authorities or other actual or potential infringement by a generic or potential generic competitor anywhere in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding with respect to an IO Licensed Product, and the course of action in such proceeding, including settlement negotiations and terms, will be made by the Post-POC Principal Party with active assistance from and in consultation with the other Party. In those proceedings where a Party is not the reference product sponsor or BLA holder, such Party reserves, and is hereby granted the right to participate in all such proceedings to the extent such participation is permissible under applicable Laws and court rules and procedures. The Post-POC Other Party will provide reasonable assistance to the Post-POC Principal Party in prosecuting any suit, and if required by Law, will join in the suit in such country; provided that neither Party will enter into any settlement with respect to the Patents of the other Party without such other Party's prior written consent (which consent shall not be unreasonably withheld or delayed). Although the Post-POC Principal Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of such other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs and expenses, including attorneys' fees, relating to such legal proceedings and then shared equally (50%/50%) by the Parties.

(c) With respect to all other such actual, potential or suspected infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully in an effort to determine a mutually agreeable course of action, provided if such agreement cannot be reached promptly, final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigation shall be referred to as the "Lead Litigation Party." The non-Lead Litigation Party will provide reasonable assistance to the Lead

Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs and expenses, including attorneys' fees, relating to such legal proceedings and then shared equally (50%/50%) by the Parties.

(d) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) or (c) related to activities in the Field in the Territory shall be treated as Other Shared Expenses.

(e) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable IO Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of IO Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.

13.2 Patent Marking. Unless otherwise mutually agreed to by the Parties in writing, each Party shall comply with the Patent marking statutes in each country in which an IO Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates or Sublicensees.

13.3 Third Party Infringement Claims; New Licenses.

(a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any IO Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it using its own counsel; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture or Commercialization of any IO Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party.

(b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a

claim) incurred in connection with any litigation referred to in this Section 13.3 shall be treated as Other Shared Expenses.

(c) For the avoidance of doubt, neither Party will [***]. Furthermore, no Party shall [***].

(d) Except to the extent shared pursuant to Section 2.11 of the IO Discovery Agreement or shared as a "Development Cost," License fees, royalties and other payments under Licenses to the extent attributable to, and based on, the Development, Manufacture or Commercialization of IO Licensed Products in the Field in the Territory, including the Manufacture of Commercial Supply Requirements, shall be treated as Other Shared Expenses in the Quarter in which such fees or other payments were incurred by a Party, and the other Party shall provide such supporting documentation as required by such License to the Party that is a party to such License as part of the Consolidated Payment Report for such Quarter.

(e) Notwithstanding the provisions of Section 13.3(d), royalty payments under Licenses that are required for the continued Development, Manufacture of Commercial Supply Requirements or Commercialization, of one or more IO Licensed Products in the Field in the Territory and which arise directly out of [***], shall be shared by the Parties, on an IO Licensed Product-by-IO Licensed Product, and country-by-country basis as follows:

[***]		[***]		[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

To the extent a Party (the "OverPaying Party") has paid more than such Party's share of [***] in a Quarter, the other Party shall, at the time of the Quarterly True-Up, pay to the OverPaying Party the required amount in order to achieve the sharing provided for in this Section 13.3(e). To the extent payments under Licenses referred to above other than [***] are required to be made, the Parties will mutually agree on an appropriate and equitable allocation of such payments between them, and the amount and timing of payments by a Party to the other Party to achieve such allocation, consistent with the sharing [***] described above. For purposes of this Section 13.3(e), [***].

ARTICLE XIV
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with such Party's Accounting Standards) shall be made for the purpose of

determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of the employees of the Party whose books are being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its own cost and expense), upon no less than thirty (30) days' advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any Contract Year, to have the books and records of the other Party and its Affiliates maintained pursuant to Section 14.1 to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days of delivery. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy of amounts incurred during any year of more than [***], the audited Party shall also reimburse the other Party for the costs and expenses of such audit (with the cost and expense of the audit to be paid by the auditing Party in all other cases). Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement. The Parties shall cause such accountants to enter into a reasonably acceptable confidentiality agreement with the audited Party and obligating such firm to retain all such financial information in confidence pursuant to terms no less stringent than those set forth in ARTICLE XVI.

(c) If any examination or audit of the records described above discloses an overpayment or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 14.2(d), (i) the Party that underpaid shall pay any amounts due plus, if such underpayment is the underpaying Party's fault, interest thereon at the Default Interest Rate accruing from the date of such underpayment, or (ii) the Party that received an overpayment shall refund such overpayment plus, if such overpayment is the fault of the Party refunding such payment, interest thereon at the Default Interest Rate accruing from the date of such overpayment, in each case (i) and (ii) within thirty (30) days after receipt of the written results of such audit.

(d) Subject to the first (1st) sentence of Section 14.2(b), any disputes with respect to the results of any audit conducted under this Section 14.2 shall be subject to dispute resolution in accordance with ARTICLE X.

14.3 GAAP/IFRS. Except as otherwise provided herein, all of a Party's costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with such Party's Accounting Standards, as generally and consistently applied.

ARTICLE XV
REPRESENTATIONS, WARRANTIES AND COVENANTS

15.1 Due Organization, Valid Existence and Due Authorization; Financial Capability. Each Party represents and warrants to the other Party, as of the Execution Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents or any other agreement by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under ARTICLE IV hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Each Party hereby represents and warrants to the other Party that such Party has, and will continue to have, sufficient liquid assets to promptly and timely pay and perform all of the payments and obligations required by such Party or its Affiliates to be paid and performed by them hereunder.

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, except for any event, circumstance, condition or other matter disclosed in any report and other document furnished to or filed with the United States Securities and Exchange Commission, as of the Execution Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator or Governmental Authority that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, except for any event, circumstance, condition or other matter disclosed in any report and other document furnished to

or filed with the United States Securities and Exchange Commission by Regeneron or as otherwise discussed between Regeneron and Sanofi, as of the Execution Date:

(a) Regeneron owns all right, title and interest in and to all Regeneron Patent Rights in existence as of the Execution Date;

(b) Regeneron has the right and authority to grant the rights granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;

(c) there is no pending litigation of which Regeneron has received written notice that alleges that any of Regeneron's activities relating to the Regeneron Intellectual Property have violated, or would violate, a Valid Claim of an issued and unexpired Patent of any Third Party;

(d) Regeneron has not received written notice of any threatened claims or litigation alleging that any of its activities relating to the Regeneron Intellectual Property have violated or would violate, a Valid Claim of an issued and unexpired Patent of any Third Party;

(e) to Regeneron’s knowledge, the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Execution Date has not constituted or involved the misappropriation of (i) trade secrets or (ii) other intellectual property rights of any Person;

(f) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Execution Date are not invalid or unenforceable, in whole or part;

(g) Regeneron has not received any written notice of any threatened litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron’s knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings;

(h) Regeneron has written agreements with all of its employees and contractors who may participate in the conduct of the Collaboration or receive confidential information hereunder assigning to Regeneron ownership of all intellectual property rights created in the course of their employment or provision of services, as applicable; and

(i) To Regeneron’s knowledge, there have been no material adverse effects reported to Regeneron from the ongoing phase I clinical trial of REGN2810 that would require Regeneron to discontinue such trial.

15.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT,

COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 Mutual Covenants. Each Party hereby covenants to the other Party as follows: (a) it will not during the Term grant any right or license to any Third Party in the Territory which would be inconsistent with or in conflict with or in derogation of the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) except with respect to the Joint Patent Rights, neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) in the course of the Development or Commercialization of an IO Licensed Product in the Field under this Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

ARTICLE XVI
CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Sanofi and Regeneron acknowledges (subject to Section 16.1(b) and the provisions of ARTICLE XIX) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement or the Ancillary Collaboration Agreements is confidential and proprietary to such other Party or its Affiliates. Furthermore, each of Sanofi and Regeneron acknowledges (subject to the further provisions of this ARTICLE XVI) that all New Information is confidential and proprietary to both Parties (and both Parties shall be deemed to be the receiving Party with respect thereto). Subject to the further provisions of this ARTICLE XVI, each of Sanofi and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided in Section 16.1(a), the restrictions provided in this ARTICLE XVI shall not apply to information that was or is (and

such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; provided that this clause (ii) shall not apply with respect to New Information; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information and not, with respect to New Information, in connection with this Agreement or any Ancillary Collaboration Agreement; (iv) similar in nature to the purported Party Information or New Information but has been independently created outside of this Agreement or any Ancillary Collaboration Agreement, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information.

(c) Notwithstanding anything provided in Section 16.1(a), each Party may use or disclose Party Information of the other Party and New Information to the extent that use or disclosure is (i) necessary to file, prosecute or defend Patents or Patent applications for which the Party has the right to assume filing, prosecution, defense or maintenance pursuant to this Agreement; provided that reasonable measures have been taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law; (ii) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the receiving Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information that is required by Governmental Authority, applicable Law or court order to be disclosed; (iii) to enforce the terms of this Agreement or any Ancillary Collaboration Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information; or (iv) to the Regulatory Authorities as required in connection with obtaining or maintaining any application of an IO Licensed Product in the Field in the Territory pursuant to the terms of this Agreement; provided, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law.

(d) Notwithstanding anything provided in this Section 16.1 or elsewhere in this Agreement, each Party and its Affiliates shall have the right to use and disclose any New Information directly related to any IO Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.

16.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties under this ARTICLE XVI are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this ARTICLE XVI, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this ARTICLE XVI, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged Party will be entitled to seek in any court of competent jurisdiction.

16.3 Publication of New Information. During the Term, if either Sanofi or Regeneron (the "Publishing Party") desires to disclose any New Information or Party Information of the other Party that relates to any IO Licensed Product in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information or such Party Information of the other Party prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to (a) prevent any specific, material negative effect to it or the IO Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material negative effect), or (b) to enable the Parties to obtain Patent protection if either Party deems it necessary, to which the Publishing Party shall give due consideration. The Publishing Party shall not unreasonably reject such comments, and, if requested by the other Party, shall delay or prevent such disclosure or publication as reasonably proposed by such other Party. Disputes concerning publication shall be resolved by the IOSC (other than Legal Disputes). In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a Patent application(s) or application(s) for a certificate of invention on the information involved.

16.4 Disclosures Concerning this Agreement. The Parties will mutually agree on the contents of their respective press releases with respect to the execution of this Agreement and the IO Discovery Agreement (and the amendments to the Existing Agreements), which press release shall be issued simultaneously by each Party on the Execution Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or the IO Discovery Agreement or any actions or activities contemplated hereunder or thereunder without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's securities (or the securities of its parent entity) are traded); provided that the Party intending to disclose such information shall (a) use reasonable efforts to (i) provide the other Party advance notice of such required disclosure and an opportunity to review and comment on such proposed disclosure (which comments shall be

considered in good faith by the disclosing Party) and (ii) assist the other Party to protect such information and (b) limit the disclosure to the information that is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements that incorporate information concerning this Agreement or the IO Discovery Agreement or any actions or activities contemplated hereunder or thereunder which information was included in a press release or public disclosure that was previously disclosed under the terms of this Agreement or the IO Discovery Agreement or which contains only non-material factual (non-financial) information regarding the Collaboration. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's securities (or the securities of its parent entity) are traded), or in connection with the enforcement of this Agreement or adjudication of any Expert Panel Dispute, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this ARTICLE XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the IO Licensed Products in the Field. Each Party acknowledges that the other Party, as a publicly traded company, is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement and the IO Discovery Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with each other and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE XVII
INDEMNITY

17.1 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees, Sublicensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' or experts' fees and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement (a "Third Party Claim") against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Sanofi or its Affiliates (or, their respective agents, contractors, Sublicensees, representatives or other persons

or entities working on their behalf) in the performance of this Agreement including, in connection with its Development, Manufacture or Commercialization of any IO Licensed Product in the Field; or

(ii) material breach by Sanofi (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Sanofi would be a material breach by Sanofi) of the terms of, or the representations and warranties made by it in, this Agreement,

except in each case ((i) and (ii)), to the extent that Damages arise out of the gross negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Regeneron or its Affiliates (or their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement or the material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and its and their respective officers, directors, employees, Sublicensees and agents ("Sanofi Indemnitees") from and against all Damages arising from a Third Party Claim against a Sanofi Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by Regeneron or its Affiliates (or their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf), including, in connection with the Development, Manufacture or Commercialization of any IO Licensed Product in the Field; or

(ii) material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of, or the representations and warranties made by it in, this Agreement,

except in each case ((i) and (ii)), to the extent that Damages arise out of the gross negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Sanofi or its Affiliates (or their respective agents, contractors, Sublicensees, representatives or other persons or entities working on their behalf) in the performance of this Agreement or the material breach by Sanofi (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Sanofi would be a material breach by Sanofi) of the terms of this Agreement.

(c) Mutual Indemnification.

(i) In the event of any Third Party Claim alleging that the Development, Manufacture or Commercialization of any IO Licensed Product under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(ii) In the event of any product liability Third Party Claim alleging that the Development, Manufacture or Commercialization of any IO Licensed Product causes damages for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(d) During the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by applicable Law, each of Regeneron and Sanofi will (i) use Commercially Reasonable Efforts to procure and maintain commercial general liability and product liability insurance in an amount not less than [***] per occurrence and in the annual aggregate or (ii) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Sanofi, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party under Section 17.1 with respect to such Damages.

(e) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Sanofi Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to ARTICLE VIII; provided, that nothing in this Section 17.1(e) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party manufacturer(s) pursuant to ARTICLE VIII.

17.2 Indemnity Procedure. The Party entitled to indemnification under this ARTICLE XVII (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of being notified of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the

extent that such failure materially prejudices the Indemnifying Party. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages under the terms of Section 17.1(c), and the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending or prosecuting any Third Party Claims subject to Section 17.1(c).

(a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending a claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld, conditioned or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed); provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

(b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.

(c) Regardless of whether the Indemnifying Party assumes the defense of any claim pursuant to this Section 17.2, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to, reasonably cooperate in the defense or prosecution thereof and, if the Indemnifying Party assumes the defense of any such claim, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to furnish such records,

information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals, in each case, as may be reasonably requested in connection therewith. Such cooperation shall include access upon reasonable notice during normal business hours afforded to the Indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and to the extent the Indemnified Party is entitled to indemnification pursuant to this ARTICLE XVII, the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection with providing such assistance.

ARTICLE XVIII
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance, and only if the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE XIX
TERM AND TERMINATION

19.1 Term/Expiration of Term.

(a) The "Term" of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated in its entirety in accordance with the terms of this ARTICLE XIX, shall expire upon the later to occur of (i) the expiration or earlier termination of the IO Discovery Agreement (including, if applicable, any "Tail Period" thereunder), and (ii) such time as neither Party nor either Party's Affiliates, nor any of their respective Sublicensees, is Developing or Commercializing any IO Licensed Product in the Field anywhere in the Territory under this Agreement (and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent).

(b) Upon expiration of the Term, except as set forth in Section 4.3 and this Agreement, all licenses and rights granted by a Party to the other Party hereunder shall automatically terminate and revert to the granting Party.

19.2 Termination Without Cause; Special Termination Products.

(a) By Sanofi.

(i) Sanofi may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the IO Discovery Program in accordance with the terms of the IO Discovery Agreement, or may terminate this Agreement in the entire Territory for a particular IO Licensed Product or particular IO Licensed Products in the Field, in any such case on twelve (12) months' prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2(a), in the event of such termination by Sanofi of this Agreement in its entirety or with respect to one or more IO Licensed Product(s) pursuant to this Section 19.2, this Agreement (including, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Sanofi Termination Notice Period") and the terms of Schedule 3 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(a) or Schedule 3, during the Sanofi Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize IO Licensed Products (including the Special Termination Products(s)) in the Field in accordance with Plans. During the Sanofi Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Sanofi hereunder and in any event upon the expiration of the Sanofi Termination Notice Period, whether or not any such notice is given by Regeneron, (A) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Special Termination Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Sanofi Termination Notice Period), (B) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Special Termination Product(s) shall terminate, and (C) Sanofi will promptly take the actions required by Schedule 3 and Regeneron will reasonably cooperate with Sanofi (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Sanofi Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Special Termination Product(s) in the Field in the Territory. In addition, during the Sanofi Termination Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Sanofi Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

(ii) In addition to Sanofi's termination rights set forth in Section 19.2(a)(i), from and after the twelfth (12^{th}) anniversary of the First

Commercial Sale of an IO Licensed Product in a country, Sanofi may, upon twenty-four (24) months' prior written notice to Regeneron, terminate this Agreement with respect to such IO Licensed Product in such country. If Sanofi exercises such right, the provisions of Section 19.2(a)(i) (except that the Sanofi Termination Notice Period referred to therein shall be twenty-four (24) months rather than twelve (12) months), and Sections 19.6(a) and 19.7 shall apply with respect to such Terminated IO Product in such country.

(b) By Regeneron.

(i) Regeneron may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the IO Discovery Program in accordance with its terms, or may terminate this Agreement in the entire Territory for a particular IO Licensed Product or particular IO Licensed Products in the Field, in any such case, on twelve (12) months' prior written notice to Sanofi. Except as otherwise provided below in this Section 19.2(b), in the event of such termination by Regeneron of this Agreement in its entirety or with respect to one or more IO Licensed Product(s) pursuant to this Section 19.2(b), this Agreement (including, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Regeneron Termination Notice Period") and the terms of Schedule 4 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(b) or Schedule 4, during the Regeneron Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize IO Licensed Products (including the Special Termination Products(s)) in the Field in accordance with Plans. During the Regeneron Termination Notice Period, to the extent set forth or requested in one or more written notices from Sanofi to Regeneron hereunder and in any event upon the expiration of the Regeneron Termination Notice Period, whether or not any such notice is given by Sanofi, (A) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Special Termination Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Regeneron Termination Notice Period), (B) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Special Termination Products(s) shall terminate, and (C) Regeneron will promptly take the actions required by Schedule 4 and Sanofi will reasonably cooperate with Regeneron (for avoidance of doubt, such cooperation shall not require Sanofi to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Sanofi) to facilitate Sanofi's (or its nominee's) expeditious assumption during the Regeneron Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Special Termination Product(s) in the Field in the Territory. In addition, during the Regeneron Termination Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any

amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Regeneron Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

(ii) In addition to Regeneron's termination rights set forth in Section 19.2(b)(i), from and after the twelfth (12th) anniversary of the First Commercial Sale of an IO Licensed Product in a country, Regeneron may, upon twenty-four (24) months' prior written notice to Sanofi, terminate this Agreement with respect to such IO Licensed Product in such country. If Regeneron exercises such right, the provisions of Section 19.2(b)(i) (except that the Regeneron Termination Notice Period referred to therein shall be twenty-four (24) months rather than twelve (12) months), and Sections 19.6(a) and 19.7 shall apply with respect to such Terminated IO Product in such country

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety or for a particular IO Licensed Product or particular IO Licensed Products in the Field in the entire Territory, upon written notice to the other Party, if such other Party commits a material breach of its obligations under this Agreement with respect to such IO Licensed Product(s) as to which such notice of termination is given (or all IO Licensed Products if such notice of termination is with respect to this Agreement in its entirety). Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination that is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days unless otherwise agreed by the Parties, so long as the breaching party is using diligent efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use diligent efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be thirty (30) days (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above) material breach by a Party, as determined by a court of competent jurisdiction.

19.4 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets,

or (b) the other Party proposes a written agreement of composition or extension of its debts, or (c) the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or (d) the other Party shall propose or become a party to any dissolution or liquidation, or (e) if the other Party shall make an assignment for the benefit of creditors. All rights and licenses granted under or pursuant to this Agreement by a Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101 (35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed under or pursuant to this Agreement, including, any Patents or Patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101 (35A) of the Bankruptcy Code subject to the protections afforded the non-rejecting Party under Section 365(n) of the Bankruptcy Code, and any similar Law or regulation in any other country. The Parties agree that this Agreement shall not be deemed terminated by virtue of any rejection by a Party or its receiver or trustee under applicable bankruptcy Laws unless the non-rejecting Party fails to exercise its rights under Section 365(n)(1)(B) of the U.S. Bankruptcy Code (or its foreign equivalents). For clarity, if the non-rejecting Party fails to exercise such rights or such rights are not available in a country outside the United States, this Agreement shall be deemed terminated. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous Laws in any other country or jurisdiction, if this Agreement is not terminated or deemed terminated, the Party hereto that is not the subject of such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property and all embodiments of such intellectual property, which, if not already in such Party's possession, shall be promptly delivered to it upon such Party's written request, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement.

19.5 Termination of IO Discovery Agreement.

(a) By Regeneron. Regeneron may terminate this Agreement in its entirety, effective upon written notice to Sanofi, if the IO Discovery Agreement has been terminated by Regeneron pursuant to Section 12.2 or Section 12.3 thereof.

(b) By Sanofi. Sanofi may terminate this Agreement in its entirety effective upon written notice to Regeneron, if the IO Discovery Agreement has been terminated by Sanofi pursuant to Section 12.2 or Section 12.3 thereof.

19.6 Effect of Termination.

(a) Except as provided in Section 19.2(b), and in Section 19.6(b)below, upon termination of this Agreement with respect to all IO Licensed Products in the Field, or for a particular IO Licensed Product or particular IO Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the provisions of Schedule 3 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated IO Product(s), and except to the extent required by Sanofi to fulfill its

obligations pursuant to Schedule 3, (i) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated IO Product(s) shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated IO Product(s) shall automatically terminate and (iii) the license from Sanofi and its Affiliates to Regeneron referred to in Schedule 3 shall automatically come into full force and effect with respect to the Terminated IO Product(s). If Regeneron terminates this Agreement pursuant to Section 19.3 or 19.4 or pursuant to Section 19.5(a) in its entirety or with respect to one or more IO Licensed Products, then Sanofi shall pay to Regeneron, in addition to any other amount payable by Sanofi to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to one hundred percent (100%) of the Development Costs incurred by Regeneron under the Global Development Plan(s) with respect to the Terminated IO Product(s) during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.

(b) Upon termination of this Agreement by Regeneron pursuant to Section 19.2(b) or by Sanofi pursuant to Section 19.3 or 19.4, in its entirety, or for a particular IO Licensed Product or particular IO Licensed Products in the Field, the provisions of Schedule 4 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated IO Product(s) and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 4, (i) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated IO Product(s) shall automatically terminate, and revert to Sanofi, (ii) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated IO Product(s) shall automatically terminate and (iii) the license from Regeneron referred to in Schedule 4 shall come into full force and effect with respect to the Terminated IO Product(s).

19.7 Survival of Obligations. Except as otherwise provided in this ARTICLE XIX, or Schedule 3 or Schedule 4, upon expiration, or upon termination of this Agreement with respect to all IO Licensed Products in the Field, or for a particular IO Licensed Product or particular IO Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the rights and obligations of the Parties hereunder with respect to the Terminated IO Product(s), in the applicable country or countries if such termination is pursuant to Section 19.2(a)(ii), shall terminate, and this Agreement shall cease to be of further force or effect to the extent of such termination, provided that notwithstanding any expiration or termination of this Agreement:

(a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the IO Development Balance payments provided for in Schedule 2 shall automatically terminate and the IO Development Balance shall equal zero;

(b) subject to the provisions of this ARTICLE XIX, including Schedule 3 and Schedule 4 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with ARTICLE XVI, as well as other provisions (including, Sections 7.4, 9.10, 9.11, 9.14, 10.3 and 10.4, the second (2nd) sentence of Section 12.1(e) and ARTICLE XII (with respect to Joint Inventions), ARTICLE XVI, ARTICLE XVII, ARTICLE XIX and ARTICLE XX) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and

(c) such expiration or termination and this ARTICLE XIX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

ARTICLE XX
MISCELLANEOUS

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Except as set forth in ARTICLE X, each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts. Each Party further agrees that service of any process, summons, notice or document delivered by reputable international overnight courier service to its address set forth in Section 20.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

20.2 Waiver . Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

20.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 5 attached hereto and shall be (a) delivered personally, or (b) sent via a reputable international overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand or one (1) Business Day after it is sent via a reputable international overnight courier service. Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement and the IO Discovery Agreement contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersede all prior understandings and writings relating to the subject matter hereof and thereof, provided that the proviso set forth in Section 14.4 of the IO Discovery Agreement shall apply with respect to any conflict or inconsistency between this Agreement and the IO Discovery Agreement. For the avoidance of doubt, the Existing Discovery Agreement and the Existing License and Collaboration Agreement shall remain in full force and effect in accordance with their respective terms and any variation between a provision of this Agreement and a corresponding or similar provision of the Existing Discovery Agreement or the Existing License and Collaboration Agreement shall not be considered in the interpretation of this Agreement, the Existing Discovery Agreement or the Existing License and Collaboration Agreement.

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

20.6 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction, provided, that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

20.7 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.8 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet a Party's obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain

primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 20.12.

20.10 Affiliates. Each Party may, and to the extent it is in the best interests of the IO Licensed Products in the Field in the Territory shall, perform its obligations under this Agreement through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of an IO Licensed Product under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

20.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. This Agreement may be executed by exchange between the Parties of electronically transmitted signatures (via facsimile, PDF format via e-mail or other electronic means) and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

20.12 Third Party Beneficiaries. Except as provided below in this Section 20.12, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, ARTICLE XVII is intended to benefit, and to be enforceable by, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is only enforceable by the Parties.

20.13 Relationship of the Parties. Each Party shall bear its own costs and expenses incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided for in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party’s employees or for any employee compensation or benefits of the other Party’s employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party

to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.14 Limitation of Damages. IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM THAT IS COVERED BY THE INDEMNIFICATION OBLIGATIONS IN ARTICLE XVII.

20.15 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any IO Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

20.16 Construction.

(a) The use of words in the singular or plural, or with a particular gender, shall not limit the scope or exclude the application of any provision of this Agreement to such person or persons or circumstances as the context otherwise permits. The words "will" and "shall" shall have the same meaning and, unless the context otherwise requires, the use of the word "or" is used in the inclusive sense (and/or). The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term, irrespective of whether such term is used with "without limitation" or "without limiting" throughout this Agreement. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

(b) The captions of this Agreement are for convenience or reference only and in no way define, describe, extend or limit the scope of intent of this Agreement or in the intent of any provision contained in this Agreement. Unless otherwise specified, (i) the references in this Agreement to any Article, Section, Schedule or Appendix means references to such Article, Section, Schedule or Appendix of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section and (iii) unless the context otherwise requires, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied,

replaced or supplemented from time to time, so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

(c) Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement within a specified time period and notification of such approval or consent is not delivered within such time period, then, unless otherwise specified, the Party whose approval or consent is required shall be conclusively deemed to have withheld its approval or consent. This Agreement has been prepared jointly and the provisions contained herein shall not be construed or interpreted for or against any Party to this Agreement because such Party drafted or caused such Party's legal representative to draft any provision contained herein.

(d) In the event of any conflict between this Agreement and the Schedules, Exhibits or Appendices hereto, this Agreement shall prevail.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Immuno-Oncology License and Collaboration Agreement to be executed by their duly authorized representatives as of the day and year first above written.

SANOFI BIOTECHNOLOGY SAS

By:	/s/ Olivier Brandicourt
Name:	Olivier Brandicourt
Title:	Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By:	/s/ Leonard S. Schleifer
Name:	Leonard S. Schleifer, M.D., Ph.D.
Title:	President & CEO

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

SCHEDULE 1

Manufacturing Cost

[***]

SCHEDULE 2

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") as follows:

(A) The Quarterly True-Up shall be equal to (a) the Profit Split True-Up, (as set forth in Part I), minus (b) the Development Compensation Payment for such Quarter payable to Sanofi (as set forth in Part II), plus or minus (c) the Development Cost True-Up for such Quarter (as set forth in Part III).

(B) If the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron in accordance with the terms set forth in ARTICLE IX.

(C) If the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi in accordance with the terms set forth in ARTICLE IX.

Two examples of the Quarterly True-Up are shown in Part IV.

PART I. PROFIT SPLIT TRUE-UP

"Regeneron Profits" in a Quarter shall mean, (a) the sum of (i) Net Sales of all IO Licensed Products by Regeneron in the Territory in the Quarter, plus (ii) Other Shared Revenues received by Regeneron in such Quarter, less (b) the sum of (i) aggregate COGS incurred by Regeneron with respect to IO Licensed Products for which Regeneron is the Lead Commercialization Party in the U.S. in the Quarter, (ii) aggregate Shared Commercial Expenses incurred by Regeneron and allocable to the Territory in the Quarter, and (iii) aggregate Other Shared Expenses incurred by Regeneron and allocable to the Territory in the Quarter.

"Sanofi Profits" in a Quarter shall mean, (a) the sum of (i) Net Sales of all IO Licensed Products by Sanofi in the Territory in the Quarter, plus (ii) Other Shared Revenues received by Sanofi in such Quarter, less (b) the sum of (i) aggregate COGS incurred by Sanofi with respect to IO Licensed Products for which Sanofi is the Lead Commercialization Party in the U.S. in the Quarter, (ii) aggregate COGS incurred by Sanofi with respect to IO Licensed Products in the ROW Territory in the Quarter, (iii) aggregate Shared Commercial Expenses incurred by Sanofi and allocable to the Territory in the Quarter, and (iii) aggregate Other Shared Expenses incurred by Sanofi and allocable to the Territory in the Quarter.

"Profits" shall mean the Regeneron Profits with respect to Regeneron and the Sanofi Profits with respect to Sanofi, as the context requires.

"Aggregate Profits" in a Quarter shall mean the Regeneron Profits for such Quarter plus the Sanofi Profits in such Quarter.

"Other Shared Revenue" shall mean any [***].

"Profit Split" shall mean fifty percent (50%) of the Aggregate Profits in a Quarter.

"Profit Split True-Up" shall mean (a) the Profit Split in a Quarter, minus (b) the Regeneron Profits in a Quarter. For clarity, if the Regeneron Profits are more than the Sanofi Profits in a Quarter, then the Profit Split True-Up will be a negative number for that Quarter and if the Regeneron Profits are less than the Sanofi Profits in a Quarter, then the Profit Split True-Up will be a positive number for that Quarter.

Two examples of a calculation of the Profit Split True-Up in a Quarter would be:

[***]

	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]			[***]
[***]			[***]
[***]	[***]		
[***]		[***]	
[***]			[***]

[***]

	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]			[***]
[***]			[***]
[***]	[***]		
[***]		[***]	
[***]			[***]

PART II. DEVELOPMENT COMPENSATION PAYMENT

"IO Development Balance Costs" shall mean (a) fifty percent (50%) of the total Development Costs for IO Licensed Products for which Sanofi is the Post-POC Principal Party (including, for the avoidance of doubt, such Development Costs for any Special Termination Product that is an IO Antibody until the time such Special Termination Product becomes an Special Termination Product) to the extent (i) directly attributable to the conduct of clinical trials of such IO Licensed Product (or Special Termination Product), (ii) incurred from and after the date that such IO Licensed Product (or Special Termination Product) first became an IO Licensed Product under this Agreement in accordance with the terms of the IO Discovery Agreement, and (iii) consistent with the Global Development Budget in respect of such IO Licensed Product (or Special Termination Product), (b) [***] of the total Program Costs attributable to clinical development of IO Discovery Program Antibodies under the IO Discovery Program, solely to the extent that Sanofi made an IO "Upfront Payment" or IO Reimbursement Payment in respect of such Program Costs pursuant to Section 4.2 of the IO Discovery Agreement, and solely to the extent that Section 4.3 of the IO Discovery Agreement expressly provides that such Program Costs are to be added to the IO Development Balance, (c) [***] of the development costs incurred by Regeneron with respect to any Non-IO Indication for an IO Licensed Product, solely to the extent that Sanofi reimburses Regeneron for [***] of such development costs pursuant to Section 9.2(c), and (d) [***] of the Additional Trial Costs incurred by Regeneron as a Post-POC Other Party, solely to the extent that Sanofi reimburses Regeneron for [***] of such Additional Trial Costs pursuant to Section 9.2(d).

The "IO Development Balance" as of the end of a Quarter shall mean (a) the aggregate amount of IO Development Balance Costs incurred after the Effective Date through the close of such Quarter, less (b) the aggregate amount of Development Compensation Payments included in the calculation of the Quarterly True-Up in all prior Quarters.

If both the IO Development Balance as of the end of a Quarter is greater than zero and the Profit Split for the Quarter is greater than zero, the "Development Compensation Payment" for such Quarter shall equal the lower of (a) ten percent (10%) of the Profit Split for the Quarter and (b) the IO Development Balance. Otherwise, the Development Compensation Payment for the Quarter shall equal zero.

Two examples of a calculation of the Development Compensation Payment in a Quarter would be:

[***]

PART III. Development Cost True-Up

The "Development Cost True-Up" for a Quarter shall mean:

(a) 100% of the aggregate Development Costs incurred by or on behalf of Regeneron with respect to IO Licensed Products for which Sanofi is the Post-POC Principal Party in such Quarter, *plus*

(b)100% of the aggregate Development Costs incurred by or on behalf of Regeneron with respect to IO Licensed Products for which Regeneron is the Post-POC Principal Party in such Quarter, *minus*

(c) [***] of the aggregate Development Costs incurred by or on behalf of the Parties with respect to IO Licensed Products for which Regeneron is the Post-POC Principal Party in such Quarter, *plus*

(d) [***] of the development costs and expenses incurred by Regeneron in respect of a Non-IO Indication for an IO Licensed Product to the extent provided in Section 9.2(c), *plus*

(e) [***] of the Additional Trial Costs incurred by Regeneron as the Post-POC Other Party to the extent provided in Section 9.2(d), *minus*

(f) [***] of the Additional Trial Costs incurred by Sanofi as the Post-POC Other Party to the extent provided in Section 9.2(d).

An example of the calculation of the Development Cost True-Up (for illustration purposes only) is set forth below:

[***]

If the Development Cost True-Up is a positive number, then it shall be added in the calculation of the Quarterly True-up, and if the Development Cost True-Up is a negative number, then the absolute value of such amount shall be subtracted in the calculation of the Quarterly True-Up.

PART IV. EXAMPLE OF QUARTERLY TRUE-UP

Two example of a calculation of the Quarterly True-Up in a Quarter would be:

[***]

SCHEDULE 3

Certain Termination Arrangements

The rights and obligations set forth in this Schedule 3 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated IO Product(s) as to which, and, if applicable pursuant to Section 19.2(a)(ii), only in the country or countries in which, this Agreement has been terminated.

1. Sanofi shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information directly related to any Terminated IO Product(s), and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to any Terminated IO Product(s). In addition, at Regeneron's request, Sanofi shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, sales training materials, samples, and product inventory. Notwithstanding the foregoing, Sanofi may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than any royalties due for any Royalty Products under the IO Discovery Agreement and any amounts payable to Third Parties for any intellectual property or technology contributed to the IO Discovery Program or Collaboration by Sanofi), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Sanofi Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing and Commercializing Terminated IO Product(s) in the Field in the Territory (and solely to the extent such Sanofi Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such IO Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Sanofi Intellectual Property retained by Sanofi.

3. Sanofi shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Terminated IO Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, if and to the extent requested by Regeneron, the following:

(a) Sanofi shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration

Filings) made or obtained by Sanofi or its Affiliates or any of its Sublicensees to the extent specifically relating to the Terminated IO Product(s).

(b) Sanofi shall assign and transfer to Regeneron (or its nominee) Sanofi's entire right, title and interest in and to all Product Trademarks for any Terminated IO Product(s) and Promotional Materials relating to the Terminated IO Product(s); provided that nothing herein is intended to convey any rights in or to Sanofi's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Sanofi shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated IO Product(s) in the Field in the Territory) of all information (including any New Information) in Sanofi's possession and control, or in Sanofi's control and accessible by Sanofi consistent with Sanofi's regular business practices, to the extent directly relating to the Terminated IO Product(s) in the Field, including, all information contained in the regulatory or safety databases, all in the format then currently maintained by Sanofi, or such other format as may be reasonably requested by Regeneron.

(d) Sanofi shall use Commercially Reasonable Efforts to assign to Regeneron any applicable Licenses and sublicenses to the extent related to the Terminated IO Product(s) and contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated IO Product(s) in the Field in the Territory, as reasonably requested by Regeneron.

(e) Without limitation of Sanofi's other obligations under this Schedule 3, to the extent Sanofi or its Affiliate is Manufacturing (in whole or in part) the Terminated IO Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Sanofi (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and Commercial Supply Requirements of such Terminated IO Product(s), and Regeneron shall purchase such Terminated IO Product(s), at the same price, and on such other terms and conditions on which Sanofi was supplying, or in the absence of termination would have been required to supply, such Terminated IO Product(s), through the second (2^{nd}) anniversary of the effective date of termination of this Agreement with respect to such Terminated IO Product(s) or such shorter period if Regeneron notifies Sanofi that Regeneron is able to Manufacture or have Manufactured such Terminated IO Product(s) on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture, and Commercialization of the Terminated IO Product(s) in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, except as expressly provided in the IO Discovery Agreement or this Agreement, Regeneron shall not be required to provide Sanofi any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 3; provided, that Regeneron shall be solely responsible for paying any royalties,

fees or other consideration that Sanofi may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

Schedule 4

Certain Termination Arrangements

The rights and obligations set forth in this Schedule 4 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated IO Product(s) as to which, and if applicable pursuant to Section 19.2(b)(ii), only in the country or countries in which this Agreement has been terminated.

1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Sanofi or, at Sanofi's request, destroy, all documents containing New Information or Party Information of Sanofi and its Affiliates directly related to any Special Termination Products, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to the Terminated IO Product(s). In addition, at Sanofi's request, Regeneron shall collect and transfer to Sanofi any remaining inventory of Promotional Materials, sales training materials, product samples and product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the IO Discovery Program or Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing, and Commercializing the Terminated IO Product(s) in the Field in the Territory (and solely to the extent such Regeneron Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such IO Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Regeneron Intellectual Property retained by Regeneron.

3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Sanofi to enable Sanofi (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Terminated IO Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, if and to the extent requested by Sanofi, the following:

(a) Regeneron shall transfer and assign to Sanofi (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to the Terminated IO Product(s).

(b) Regeneron shall assign and transfer to Sanofi (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for the Terminated IO Product(s) and Promotional Materials relating to the Terminated IO Product(s); provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Regeneron shall provide to Sanofi (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated IO Product(s) in the Field in the Territory) of all information (including any New Information) in Regeneron's possession and control, or in Regeneron's control and accessible by Regeneron consistent with Regeneron's regular business practices, to the extent directly relating to the Terminated IO Product(s) in the Field, including, all information contained in the regulatory or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Sanofi.

(d) Regeneron shall use Commercially Reasonable Efforts to assign to Sanofi any applicable Licenses and sublicenses to the extent related to the Terminated IO Product(s) and contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated IO Product(s) in the Field in the Territory, as reasonably requested by Sanofi.

(e) Without limitation of Regeneron's other obligations under this Schedule 4, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) the Terminated IO Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Sanofi with Clinical Supply Requirements and Commercial Supply Requirements of such Terminated IO Product(s), and Sanofi shall purchase such Terminated IO Product(s), at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Terminated IO Product(s), through the second (2^{nd}) anniversary of the effective date of termination of this Agreement with respect to such Terminated IO Product(s) or such shorter period if Sanofi notifies Regeneron that Sanofi is able to Manufacture or have Manufactured such Terminated IO Product(s) on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Terminated IO Product(s) in the Field hereunder to Sanofi (or its Sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, Sanofi shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 4; provided, that Sanofi shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Sanofi of such licenses or other rights.

Schedule 5

Notices

(a) If to Sanofi:

Sanofi Biotechnology SAS
54, rue La Boétie
75008 Paris
France
Attn: President

Copy (which shall not constitute notice) to:

Sanofi
54, rue La Boétie
75008 Paris
France

Attn: Executive Vice President and General Counsel

(b) If to Regeneron:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President

Copy: General Counsel

Exhibit 10.3

AMENDMENT NO. 1 TO AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

This **AMENDMENT NO. 1** (this "First Amendment") to that certain **AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT** by and between Sanofi Biotechnology SAS, a société par actions simplifee organized under the laws of France, as successor-in-interest to Aventis Pharmaceuticals, Inc. ("Sanofi") and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of the State of New York ("Regeneron") effective as of November 10, 2009 (the "Existing Discovery Agreement"), dated as of July 1, 2015 (the "Amendment Effective Date") and executed as of July 27, 2015, is by and between Sanofi and Regeneron. Capitalized terms used but not defined in this First Amendment have the respective meanings set forth with respect thereto in the Existing Discovery Agreement. Each of Sanofi and Regeneron may be referred to in this First Amendment individually as a "Party" and collectively as the "Parties".

WHEREAS, in connection with entering into that certain Immuno-Oncology Discovery and Development Agreement dated as of July 1, 2015 (the "IO Discovery Agreement"), the Parties have agreed to certain amendments to the Existing Discovery Agreement; and

WHEREAS, in accordance with Section 14.5 (*Amendments*) of the Existing Discovery Agreement, the Parties desire to memorialize such amendments in this First Amendment.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. Amendments to Definitions.

(a) The definition of "Antibody" in Article 1 of the Existing Discovery Agreement is hereby amended as follows (inserted language underlined and in italics for ease of reference):

"'Antibody' shall mean (i) solely for purposes of this Agreement, [***]. The foregoing shall not include [***]."

(b) The following sentence is hereby added to become the final sentence of the definition of "Excluded Candidates" in Article 1 of the Existing Discovery Agreement:

"Excluded Candidates also shall include any "Refused Candidate" (as defined in the IO Discovery Agreement)."

(c) The following definitions are hereby added to Article 1 of the Existing Discovery Agreement:

"'Ancillary Collaboration Agreements' shall mean the License and Collaboration Agreement, the IO Discovery Agreement and the IO License and Collaboration Agreement."

"'CAR-T Cell Therapies' shall mean [***]."

"'Indication' shall mean any disease, state or condition."

"IO Antibody" shall have the meaning ascribed to such term in the IO Discovery Agreement.

"'IO Discovery Agreement' shall mean the Immuno-Oncology Discovery and Development Agreement by and between Sanofi and Regeneron, dated as of July 1, 2015, as the same may be amended from time-to-time."

"'IO Discovery Program' shall have the meaning ascribed to such term in the IO Discovery Agreement."

"'IO Discovery Program Antibody' shall have the meaning ascribed to such term in the IO Discovery Agreement."

"'IO License and Collaboration Agreement' shall mean the Immuno-Oncology License and Collaboration Agreement by and between Sanofi and Regeneron, dated as of July 1, 2015, as the same may be amended from time-to-time."

"'IO Licensed Product' shall have the meaning ascribed to such term in the IO License and Collaboration Agreement."

"'Multi-Indication Antibody' shall have the meaning set forth in Section 2.1(d)."

"'Non-IO Indication' shall mean any Indication that is [***]. For clarity, any [***] is a Non-IO Indication."

[***]

(d) The definition of "Confidential Information" in Section 9.1 of the Existing Discovery Agreement is hereby amended by adding the phrase "or the IO Discovery Agreement" immediately before the words "(the "Confidential Information")" appearing therein.

(e) The definition of "Aventis Stock Purchase Agreement" in Section 12.4 of the Existing Discovery Agreement is hereby amended by adding the words "as amended by the

Investor Agreement, and as may be further amended from time to time" immediately after the words "by and between Sanofi and Regeneron" appearing therein.

2. Amendments to Article 2 (Discovery Program).

(a) Section 2.1 (*Discovery Program*) of the Existing Discovery Agreement is hereby amended by adding a new subsection (d) as follows:

> "(d) Multi-Indication Antibodies. Multi-Indication Antibodies may be developed under either this Agreement pursuant to this Section 2.1(d) or under the IO Discovery Agreement pursuant to Section 2.1(d) thereof, as applicable. If any IO Discovery Program Antibody is also an Antibody being developed in any Non-IO Indication under this Agreement (a "Multi-Indication Antibody"), then [***] under [***] and [***], except to the extent that [***], the results of which may be useful for development in an immuno-oncology Indication as well as Non-IO Indications (e.g., process development work and cell line scale up), [***] and [***]. [***]. For clarity, any preclinical development costs for a Multi-Indication Antibody incurred [***]."

(b) The first two sentences of Section 2.8(a)(i) (*Exclusive Discovery Program; Exclusivity; General*) of the Existing Discovery Agreement are hereby amended as follows (inserted language underlined and in italics and deleted language in strikethrough text for ease of reference):

> "(i) General. Subject to the other subparagraphs in this Section 2.8, until the end of the Term, neither Party nor any of their respective Affiliates will either directly, or with any Third Party, work to discover Antibodies against, or develop or commercialize Antibodies against, Program Targets in the Territory, except pursuant to this Agreement or the License and Collaboration Agreement, *the IO Discovery Agreement or the IO License and Collaboration Agreement*. Furthermore, subject to the other subparagraphs in this Section 2.8, until the earlier to occur of (A) the Discovery Expiration Date, and (B) the effective termination of this Agreement, neither Regeneron nor any of its Affiliates will, either directly or with any Third Party, work to discover, develop or commercialize Antibodies in the Territory, except pursuant to this Agreement, ~~or~~ the License and Collaboration Agreement, *the IO Discovery Agreement or the IO License and Collaboration Agreement*."

(c) From and after the Amendment Effective Date, the reference in Section 2.4(a)(i) (*Target List*) of the Existing Discovery Agreement to [***] is hereby changed to refer to [***].

(d) The following new Section 2.19 is hereby added to Article 2 of the Existing Discovery Agreement and shall become the final section of such Article:

"2.19 Combination Therapies.

(a) Notwithstanding anything to the contrary herein, the development of any Antibody that is the subject of development under the Discovery Program (and that is not an IO Antibody or a Multi-Indication Antibody or a Refused Candidate) for use in combination with (i) any IO Discovery Program Antibody shall be permitted under this Agreement and governed by Section 2.10(b)(ii) of the IO Discovery Agreement, and (ii) any IO Licensed Product shall be permitted under this Agreement and governed by Section 5.6(d)(i) of the IO License and Collaboration Agreement.

(b) If the Parties do not agree to the development of any Antibody that is the subject of development under the Discovery Program (and that is not an IO Antibody or a Multi-Indication Antibody or a Refused Candidate) for use with an IO Discovery Program Antibody that is proposed by [***], then, notwithstanding anything to the contrary herein, [***] may [***]."

3. Amendments to Article 4 (Payments).

(a) The "Maximum Annual Discovery Program Costs" in Section 4.2 of the Existing Discovery Agreement are hereby amended and restated in their entirety to read as follows:

Contract Year	Maximum Annual Discovery Program Costs
1 (ending December 31, 2008)	US $75,000,000
2	US $100,000,000
3	US $160,000,000
4	US $160,000,000
5	US $160,000,000
6	US $160,000,000
7	US $160,000,000
8	US $145,000,000
9	US $130,000,000
10 (ending December 31, 2017)	US $130,000,000

(b) The following sentence is hereby added to become the final sentence of Section 4.5 (*Royalty Payments for Royalty Products*) of the Existing Discovery Agreement:

"For clarity, Regeneron shall not owe any royalty or other payment to Sanofi under this Agreement with respect to any product that is an IO Licensed Product under the IO License and Collaboration Agreement or a Licensed Product under the License and Collaboration Agreement. For the avoidance of doubt, neither Party shall owe any royalty or other payment to the other Party under this Agreement with respect to "REGN2810" (as defined in the IO License and Collaboration Agreement)."

(c) The following new Section 4.11 is hereby added to Article 4 of the Existing Discovery Agreement as the penultimate section of such Article:

> "4.11 Right to Offset Payments. Subject to Section 4.9, each Party shall have the right to offset any amount owed by the other Party to such first Party under or in connection with this Agreement [***], including pursuant to this Article 4 or in connection with any breach, against any payments owed by such first Party to such other Party under this Agreement; provided, however, that no such offset shall be permitted to the extent and for so long as such other Party is contesting in good faith its obligation to make any such payment to such first Party under the applicable dispute resolution procedures of this Agreement [***]. Such offsets shall be in addition to any other rights or remedies available under this Agreement and applicable Law."

(d) The following new Section 4.12 is hereby added to Article 4 of the Existing Discovery Agreement as the final section of such Article:

> "4.12 No Double Counting. Any specific cost or expense paid or reimbursed under this Agreement or any Ancillary Collaboration Agreements shall be paid or reimbursed only once so as to avoid any "double counting," regardless of whether such cost or expense is reflected in more than one plan or budget under this Agreement or the Ancillary Collaboration Agreements."

4. Amendments to Article 5 (Opt-In Rights to License Product Candidates).

(a) The following sentence is hereby added to become the final sentence of Section 5.6(i) (*Refused Candidate*) of the Existing Discovery Agreement:

> "Notwithstanding anything to the contrary in this Agreement or any Ancillary Collaboration Agreement, Regeneron shall not owe any royalty or other payments to Sanofi under this Agreement with respect to any "IO Royalty Product" (as defined in the IO Discovery Agreement) or any "IO Licensed Product" or "Terminated IO Product" (each as defined in the IO License and Collaboration Agreement)."

(b) The following new Section 5.7 is hereby added to Article 5 of the Existing Discovery Agreement and shall become the final section of such Article:

> "5.7 Rights with respect to IO Antibodies that are also non-IO Antibodies. Notwithstanding anything to the contrary in this Agreement or the License and Collaboration Agreement, but subject to Section 5.6 of this Agreement, in the event that Sanofi exercises its "Opt-In Rights" (under and as defined in the IO Discovery Agreement) with respect to a Multi-Indication Antibody that targets a Target, and such Multi-Indication Antibody becomes an IO Licensed Product under the IO License and Collaboration Agreement, such

Multi-Indication Antibody shall automatically cease to be an Antibody under this Agreement and shall instead be governed by the IO License and Collaboration Agreement, and any ongoing costs and expenses in connection with such Multi-Indication Antibodies shall be reimbursed by Sanofi under the IO License and Collaboration Agreement to the extent reimbursable for IO Licensed Products thereunder. Notwithstanding anything to the contrary in this Agreement or the IO Discovery Agreement, if any Multi-Indication Antibody becomes a "Refused Candidate" (as defined in the IO Discovery Agreement) pursuant to Section 5.3(a) of the IO Discovery Agreement, Regeneron shall have the right to develop such Multi-Indication Antibody outside of the Development Program at its own cost and expense."

5. Amendment to Article 6 (Newly Created Inventions). Section 6.2(e) of the Existing Discovery Agreement is hereby amended as follows (inserted language underlined and in italics and deleted language in strikethrough text for ease of reference):

"(e) ~~Each~~ *Neither* ~~P~~*p*arty shall have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004 *(Pub. L. 108-453, 118 Stat. 3596 (2004))*~~, 35 U.S.C. 103(c)(2)-(c)(3)~~ (the "CREATE Act") *by making filings or undertaking other activities under pre-AIA (Leahy-Smith America Invents Act), 35 U.S.C. § 103(c)(2)-(c)(3), or post-AIA, 35 U.S.C. § 102(c),* with respect to Joint Inventions, without the prior written consent of the other Party. In the event that a Party intends to invoke the CREATE Act, as permitted by the preceding sentence, it shall notify the other Party and the Parties shall reasonably cooperate and coordinate their activities with respect to any *such* submissions, filings or other activities ~~in support thereof~~. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act*, pre-AIA, 35 U.S.C. § 103(c)(2)-(c)(3), and post-AIA, 35 U.S.C. § 102(c)*. For the avoidance of doubt, nothing in this Section 6.2(e) shall amend or modify the determination of ownership of intellectual property as set forth in Section 6.1."

6. Amendment to Article XIV (Miscellaneous). The following sentence is hereby added to become the final sentence of Section 14.4 (*Entire Agreement*) of the Existing Discovery Agreement:

"Any variation between a provision of this Agreement and a corresponding or similar provision of the IO License and Collaboration Agreement or the IO Discovery Agreement shall not be considered in the interpretation of this Agreement, the IO Discovery Agreement or the IO License and Collaboration Agreement."

7. Miscellaneous.

(a) In accordance with Section 9.4 of the IO Discovery Agreement, the Parties shall mutually agree on the contents of their respective press releases with respect to the amendments made to the Existing Discovery Agreement pursuant to this First Amendment. Regeneron shall have the right to file or register this First Amendment and a notification thereof with the United States Securities and Exchange Commission.

(b) Each Party hereby represents and warrants to the other Party that the Existing Discovery Agreement, as hereby amended, constitutes the legal, valid and binding obligation of such Party and is enforceable against such Party in accordance with its terms, subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or at law). The Parties agree that the Existing Discovery Agreement, as specifically amended by this First Amendment, continues to remain in full force and effect.

(c) Unless the context suggests otherwise, if there is a direct conflict between the provisions of this First Amendment and the IO Discovery Agreement, then the IO Discovery Agreement shall govern.

(d) Nothing in this First Amendment is intended to alter or modify the rights and obligations of the Parties set forth in that certain (i) letter agreement between Sanofi (as successor-in-interest to Aventis Pharmaceuticals, Inc.) and Regeneron regarding the Existing Discovery Agreement as it relates to “PDGF,” dated as of May 1, 2013, or (ii) First Amendment to the Existing License and Collaboration Agreement dated as of May 1, 2013.

(e) The Parties shall execute such additional amendments to the Existing Discovery Agreement as the Parties determine in good faith are necessary to (i) give effect to the purpose and intent of the IO Discovery Agreement and/or the IO License and Collaboration Agreement and/or (ii) maintain the purpose and intent of the Existing Discovery Agreement in view of the IO Discovery Agreement and/or the IO License and Collaboration Agreement. This First Amendment may be amended only by a written instrument executed by Sanofi and Regeneron.

(f) This First Amendment may be executed in any number of individual counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Any executed counterpart of this First Amendment that is delivered via facsimile or electronic transmission (for example, through use of a Portable Document Format or “PDF” file) shall be deemed to have been so delivered with the intention that such facsimiled or electronically transmitted counterpart shall have the same effect as an executed original counterpart of this First Amendment.

(g) This First Amendment is governed by, construed and enforced in accordance with the laws of the State of New York, U.S.A., without regard to its conflict of laws principles that would require the application of the law of any other jurisdiction. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this First Agreement.

[*Signature Page Follows*]

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

IN WITNESS WHEREOF, each of the Parties has caused this First Amendment to be executed as of the date hereof by a duly authorized corporate officer.

SANOFI BIOTECHNOLOGY SAS

By:	/s/ Olivier Brandicourt
Name:	Olivier Brandicourt
Title:	Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By:	/s/ Leonard S. Schleifer
Name:	Leonard S. Schleifer, M.D., Ph.D.
Title:	President & CEO

Exhibit 10.4

AMENDMENT NO. 2 TO AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

This **AMENDMENT NO. 2** (this "Second Amendment") to that certain **AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT** by and between Sanofi Biotechnology SAS, a société par actions simplifee organized under the laws of France, as successor-in-interest to Aventis Pharmaceuticals, Inc. ("Sanofi"), sanofi-aventis Amerique du Nord, a partnership organized under the laws of France ("Sanofi Amerique") and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of the State of New York ("Regeneron") effective as of November 10, 2009 and amended as of May 1, 2013 (the "Existing License and Collaboration Agreement"), dated as of July 1, 2015 and executed as of July 27, 2015, is by and between Sanofi and Regeneron. Capitalized terms used but not defined in this Second Amendment have the respective meanings set forth with respect thereto in the Existing License and Collaboration Agreement. Each of Sanofi and Regeneron may be referred to in this Second Amendment individually as a "Party" and collectively as the "Parties".

WHEREAS, in connection with entering into that certain Immuno-Oncology License and Collaboration Agreement dated as of July 1, 2015 (the "IO License and Collaboration Agreement"), the Parties have agreed to certain amendments to the Existing License and Collaboration Agreement; and

WHEREAS, in accordance with Section 20.5 (*Amendments*) of the Existing License and Collaboration Agreement, the Parties desire to memorialize such amendments in this Second Amendment.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. Amendments to Definitions.

(a) References to the "Discovery Agreement" in the Existing License and Collaboration Agreement shall be deemed to refer to such Discovery Agreement, as the same may be amended from time-to-time, including by the amendment agreement between Sanofi and Regeneron of even date herewith.

(b) The definition of "Indication" in Section 1.59 of the Existing License and Collaboration Agreement is hereby amended and restated in its entirety to read as follows: "'Indication' means any disease, state or condition."

(c) The following definitions are hereby added to the Existing License and Collaboration Agreement as Sections 1.126, 1.127, 1.128, 1.129, 1.130, and 1.131 respectively:

"'Ancillary Collaboration Agreements' shall mean the Existing Discovery Agreement, the IO Discovery Agreement and the IO License and Collaboration Agreement."

"'IO Discovery Agreement' shall mean the Immuno-Oncology Discovery and Development Agreement by and between Sanofi and Regeneron, dated as of July 1, 2015, as the same may be amended from time-to-time."

"'IO Discovery Program Antibody' shall have the meaning ascribed to such term in the IO Discovery Agreement."

"'IO License and Collaboration Agreement' shall mean the Immuno-Oncology License and Collaboration Agreement by and between Sanofi and Regeneron, dated as of July 1, 2015, as the same may be amended from time-to-time."

"'IO Licensed Product' shall have the meaning ascribed to such term in the IO License and Collaboration Agreement."

[***]

2. Amendment to Article II (Collaboration). Section 2.6(a) (*Non-Compete*) of the Existing License and Collaboration Agreement is hereby amended as follows (inserted language underlined and in italics and deleted language in strikethrough text for ease of reference):

"Non-Compete. Without limitation of and in addition and subject to Section 2.8 of the Discovery Agreement, during the Term, except as set forth in this Agreement *(including in Section 5.7)* or Section 2.8 *or Section 5.7* of the Discovery Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall ~~D~~*d*evelop or ~~C~~*c*ommercialize any Competing Product."

3. Amendment to Article V (Development). The following new Section 5.7 is hereby added to Article V of the Existing License and Collaboration Agreement as the final section of such Article:

"5.7 Combination Therapies.

(a) The development of any Licensed Product for use with an "IO Discovery Program Antibody" (as defined in the IO Discovery Agreement) shall be permitted under this Agreement and governed by the terms of Section 2.10(b)(ii) of the IO Discovery Agreement. The development of any Licensed Product for use with an IO Licensed Product shall be permitted under this Agreement and governed by the terms of Section 5.6(d)(i) of the IO License and Collaboration Agreement.

(b) If the Parties do not agree to the development of any Licensed Product for use with an IO Licensed Product that is proposed by [***], then, notwithstanding anything to the contrary herein, [***] may [***].

(c) If the Parties do not agree to the development of any Licensed Product for use with an IO Discovery Program Antibody that is proposed by [***], then, notwithstanding anything to the contrary herein, [***] may [***]."

4. Amendment to Article IX (Periodic Reports; Payments). The following sentence is hereby added to become the final sentence of Section 9.3 (*Royalties*) of the Existing License and Collaboration Agreement:

"For the avoidance of doubt, no royalty or other payments shall be payable pursuant to Section 2.6(d) and 5.6 of this Agreement with respect to any product that is an "IO Licensed Product" or a "Special Termination Product" under the IO License and Collaboration Agreement. For the avoidance of doubt, neither Party shall owe any royalty or other payment to the other Party under this Agreement with respect to "REGN2810" (as defined in the IO License and Collaboration Agreement)."

5. Amendment to Article IX (Periodic Reports; Payments).

(a) The following new Section 9.13 is hereby added to Article IX of the Existing License and Collaboration Agreement as the penultimate section of such Article:

"9.13 Right to Offset Payments. Subject to Section 9.10, each Party shall have the right to offset any amount owed by the other Party to such first Party under or in connection with this Agreement **[***]**, including pursuant to this Article IX or in connection with any breach, against any payments owed by such first Party to such other Party under this Agreement; provided, however, that no such offset shall be permitted to the extent and for so long as such other Party is contesting in good faith its obligation to make any such payment to such first Party under the applicable dispute resolution procedures of this Agreement [***]. Such offsets shall be in addition to any other rights or remedies available under this Agreement and applicable Law."

(b) The following new Section 9.14 is hereby added to Article IX of the Existing License and Collaboration Agreement as the final section of such Article:

"9.14 No Double Counting. Any specific cost or expense paid or reimbursed under this Agreement or any Ancillary Collaboration Agreements shall be paid or reimbursed only once so as to avoid any "double counting," regardless of whether such cost or expense is reflected in more than one plan or budget under this Agreement or the Ancillary Collaboration Agreements."

6. Amendment to Article XX (Miscellaneous). Section 20.4 (*Entire Agreement*) of the Existing License and Collaboration Agreement is hereby amended as follows (inserted language underlined and in italics and deleted language in strikethrough text for ease of reference):

> "20.4 Entire Agreement. This Agreement, together with the Discovery Agreement and, solely to the extent referred to herein, the Ancillary Agreements contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof, provided that the ~~last~~ *penultimate* sentence of Section 14.4 of the Discovery Agreement shall apply with respect to any conflict or inconsistency between this Agreement and the Discovery Agreement. *Any variation between a provision of this Agreement and a corresponding or similar provision of the IO License and Collaboration Agreement or the IO Discovery Agreement shall not be considered in the interpretation of this Agreement, the IO Discovery Agreement or the IO License and Collaboration Agreement*."

7. Miscellaneous.

(a) In accordance with Section 9.4 of the IO Discovery Agreement, the Parties shall mutually agree on the contents of their respective press releases with respect to the amendments made to the Existing License and Collaboration Agreement pursuant to this Second Amendment. Regeneron shall have the right to file or register this Second Amendment and a notification thereof with the United States Securities and Exchange Commission.

(b) Each Party hereby represents and warrants to the other Party that the Existing License and Collaboration Agreement, as hereby amended, constitutes the legal, valid and binding obligation of such Party and is enforceable against such Party in accordance with its terms, subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or at law). The Parties agree that the Existing License and Collaboration Agreement, as specifically amended by this Second Amendment, continues to remain in full force and effect.

(c) Unless the context suggests otherwise, if there is a direct conflict between the provisions of this Second Amendment and the IO License and Collaboration Agreement, then the IO License and Collaboration Agreement shall govern.

(d) Nothing in this Second Amendment is intended to alter or modify the rights and obligations of the Parties set forth in that certain (i) letter agreement between Sanofi (as successor-in-interest to Aventis Pharmaceuticals, Inc.) and Regeneron regarding the Existing Discovery Agreement as it relates to "PDGF," dated as of May 1, 2013, or (ii) First Amendment to the Existing License and Collaboration Agreement dated as of May 1, 2013.

(e) The Parties shall execute such additional amendments to the Existing License and Collaboration Agreement as the Parties determine in good faith are necessary to (i) give effect to the purpose and intent of the IO Discovery Agreement and/or the IO License and Collaboration Agreement and/or (ii) maintain the purpose and intent of the Existing License and Collaboration Agreement in view of the IO Discovery Agreement and/or the IO License and Collaboration Agreement. This Second Amendment may be amended only by a written instrument executed by Sanofi and Regeneron.

(f) This Second Amendment may be executed in any number of individual counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Any executed counterpart of this Second Amendment that is delivered via facsimile or electronic transmission (for example, through use of a Portable Document Format or "PDF" file) shall be deemed to have been so delivered with the intention that such facsimiled or electronically transmitted counterpart shall have the same effect as an executed original counterpart of this Second Amendment.

(g) This Second Amendment is governed by, construed and enforced in accordance with the laws of the State of New York, U.S.A., without regard to its conflict of laws principles that would require the application of the law of any other jurisdiction. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Second Amendment.

[*Signature Page Follows*]

IN WITNESS WHEREOF, each of the Parties has caused this Second Amendment to be executed as of the date hereof by a duly authorized corporate officer.

SANOFI BIOTECHNOLOGY SAS

By:	/s/ Olivier Brandicourt
Name:	Olivier Brandicourt
Title:	Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By:	/s/ Leonard S. Schleifer
Name:	Leonard S. Schleifer, M.D., Ph.D.
Title:	President & CEO

Exhibit 10.5

Date:	August 5, 2015
To:	Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707
Attention:	Dominick Agron VP and Treasurer 777 Old Saw Mill River Road Tarrytown, NY 10591-6707
Facsimile:	(914) 847-1555
From:	Morgan Stanley & Co. International plc c/o Morgan Stanley & Co. LLC 1585 Broadway New York, NY 10036
Re:	Second Amendment of the Warrant Transaction between Morgan Stanley and Regeneron Pharmaceuticals, Inc. (this "**Amendment**")

Dear Sir/Madam:

Morgan Stanley & Co. International plc ("**Morgan Stanley**") and Regeneron Pharmaceuticals, Inc. ("**Issuer**") are parties to a warrant transaction evidenced by the Master Terms and Conditions for Base Warrants Issued by Regeneron Pharmaceuticals, Inc. dated as of October 18, 2011, supplemented by the written confirmation dated as of October 18, 2011 (as amended prior to the date hereof, the "**Confirmation**"). Terms used herein but are not otherwise defined shall have meanings assigned to them in the Confirmation.

Upon the effectiveness of each daily amendment as set forth in Paragraph 1 below, all references in the Confirmation to the "Number of Warrants" will be deemed to be to the Number of Warrants as amended hereby and all references in the Confirmation to the "Transaction" will be deemed to be to the Transaction as amended hereby.

1. *Amendments*. For each Unwind Date (as defined below), effective upon the closeout of Dealer's Hedge Positions on such Unwind Date, the Number of Warrants for each Component of the Transaction shall be reduced by $1/80^{th}$ of the Daily Number of Warrants (as defined below) for such Unwind Date, with each such Number of Warrants rounded up to the nearest whole number, except that the Number of Warrants for the Component with the latest Expiration Date shall be reduced by the aggregate number resulting from such rounding.

2. *Amendment Payment*. In consideration of the amendments to the Transaction, Issuer agrees to pay to Dealer on each Payment Date (as defined below) an amount in USD (the "**Daily Amendment Payment**") equal to the product of the Daily Number of Warrants for the related Unwind Date and the Amendment Payment Amount per Warrant (each as defined below); *provided* that the sum of the Daily Amendment Payments shall not exceed the Maximum Amendment Payment Amount (as defined below); *provided further*, that in lieu of payment in USD, Issuer may elect in its sole

discretion to satisfy, with respect to any Unwind Date, the Daily Amendment Payment in Shares as provided in Annex B hereto.

Daily Number of Warrants:	For any Unwind Date, a number of Warrants as determined by Dealer, in its good-faith, commercially reasonable discretion, with respect to which Dealer has closed out its Hedge Positions on such Unwind Date; *provided* that the sum of the Daily Number of Warrants shall not exceed the Maximum Number of Warrants (as defined below).
Maximum Number of Warrants:	909,112
Amendment Payment Amount per Warrant:	As set forth in Annex A, to be the amount specified for the relevant Unwind Date Price.
Maximum Amendment Payment Amount:	USD 398,957,597.38 (in the aggregate); *provided, however*, that: (i) the Maximum Amendment Payment Amount with respect to Unwind Dates where the Unwind Date Price is greater than USD 575.00 shall be USD 100,000,000.00 (in the aggregate); (ii) the Maximum Amendment Payment Amount with respect to Unwind Dates where the Unwind Date Price is greater than USD 550.00 shall be USD 200,000,000.00 (in the aggregate); and (iii) the Maximum Amendment Payment Amount with respect to Unwind Dates where the Unwind Date Price is greater than USD 525.00 shall be USD 300,000,000 (in the aggregate).
Payment Date:	For each Unwind Date, the third Currency Business Day following such Unwind Date.
Unwind Date:	Each Scheduled Trading Day during the Unwind Period on which Dealer has closed out its Hedge Positions in respect of Warrants.
Unwind Period:	Each Exchange Business Day during the period commencing on August 6, 2015 and ending on November 3, 2015 (inclusive).
Unwind Date Price:	For any Unwind Date, the volume-weighted average of the per Share prices at which Dealer purchases Shares in order to close out its Hedge Positions in respect of the Daily Number of Warrants on such Unwind Date; *provided* that Dealer shall not effect any such purchases at a price per Share in excess of the Limit Price.
Limit Price:	USD 585.00

3. *Representations and Warranties.*

(a) Each party represents to the other party that:

(i) It is duly organized and validly existing under the laws of the jurisdiction of its organization or incorporation and, if relevant under such laws, in good standing.

(ii) It has the power to execute this Amendment and any other documentation relating to this Amendment to which it is a party, to deliver this Amendment and any other documentation relating to this Amendment that it is required by this Amendment to deliver and to perform its obligations under this Amendment and has taken all necessary action to authorize such execution, delivery and performance.

(iii) Such execution, delivery and performance do not violate or conflict with any law applicable to it, any provision of its constitutional documents, any order or judgment of any court or other agency of government applicable to it or any of its assets or any contractual restriction binding on or affecting it or any of its assets.

(iv) All governmental and other consents that are required to have been obtained by it with respect to this Amendment have been obtained and are in full force and effect and all conditions of any such consents have been complied with.

(v) Its obligations under this Amendment constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms (subject to applicable bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditors' rights generally and subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or at law)).

(b) Issuer represents and warrants to and for the benefit of Dealer as follows:

(i) (A) On the date hereof, Issuer is not aware of any material non-public information regarding Issuer or the Shares and (B) its most recent Annual Report on Form 10-K, taken together with all reports and other documents subsequently filed by Issuer with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), when considered as a whole (with the more recent such reports and documents deemed to amend inconsistent statements contained in any earlier such reports and documents), does not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances in which they were made, not misleading.

(ii) On the date hereof and on each Payment Date, (A) the assets of Issuer at their fair valuation exceed the liabilities of Issuer, including contingent liabilities, (B) the capital of Issuer is adequate to conduct the business of Issuer and (C) Issuer has the ability to pay its debts and obligations as such debts mature and does not intend to, or does not believe that it will, incur debt beyond its ability to pay as such debts mature.

(iii) Issuer acknowledges its responsibilities under applicable federal securities laws, including, without limitation, Rule 10b-5 under the Exchange Act, in relation to the Transaction and its amendment.

(iv) Issuer is entering into this Amendment in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 under the Exchange Act ("**Rule 10b5-1**") or any other antifraud or anti-manipulation provisions of the federal or applicable state securities laws and that it has not entered into or altered and will not enter into or alter any corresponding or hedging transaction or position with respect to the Shares. Issuer acknowledges that it is the intent of the parties that this Amendment comply with the requirements of paragraphs (c)(1)(i)(A) and (B) of Rule 10b5-1 and this Amendment shall be interpreted to comply with the requirements of Rule 10b5-1(c).

(v) Issuer will not seek to control or influence Dealer's decision to make any "purchases or sales" (within the meaning of Rule 10b5-1(c)(1)(i)(B)(3)) of Shares during the period beginning on the first Unwind Date and ending on the last Unwind Date (such period, the "**Unwind Period**"), including, without limitation, Dealer's decision to enter into any hedging transactions. Issuer represents and warrants that it has consulted with its own advisors as to the legal aspects of its adoption and implementation of this Amendment under Rule 10b5-1.

(vi) Issuer acknowledges and agrees that any amendment, modification, waiver or termination of this Amendment must be effected in accordance with the requirements for the amendment or termination of a "plan" as defined in Rule 10b5-1(c). Without limiting the generality of the foregoing, any such amendment, modification, waiver or termination shall be made in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1,

and no such amendment, modification or waiver shall be made at any time at which Issuer is aware of any material non-public information regarding Issuer or the Shares.

(vii) In the event Issuer elects to pay the Amendment Payment by delivering Shares in accordance with Annex B hereto, the representation and agreement set forth in Section 9.11 of the Equity Definitions shall be true and correct at the time of such delivery, excluding any representations therein relating to restrictions, obligations, limitations or requirements under applicable securities laws.

4. *Covenants of Issuer during Unwind Period*. Issuer agrees with Dealer that during the Unwind Period:

(a) (i) the Shares or securities that are convertible into, or exchangeable or exercisable for Shares, are not, and shall not be, subject to a "restricted period," as such term is defined in Regulation M and (ii) Issuer shall not engage in any "distribution," as such term is defined in Regulation M, from the beginning of the Unwind Period until the second Exchange Business Day immediately following the Unwind Period;

(b) On any Unwind Date, neither Issuer nor any "affiliated purchaser" (as defined in Rule 10b-18) shall directly or indirectly (including, without limitation, by means of any cash-settled or other derivative instrument) purchase, offer to purchase, place any bid or limit order that would effect a purchase of, or commence any tender offer relating to, any Shares (or an equivalent interest, including a unit of beneficial interest in a trust or limited partnership or a depository share) or any security convertible into or exchangeable or exercisable for Shares; *provided* that, for the avoidance of doubt, (i) for purposes of this Section 4(b) "affiliated purchaser" shall not include Sanofi or any of its directly or indirectly wholly owned subsidiaries; and (ii) this Section 4(b) shall not preclude Issuer from receiving (or retaining) any Shares in payment of the option exercise price or receiving (or retaining) any Shares in respect of tax withholding or other similar tax obligation in connection with the exercise, vesting or delivery of any awards granted under Issuer's equity incentive award plans; *provided, further,* that nothing contained herein shall be deemed to prevent the exercise and settlement of any convertible bond hedging transaction entered into by the Issuer in connection with the issuance of its 1.875% Senior Convertible Notes due 2016; and

(c) it (A) will not make any public announcement (as defined in Rule 165(f) under the Securities Act) of any Merger Transaction or potential Merger Transaction unless such public announcement is made prior to the opening or after the close of the regular trading session on the Exchange for the Shares; and (B) shall promptly (but in any event prior to the next opening of the regular trading session on the Exchange on the first Unwind Date following such announcement) notify Dealer following any such announcement that such announcement has been made.

5. *Dealer. Activities during Unwind Period*.

(a) Dealer agrees with Issuer that, in connection with the closeout of any Hedge Positions pursuant to this Amendment on each Unwind Date, it shall use commercially reasonable efforts to make all purchases of Shares in a manner that would comply with the limitations set forth in clauses (b)(1), (b)(2), (b)(3), (b)(4) and (c) of Rule 10b-18, as if such rule were applicable to such purchases, taking into account any applicable Securities and Exchange Commission no-action letters as appropriate and subject to any delays between the execution and reporting of a trade of the Shares on the Exchange and other circumstances beyond Dealer's control.

(b) Dealer and Issuer agree and acknowledge that any transactions with respect to the Shares (including, without limitation, any hedging transactions) entered into by Dealer on any Unwind Date are entered into for Dealer's own account and on its own behalf and not for the account of, or on behalf of, Issuer.

6. *No Additional Amendments or Waivers*. Except as amended hereby, all the terms of the Transaction and provisions in the Confirmation shall remain and continue in full force and effect and are hereby confirmed in all respects.

7. *Counterparts*. This Amendment may be signed in any number of counterparts, each of which shall be an original, with the same effect as if all of the signatures thereto and hereto were upon the same instrument.

8. *Governing Law*. The provisions of this Amendment shall be governed by the New York law (without reference to choice of law doctrine).

Please confirm that the foregoing correctly sets forth the terms of our agreement by executing this Amendment and returning it in the manner indicated in the attached cover letter.

MORGAN STANLEY & CO. INTERNATIONAL PLC

By:	/s/ Stefan Ploetscher
Name:	Stefan Ploetscher
Title:	Executive Director

MORGAN STANLEY & CO. LLC
as Agent

By:	/s/ Sebastian Crapanzano
Name:	Sebastian Crapanzano
Title:	Managing Director

Agreed and Accepted By:

REGENERON PHARMACEUTICALS, INC.

By:	/s/ Dominick Agron
Name:	Dominick Agron
Title:	VP & Treasurer

ANNEX A

Unwind Date Price	Amendment Payment Amount per Warrant
$500.00	$398.12
$505.00	$403.10
$510.00	$408.09
$515.00	$413.07
$520.00	$418.06
$525.00	$423.04
$530.00	$428.03
$535.00	$433.01
$540.00	$438.00
$545.00	$442.98
$550.00	$447.97
$555.00	$452.95
$560.00	$457.94
$565.00	$462.92
$570.00	$467.91
$575.00	$472.89
$580.00	$477.88
$585.00	$482.86

For an Unwind Date Price falling between the amounts appearing in such column, the Amendment Payment Amount per Warrant will be calculated by Dealer using linear interpolation. If the Amendment Payment Amount per Warrant is otherwise not determinable pursuant to the foregoing because the Unwind Date Price is less than the lowest Unwind Date Price set forth above, the Amendment Payment Amount per Warrant will be determined by Dealer by linear extrapolation based on the two lowest Unwind Date Prices set forth above.

ANNEX B

SHARE SETTLEMENT PROVISIONS

1. Payment of any Daily Amendment Payment in Shares by Issuer shall be made by delivery on the Payment Date of a number of Shares satisfying the conditions set forth in paragraph 2 below (the "**Registered Settlement Shares**"), or a number of Shares not satisfying such conditions (the "**Unregistered Settlement Shares**"), in either case with a value equal to such Daily Amendment Payment, with such Shares' value determined by Dealer in good faith and in a commercially reasonable manner (which value shall, in the case of Unregistered Settlement Shares, take into account a commercially reasonable illiquidity discount).

2. Issuer may only deliver Registered Settlement Shares pursuant to paragraph 1 above if:

(a) a registration statement covering the public resale of the Registered Settlement Shares by Dealer (the "**Registration Statement**") shall have been filed with the Securities and Exchange Commission under the Securities Act and been declared or otherwise become effective on or prior to the date of delivery, and no stop order shall be in effect with respect to the Registration Statement; a printed prospectus relating to the Registered Settlement Shares (including any prospectus supplement thereto, the "**Prospectus**") shall have been delivered to Dealer, in such quantities as Dealer shall reasonably have requested, on or prior to the date of delivery;

(b) the form and content of the Registration Statement and the Prospectus (including, without limitation, any sections describing the plan of distribution) shall be reasonably satisfactory to Dealer;

(c) as of or prior to the date of delivery, Dealer and its agents shall have been afforded a reasonable opportunity to conduct a due diligence investigation with respect to Issuer customary in scope for underwritten offerings of equity securities and the results of such investigation are satisfactory to Dealer, in its good faith discretion; and

(d) as of the date of delivery, an agreement (the "**Underwriting Agreement**") shall have been entered into with Dealer in connection with the public resale of the Registered Settlement Shares by Dealer substantially similar to underwriting agreements customary for underwritten offerings of equity securities of a similar size by companies similar to Issuer, in form and substance reasonably satisfactory to Dealer, which Underwriting Agreement shall include, without limitation, provisions substantially similar to those contained in such underwriting agreements for offerings of a similar size by companies similar to Issuer relating, without limitation, to the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates and the provision of customary opinions, accountants' comfort letters and lawyers' negative assurance letters.

3. If Issuer delivers Unregistered Settlement Shares pursuant to paragraph 1 above:

(a) all Unregistered Settlement Shares shall be delivered to Dealer (or any affiliate of Dealer designated by Dealer) pursuant to the exemption from the registration requirements of the Securities Act provided by Section 4(a)(2) thereof;

(b) as of or prior to the date of delivery, Dealer and any potential purchaser of any such Unregistered Settlement Shares from Dealer (or any affiliate of Dealer designated by Dealer) identified by Dealer shall be afforded a commercially reasonable opportunity to conduct a due diligence investigation with respect to Issuer customary in scope for private placements of equity securities of a similar size by companies similar to Issuer (including, without limitation, the right to have made available to them for inspection all financial and other records, pertinent corporate documents and other information reasonably requested by them);

(c) as of the date of delivery, Issuer shall enter into an agreement (a "**Private Placement Agreement**") with Dealer (or any affiliate of Dealer designated by Dealer) in connection with the private placement

of such Unregistered Settlement Shares by Issuer to Dealer (or any such affiliate) and the private resale of such Unregistered Settlement Shares by Dealer (or any such affiliate), substantially similar to private placement purchase agreements customary for private placements of equity securities of a similar size by companies similar to Issuer, in form and substance commercially reasonably satisfactory to Dealer, which Private Placement Agreement shall include, without limitation, provisions substantially similar to those contained in such private placement purchase agreements for offerings of similar size by companies similar to Issuer relating, without limitation, to the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates and the provision of customary opinions, accountants' comfort letters and lawyers' negative assurance letters, and shall provide for the payment by Issuer of all commercially reasonable fees and expenses in connection with such resale, including all commercially reasonable fees and expenses of counsel for Dealer, and shall contain representations, warranties, covenants and agreements of Issuer reasonably necessary or advisable to establish and maintain the availability of an exemption from the registration requirements of the Securities Act for such resale; and

(d) in connection with the private placement of such shares by Issuer to Dealer (or any such affiliate) and the private resale of such shares by Dealer (or any such affiliate), Issuer shall, if so requested by Dealer, prepare, in cooperation with Dealer, a private placement memorandum in form and substance reasonably satisfactory to Dealer and customary for private placements of equity securities of similar size by companies similar to Issuer.

4. Dealer, itself or through an affiliate (the "**Selling Agent**") or any underwriter(s), will sell, in a commercially reasonable manner and over a commercially reasonable period, all, or such lesser portion as may be required hereunder, of the Registered Settlement Shares or Unregistered Settlement Shares and any Makewhole Shares (as defined below) (together, the "**Settlement Shares**") delivered by Issuer to Dealer pursuant to paragraph 5 below in a commercially reasonable manner commencing on the date one Settlement Cycle following the Termination Date (such date, the "**Net Share Settlement Date**" for purposes of Net Share Settlement by Issuer) and continuing until the date on which the aggregate Net Proceeds (as such term is defined below) of such sales, as determined by Dealer in a commercially reasonable manner, is equal to the Amendment Payment (such date, the "**Final Resale Date**"). If the proceeds of any sale(s) made by Dealer, the Selling Agent or any underwriter(s), net of any commercially reasonable fees and commissions (including, without limitation, commercially reasonable underwriting or placement fees) customary for similar transactions of a similar size under the circumstances at the time of the offering, together with commercially reasonable carrying charges and expenses incurred in connection with the offer and sale of the Shares (including, but without limitation to, the covering of any over-allotment or short position (syndicate or otherwise)) (the "**Net Proceeds**") exceed the Amendment Payment, Dealer will refund, in USD, such excess to Issuer on the date that is three (3) Currency Business Days following the Final Resale Date, and, if any portion of the Settlement Shares remains unsold, Dealer shall return to Issuer on that date such unsold Shares.

5. If the Calculation Agent determines that the Net Proceeds received from the sale of the Registered Settlement Shares or Unregistered Settlement Shares or any Makewhole Shares, if any, pursuant to this paragraph 5 are less than the Amendment Payment (the amount in USD by which the Net Proceeds are less than the Amendment Payment being the "**Shortfall**" and the date on which such determination is made, the "**Deficiency Determination Date**"), Issuer shall on the Exchange Business Day next succeeding the Deficiency Determination Date (the "**Makewhole Notice Date**") deliver to Dealer, through the Selling Agent, a notice of Issuer's election that Issuer shall either (i) pay an amount in cash equal to the Shortfall on the day that is one (1) Currency Business Day after the Makewhole Notice Date, or (ii) deliver additional Shares. If Issuer elects to deliver to Dealer additional Shares, then Issuer shall deliver additional Shares in compliance with the terms and conditions of paragraph 2 or paragraph 3 above, as the case may be (the "**Makewhole Shares**"), on the first Clearance System Business Day which is also an Exchange Business Day following the Makewhole Notice Date in such number as the Calculation Agent commercially reasonably believes would have a market value on that Exchange Business Day equal to the Shortfall. Such Makewhole Shares shall be sold by Dealer in accordance with the provisions above; *provided* that if the sum of the Net Proceeds from the sale of the originally delivered Shares and the Net Proceeds from the sale of any Makewhole Shares is less than the Amendment Payment then Issuer shall, at its election, either make such cash payment or deliver to Dealer further Makewhole Shares until such Shortfall has been reduced to zero.

6. Notwithstanding the foregoing, and without limiting the Issuer's ability to elect to settle any Daily Amendment Payment in Shares, as provided in this Annex B, in no event shall the aggregate number of Settlement

Shares and Makewhole Shares required to be delivered by the Issuer upon settlement of all Daily Amendment Payments so settled in Shares, in the aggregate, be greater than 250,000 Shares (the "**Maximum Number of Shares**"). For the avoidance of doubt, in no event will the Company be required to deliver cash in the event the aggregate number of Settlement Shares and Makewhole Shares required to be delivered by the Issuer upon settlement of all Daily Amendment Payments so settled in Shares, in the aggregate, would, but for the foregoing sentence, exceed the Maximum Number of Shares.

SEVENTEENTH AMENDMENT TO LEASE

THIS SEVENTEENTH AMENDMENT TO LEASE (this "Amendment") is entered into as of this 10th day of August, 2015, by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of December 21, 2006, as amended by that certain First Amendment to Lease dated as of October 24, 2007, that certain Second Amendment to Lease dated as of September 30, 2008, that certain Third Amendment to Lease dated as of April 29, 2009, that certain Fourth Amendment to Lease dated as of December 3, 2009, that certain Fifth Amendment to Lease dated as of February 11, 2010, that certain Sixth Amendment to Lease dated as of June 4, 2010, that certain Seventh Amendment to Lease dated as of December 22, 2010, that certain Eighth Amendment to Lease dated as of August 1, 2011, that certain Ninth Amendment to Lease dated as of September 30, 2011, that certain Tenth Amendment to Lease dated as of October 25, 2012, that certain Eleventh Amendment to Lease dated as of April 3, 2013, that certain Twelfth Amendment to Lease dated as of May 31, 2013, that certain Thirteenth Amendment to Lease dated as of May 31, 2013, that certain Fourteenth Amendment to Lease dated as of October 25, 2013, that certain Fifteenth Amendment to Lease dated as of June 12, 2014 and that certain Sixteenth Amendment to Lease dated as of June 30, 2015 (the "Sixteenth Amendment") (collectively, and as the same may have been further amended, amended and restated, supplemented or modified from time to time, the "Existing Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 755, 765, 767 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings" and each, a "Building");

B. WHEREAS, Landlord and Tenant desire to modify certain, terms, conditions and provisions of the Sixteenth Amendment; and

C. WHEREAS, Landlord and Tenant desire to modify and amend the Existing Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Existing Lease unless otherwise defined herein. The Existing Lease, as amended by this Amendment, is referred to collectively herein as the "Lease." From and

after the date hereof, the term "Lease," as used in the Existing Lease, shall mean the Existing Lease, as amended by this Amendment.

2. 777-G03 Surrender Premises. Notwithstanding anything to the contrary in the Sixteenth Amendment, Tenant desires to continue to lease from Landlord, and Landlord desires to continue to lease to Tenant, the 777-G03 Surrender Premises. In furtherance of the foregoing,

(a) the following terms, conditions and provisions of the Sixteenth Amendment are hereby deleted in their entirety (effective as of the Execution Date of the Sixteenth Amendment, as if such terms, conditions and provisions were not included therein): Recital G, Section 3.3(c) and Exhibit F;

(b) the following terms, conditions and provisions of the Sixteenth Amendment are hereby modified as follows (effective as of the Execution Date of the Sixteenth Amendment, as if such modifications were included therein):

(i) all of Section 2.1 (including subparts (a) and (b)) are hereby deleted and replaced with the following: "Surrender Requirements. The term "Surrender Requirements" as used in this Sixteenth Amendment shall mean with respect to any Premises surrendered, that such Premises are surrendered to Landlord in broom clean condition and in the condition required by the Lease for, and in accordance with the terms of the Lease with respect to, surrendering Premises, including, Section 19.2 of the Lease"; and

(ii) the first grammatical sentence of Section 3.3(b) is hereby amended by replacing the term "the later of (i) the 777-G03 Surrender Date and (ii) the 777-G03 Surrender Effective Date" with "August 10, 2015."

3. 777-SL1 Surrender Premises. The first grammatical sentence of Section 2.2(a) of the Sixteenth Amendment is hereby amended by replacing the phrase "the date (the "777-SL1 Surrender Date") that is five (5) business days after Tenant occupies Building 8 (or any portion thereof)" with "August 31, 2015 (the "777-SL1 Surrender Date")".

4. 777 C-Level 777C04 Premises. Notwithstanding anything to the contrary in the Sixteenth Amendment, Landlord and Tenant desire to modify the configuration of the 777 C-Level 777C04 Premises. In furtherance of the foregoing, the following terms, conditions and provisions of the Sixteenth Amendment are hereby modified as follows (effective as of the Execution Date of the Sixteenth Amendment, as if such modifications were included therein):

(a) Recital E. Recital E of the Sixteenth Amendment is hereby modified by replacing the term "sixteen thousand eight hundred sixty-three (16,863)" with the term "nine thousand nine hundred sixty-three (9,963)."

(b) Section 9.4. The first grammatical sentence of Section 9.4 of the Sixteenth Amendment is hereby amended by replacing the term "Eighty-One Thousand Five Hundred Forty-Five Dollars ($81,545)" with the term "Forty-Nine Thousand Eight Hundred Fifteen Dollars ($49,815)."

(c) Exhibit D. Exhibit D attached to the Sixteenth Amendment is hereby deleted in its entirety and replaced with the New Exhibit D attached to this Amendment.

(d) Exhibit I. Exhibit I attached to the Sixteenth Amendment is hereby deleted in its entirety and replaced with the New Exhibit I attached to this Amendment.

5. Broker. Tenant represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, other than Savills Studley, Inc. ("Tenant's Broker"), and agrees to reimburse, indemnify, save, defend and hold harmless Landlord for, from and against any and all cost or liability for compensation claimed by any such broker or agent, other than Tenant's Broker, employed or engaged by it or claiming to have been employed or engaged by it. Landlord represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, other than Matthew McDevitt and Transwestern (collectively, "Landlord's Broker" and together with Tenant's Broker, the "Brokers"), and agrees to reimburse, indemnify, save, defend and hold harmless Tenant for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by it or claiming to have been employed or engaged by it.

6. No Default. Tenant represents, warrants and covenants that, to the best of Tenant's knowledge, Landlord and Tenant are not in default of any of their respective obligations under the Existing Lease and no event has occurred that, with the passage of time or the giving of notice (or both) would constitute a default by either Landlord or Tenant thereunder.

7. Notices. Tenant confirms that, notwithstanding anything in the Lease to the contrary, notices delivered to Tenant pursuant to the Lease should be sent to:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attn: General Counsel;

with a copy to:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attn: Vice President of Facilities.

8. Effect of Amendment. Except as modified by this Amendment, the Existing Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. In the event of any conflict between the terms contained in this Amendment and the Existing Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties.

9. Successors and Assigns. Each of the covenants, conditions and agreements contained in this Amendment shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns and sublessees. Nothing in this section shall in any way alter the provisions of the Lease restricting assignment or subletting.

10. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

11. Authority. Tenant guarantees, warrants and represents that the individual or individuals signing this Amendment have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

12. Counterparts; Facsimile and PDF Signatures. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. A facsimile or portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the date and year first above written.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC,
a Delaware limited liability company

By:	/s/ Kevin M. Simonsen
Name:	Kevin M. Simonsen
Title:	Sr. VP, Real Estate Legal

TENANT:

REGENERON PHARMACEUTICALS, INC.,
a New York corporation

By:	/s/ Robert E. Landry
Name:	Robert E. Landry
Title:	SVP - Finance and Chief Financial Officer

NEW EXHIBIT D

777 C-LEVEL 777CO4 PREMISES

[Image]

NEW EXHIBIT I

TENANT'S PRO RATA SHARES

Portion of added "Premises" Means the Following:	**Square Feet of Rentable Area**	**Tenant's Pro Rata Share of the applicable Building**	**Tenant's Pro Rata Share of Existing Project (833,204)**	**Tenant's Pro Rata Share of the Entire Project (1,490,724)**
767 Premises	78,414	100%	9.411%	5.260%
777-01 North ROFO Premises	7,409	2.025%	0.889%	0.497%
777-02 North ROFO Premises	10,486	2.867%	1.259%	.703%
777 C-Level 777C04 Premises	9,963	2.724%	1.196%	0.668%
777-01 Northeast ROFO Premises	3,033	0.829%	0.364%	0.203%

Exhibit 10.7

COLLABORATION AGREEMENT

by and between

REGENERON IRELAND

and

MITSUBISHI TANABE PHARMA CORPORATION

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY. SUCH OMITTED PORTIONS, WHICH ARE MARKED WITH BRACKETS AND THREE ASTERISKS [***], HAVE BEEN SEPARATELY FILED WITH THE COMMISSION.

COLLABORATION AGREEMENT

This Collaboration Agreement (this "**Agreement**") effective as of September 29, 2015 (the "**Effective Date**"), is by and between Regeneron Ireland, a company organized and existing under the laws of Ireland ("**Regeneron**"), and Mitsubishi Tanabe Pharma Corporation, a company organized and existing under the laws of Japan ("**MTPC**"). Regeneron and MTPC are sometimes hereinafter referred to each as a "**Party**" and collectively as the "**Parties**."

WITNESSETH:

WHEREAS, Regeneron is developing a biopharmaceutical product incorporating an anti-NGF antibody known as fasinumab, as further described herein;

WHEREAS, MTPC and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing biopharmaceutical products in the Territory;

WHEREAS, Regeneron wishes to grant to MTPC, and MTPC wishes to accept, the exclusive right to develop and commercialize such biopharmaceutical product in the Field in the Territory, as more fully described in this Agreement;

WHEREAS, Regeneron wishes to supply, and MTPC wishes to have supplied, such biopharmaceutical product to MTPC for such development and commercialization, as more fully described in this Agreement; and

WHEREAS, Regeneron and MTPC desire to collaborate on such development and commercialization, as more fully described in this Agreement.

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I
DEFINITIONS

1.1 **Definitions**. When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement.

1.1.1 "**Accounting Standards**" means generally accepted accounting principles applicable to a Party in a particular country (e.g., Japanese Accounting Standards, U.S. Generally Accepted Accounting Principles or IFRS) as consistently applied throughout the applicable periods indicated herein by or on behalf of the relevant Party.

1.1.2 "**Adverse Event**" means any adverse medical occurrence in a patient or clinical investigation subject to whom a Product is administered and which could but does not necessarily have a causal relationship with the Product, including any unfavorable and unintended sign (including an abnormal laboratory finding, for example),

symptom, or disease temporally associated with the administration of the Product, whether or not considered related to or caused by Product administration.

1.1.3 "**Affiliate**" with respect to a Party means a Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with that Party. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interest of a legal entity; provided, that if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests. For avoidance of doubt, as of the Effective Date, Affiliates of Regeneron shall include Regeneron Pharmaceuticals, Inc., a wholly owned parent company of Regeneron.

1.1.4 "**Alliance Manager**" will have the meaning set forth in Section 3.1.7.

1.1.5 "**Alternate Manufacturing**" will have the meaning set forth in Section 8.6.

1.1.6 "**Antibody(ies)**" means a monoclonal antibody (whether fully human, fully mouse, humanized, phage display, chimeric, or any other type of antibody), whether multiple or single chain, recombinant, in vivo, in vitro or naturally occurring or a combination of the foregoing in any species, whole or fragment and any analogs, constructs, conjugates, fusions or chemical or other modifications or attachments thereof, or any derivative, or fragment thereof, and any composition or formulation that incorporates or includes any of the foregoing.

1.1.7 **"Anti-Corruption Laws"** means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, Article 197 of Japan's Penal Code, the Organization for Economic Co-operation and Development (OECD) Convention on combating bribery of foreign public officials in international business transactions, and any other applicable anti-corruption laws where MTPC operates.

1.1.8 "**Anti-NGF Antibody Product**" means a product that contains any Antibody that is intended to bind Nerve Growth Factor.

1.1.9 "**Applicable Laws**" means any federal, state, local, national and/or supra-national laws, statutes, rules and/or regulations, including any rules, regulations, guidance, guidelines or requirements of Regulatory Authorities, national securities exchanges or securities listing organizations, that may be in effect from time to time during the Term and apply to a particular activity hereunder and including laws, regulations and guidelines governing the import, export, development, manufacture,

marketing, distribution and/or sale of any Product in and outside of the Territory, as applicable to each Party.

1.1.10 "**Backup Product(s)**" means all [***]. Backup Product includes any of the foregoing [***] in any formulation, including any combination with one or more other active agents.

1.1.11 "**Biosimilar Product**" means, with respect to a Product in a particular country in the Territory, a product that (a) [***], (b) [***] and (c) [***].

1.1.12 "**BLA**" means with respect to each Product in a particular country or region in the Territory, an application seeking Marketing Approval from the Regulatory Authority in such country or region, including such an application submitted to the PMDA, to market and sell Product in such particular country or region.

1.1.13 "**Business Day**" means a day that is not a Saturday, Sunday or a day on which banking institutions in Tokyo, Japan, Dublin, Ireland or New York, New York are required by law to remain closed.

1.1.14 "**Calendar Quarter**" means (a) the period beginning on the Effective Date and ending on the next to occur of March 31, June 30, September 30 or December 31, and (b) each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31.

1.1.15 "**Calendar Year**" means the period beginning on the Effective Date and ending on the next December 31 to occur, and thereafter each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.1.16 "**Change of Control**" shall mean, with respect to MTPC, (a) a merger or consolidation of MTPC with a Competitive Third Party as of the closing, that results in the voting securities of MTPC outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Competitive Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of MTPC, or (c) the sale or other transfer to a Competitive Third Party of all or substantially all of MTPC's business to which the subject matter of this Agreement relates.

1.1.17 "**Clinical Supply Agreement**" will have the meaning set forth in Section 8.2.

1.1.18 "**Commercial Supply Agreement**" will have the meaning set forth in Section 8.3.

1.1.19 "**Commercialize**" or "**Commercialization**" means any and all activities relating to any registration, importing, distributing, marketing, selling, or other Sales and Marketing Activities for the Product in the Field in the Territory, including packaging, labeling, promotion, advertising, launching, marketing, sales, market research, obtaining pricing approvals, strategy, market access, pre-launch marketing, educational activities, distribution and/or import of the Product in compliance with this Agreement, and conducting medical affairs activities, whether conducted by a Party or for such Party by another; provided, however, that no Manufacturing activities are included in the Commercialization activities of MTPC under this Agreement.

1.1.20 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective as a global biopharmaceutical company similarly situated to such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that such efforts shall be at least substantially equivalent to those efforts and resources commonly used by such Party for a product owned by it, which product is at a similar stage in its development or product life and is of similar market potential (taking into consideration both anticipated total sales and overall profitability without consideration of any of the payments required to be made by such Party to the other Party under this Agreement). Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated or actual labeling, competitiveness of the product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical, marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time.

1.1.21 "**Committees**" will have the meaning set forth in Section 3.1.1.

1.1.22 "**Competitive Third Party**" means, as of any date, any Third Party that is [***].

1.1.23 "**Compliance Records**" will have the meaning set forth in Section 13.3(g).

1.1.24 "**Confidential Information**" of a Party hereunder means information of a confidential or proprietary nature disclosed by such Party to the other Party hereunder, whether disclosed in oral, written, graphic or electronic form, in connection with this Agreement or the performance of its obligations hereunder, including any such information related to any scientific, clinical, engineering, manufacturing, marketing, financial or personnel matters relating to a Party, or related to a Party's present or future products, sales, suppliers, customers, employees, investors, business plans, Know-How, regulatory filings, data, compounds, research projects, work in progress, future developments or business, in all such cases whether disclosed in oral, written, graphic or electronic form, and whether or not specifically marked as confidential or

proprietary, where under the circumstances in which such disclosure was made or the nature of information disclosed, such information would be reasonably expected to be confidential by the receiving party; provided, however, that in any event, Confidential Information excludes any information that (i) is known by recipient at the time of its receipt, and not through a prior disclosure by or on behalf of the disclosing Party, as documented by contemporaneous business records; (ii) is or becomes properly in the public domain through no fault of the recipient; (iii) is subsequently disclosed to the recipient, without obligations of non-disclosure or non-use, by a Third Party who may lawfully do so and is not directly or indirectly under an obligation of confidentiality to the disclosing Party, as documented by written business records in existence prior to the receipt of such information from the disclosing Party; or (iv) is developed by the recipient independently of, and without reference to or use of, the information received from the disclosing Party.

1.1.25 "**Control**" means with respect to any patent, patent application, trade secret, know-how, information, data or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to grant a license, sublicense or other right or access to or under, such patent, patent application, trade secret, know-how, information, data or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party at the time when such license, sublicense or other right or access is first granted hereunder.

1.1.26 **"Cost"** means both internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate.)

1.1.27 **"Country Net Sales Percentage"** will have the meaning set forth in Section 7.2.2.

1.1.28 **"CPI"** means the Consumer Price Index – All Urban Consumers for the applicable area in which the personnel are located (for example, CPI-U for New York-Northern New Jersey) published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index), or an equivalent index in a foreign country applicable to FTEs in such country, accounting if possible for the area in such country where the personnel are located.

1.1.29 **"CPI Adjustment"** means the percentage increase or decrease, if any, in the CPI applicable to applicable personnel for the twelve (12) months ending June 30 of the Calendar Year prior to the Calendar Year for which the adjustment is being made.

1.1.30 "**Develop**" or "**Development**" means activities directly and specifically relating to (a) clinical development, including, without limitation data collection and management, clinical studies (including research to design clinical studies), project management and drug safety surveillance activities related to clinical studies; (b) regulatory activities, including without limitation the preparation, submission and

maintenance of Regulatory Filings and Regulatory Approvals (including post-marketing clinical trials imposed by Applicable Law or as required by a Regulatory Authority) and seeking, obtaining and/or maintaining any Marketing Approval; and (c) any other development activities, including, without limitation, activities to support new indications in the Field either before or after the First Commercial Sale; in each case of (a), (b) and (c), solely for the Product in the Field in the Territory; provided, however, that no Manufacturing activities are included in the Development activities of MTPC under this Agreement. Regulatory Activities are included within Development activities.

1.1.31 **"Development Expenses Reimbursement"** will have the meaning set forth in Section 7.1.3.

1.1.32 "**Development Milestone Payment**" will have the meaning set forth in Section 7.1.4.

1.1.33 "**Distribution Rights Payment**" will have the meaning set forth in Section 7.1.2.

1.1.34 "**Embargoed Countries**" will have the meaning set forth in Section 13.4(b).

1.1.35 "**Executive Officers**" will have the meaning set forth in Section 3.6.2.

1.1.36 "**Export Control Laws**" will have the meaning set forth in Section 13.4(a).

1.1.37 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.1.38 "**Field**" means all human use.

1.1.39 "**Financing Sources**" will have the meaning set forth in Section 11.1.3.

1.1.40 "**First Commercial Sale**" means, with respect to a country in the Territory, the first commercial sale of a Product to a Third Party (or an Affiliate, if an end user of the Product) for use, consumption or resale in that country after obtaining Marketing Approval in that country.

1.1.41 **"FTE"** means a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [***] hours per year.

1.1.42 **"FTE Rate"** means [***] ($[***]), for the calendar years ending December 31, 2015 and December 31, 2016, such amount to be adjusted (effective as of January 1 of each subsequent Calendar Year, but such adjustment determined no later than the preceding June 30) with respect to the FTEs in a particular location, by the applicable CPI Adjustment.

1.1.43 "**Fully-Burdened Manufacturing Cost**" means the calculation of the fully burdened manufacturing cost of Products, Materials, placebo, comparator products and any device supplied by Regeneron to MTPC, its Affiliates or MTPC Distributors (or their designees) for use with the foregoing, as provided in Section 7.2.5, which equals [***].

[***]

1.1.44 "**Global Commercialization Plan**" means Regeneron's worldwide plan for the commercialization of the Products.

1.1.45 "**Global Development Plan**" means Regeneron's worldwide plan for the development of the Products.

1.1.46 "**GMP**" means the then-current good manufacturing practices required by the FDA and as set forth in the laws and regulations in the United States with respect thereto, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Laws and requirements of Regulatory Authorities applicable to the manufacture and testing of pharmaceutical materials in jurisdictions within the Territory, as they may be updated from time to time, including applicable rules and guidelines promulgated under the International Conference on Harmonization.

1.1.47 "**Governance Disputes**" will have the meaning set forth in Section 3.6.

1.1.48 **"Government Official**" will have the meaning set forth in Section 13.3(c).

1.1.49 "**Governmental Authority**" shall mean any court, agency, authority, department, regulatory body, or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city, or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.1.50 "**Indemnifying Party**" will have the meaning set forth in Section 14.3.

1.1.51 "**Indemnitee**" will have the meaning set forth in Section 14.3.

1.1.52 **"Indirect Taxes"** will have the meaning set forth in Section 7.9.2

1.1.53 "**Initial Purchase Price**" will have the meaning set forth in Section 7.2.1(a).

1.1.54 "**Interested Persons**" will have the meaning set forth in Section 13.3(d).

1.1.55 "**Invention**" means any Regeneron Invention, MTPC Invention or Joint Invention.

1.1.56 **"Inventory Report"** will have the meaning set forth in Section 7.2.1(c).

1.1.57 "**Joint Commercialization Committee**" or "**JCC**" will have the meaning set forth in Section 3.1.1.

1.1.58 "**Joint Development Committee**" or "**JDC**" will have the meaning set forth in Section 3.1.1.

1.1.59 "**Joint Development Study**" will have the meaning set forth in Section 4.3.1.

1.1.60 "**Joint Invention**" means any invention or discovery that is conceived, made, generated or reduced to practice during the Term in the performance of activities undertaken pursuant to this Agreement by employees, agents, or independent contractors of both (a) MTPC or its Affiliates or MTPC Distributors or MTPC Contractors and (b) Regeneron or its Affiliates.

1.1.61 "**Joint Manufacturing Committee**" or "**JMC**" will have the meaning set forth in Section 3.1.1.

1.1.62 "**Joint Steering Committee**" or "**JSC**" will have the meaning set forth in Section 3.1.1.

1.1.63 **"Key Regulatory Filings"** means (a) Investigational New Drug Applications (or similar filings in the Territory); (b) BLAs; (c) briefing books; and (d) any other material Regulatory Filing designated a Key Regulatory Filing by Regeneron.

1.1.64 "**Know-How**" means any and all proprietary, non-public information and data that is Controlled by Regeneron and that Regeneron in its reasonable discretion deems to be necessary for MTPC to Develop or Commercialize Products in the Field in the Territory and in accordance with this Agreement.

1.1.65 "**Legal Dispute**" will have the meaning set forth in Section 16.1.2(a).

1.1.66 "**Losses**" will have the meaning set forth in Section 14.1.

1.1.67 **"Manufacture"** or **"Manufacturing"** means activities directed to producing, manufacturing, processing and filling and finishing a product, including, without limitation, Product, placebo or a comparator agent, as the case may be.

1.1.68 "**Manufacturing Process Improvements**" will have the meaning set forth in Section 8.6.

1.1.69 "**Marketing Approval**" means, with respect to a Product, all Regulatory Approvals (including any applicable pricing approvals and reimbursement approvals) required by Applicable Laws to market and sell such Product for use within the Field in a country or region in the Territory.

1.1.70 "**Materials**" means any and all materials necessary, or, in Regeneron's reasonable judgment, useful, for MTPC to test or validate the Product in connection with MTPC's Development or Commercialization of the Product, supplied by Regeneron as set forth in Section 2.9.1.

1.1.71 [***]

1.1.72 "**MTPC Clinical Data**" will have the meaning set forth in Section 4.5.1.

1.1.73 "**MTPC Contractor**" means any Third Party that (i) MTPC or its Affiliates engages to perform any of MTPC's designated activities under this Agreement other than (a) to sell the Product or (b) to Develop and/or Commercialize the Product under the rights granted by Regeneron to MTPC hereunder and (ii) is either listed on the Approved MTPC Distributor/Contractor Appendix or otherwise approved by Regeneron in accordance with Section 2.6. Although the Parties do not currently anticipate that MTPC will grant any MTPC Distributor or MTPC Contractor the right to itself engage Third Parties to perform the functions of a MTPC Contractor as set forth in this definition, if a MTPC Distributor or MTPC Contractor does so, such Third Party shall be considered a MTPC Contractor for purposes of this Agreement.

1.1.74 "**MTPC Cost Share**" will have the meaning set forth in Section 4.3.1.

1.1.75 **"MTPC Cost Share True Up Payment"** will have the meaning set forth in Section 4.3.2.

1.1.76 [***]

1.1.77 "**MTPC Distributor**" means any Third Party that (i) MTPC or its Affiliates (a) engages to sell the Product or (b) grants any rights to Develop and/or Commercialize the Product under the rights granted by Regeneron to MTPC hereunder and (ii) is either listed on the Approved MTPC Distributor/Contractor Appendix or otherwise approved by Regeneron in accordance with Section 2.6. Although the Parties

do not currently anticipate that MTPC will grant any MTPC Distributor the right to itself engage Third Parties to perform the functions of a MTPC Distributor as set forth in this definition, if a MTPC Distributor does so, such Third Party shall be considered a MTPC Distributor for purposes of this Agreement. For the avoidance of doubt, a wholesale distributor, other distributor, pharmacy or end user who purchases Product from MTPC, its Affiliate or MTPC Distributor, in a bona fide, arm's length sale, shall not by virtue of such purchase be deemed a MTPC Distributor without otherwise meeting the definition of MTPC Distributor.

1.1.78 "**MTPC Indemnitees**" will have the meaning set forth in Section 14.2.

1.1.79 "**MTPC Invention**" means any invention or discovery that is conceived, made, generated or reduced to practice during the Term in the performance of activities undertaken pursuant to this Agreement by employees, agents, or independent contractors of MTPC or its Affiliates or MTPC Distributors or MTPC Contractors and is not a Joint Invention.

1.1.80 "**MTPC Product Trademark**" will have the meaning set forth in Section 10.8.4.

1.1.81 "**MTPC Regulatory Data**" means all data associated with all Regulatory Filings made by or on behalf of MTPC or its Affiliates or MTPC Distributors or MTPC Contractors with respect to Products and all data generated by or on behalf of MTPC or its Affiliates or MTPC Distributors or MTPC Contractors in the performance of Regulatory Activities.

1.1.82 "**MTPC Trademark**" means any trademark or trade name, and registrations and applications therefor, Controlled by MTPC in the Territory and covering MTPC's (or its Affiliate's) corporate name or company logo.

1.1.83 "**Net Sales**" means with respect to the Product, the gross amounts invoiced by MTPC or its Affiliates or MTPC Distributors to any Third Party for bona fide, arm's length sales of the Products in the Territory, less the following items, provided that they are bona fide and determined in the ordinary course of business in accordance with Accounting Standards, consistently applied:

(a) credits, refunds or allowances actually issued or granted to Third Party customers for spoiled, damaged, rejected, recalled, outdated and reasonably returned Product;

(b) normal and customary trade, cash and/or quantity discounts allowed and taken with respect to the Product sales;

(c) compulsory payments and rebates directly related to the sale of the Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;

(d) transportation charges, freight, postage and insurance (but only insurance related to protecting the particular shipment against physical loss or damage) if shown separately in the invoice; and

(e) sales, use or excise Taxes and import/export duties or tariffs and similar governmental charges actually due or incurred in connection with the sales of the Product (but excluding Taxes on income), if shown separately in the invoice.

Any of the items set forth in subsections (a)-(e) above that would otherwise be deducted from the invoice price in the calculation of Net Sales, but which are separately charged to and paid by Third Parties, shall not be deducted from the invoice price in the calculation of Net Sales.

Components of, and the timing of revenue recognition of, Net Sales shall be determined in the ordinary course of business in accordance with Accounting Standards, consistently applied. For purposes of determining when a sale of the Product occurs for purposes of calculating Net Sales, the sale will be deemed to occur when MTPC records such sale consistent with Accounting Standards. No deductions shall be made for commissions paid to individuals or agents, nor shall any deductions be permitted for the cost of collections. For purposes of determining Net Sales, a "sale" shall not include transfers or dispositions, at no cost, of the Products for charitable, pre-clinical, clinical or regulatory purposes or for promotional samples or free goods. Amounts invoiced by MTPC or its Affiliates or MTPC Distributors for the sale of the Products to or among such Affiliates or MTPC Distributors for resale shall not be included in the computation of Net Sales hereunder.

In the event that MTPC or its Affiliate or a MTPC Distributor sells a Product to any Third Party (a) in a bona fide arm's length transaction, for material consideration, in whole or in part, other than cash (but excluding, for the avoidance of doubt, consideration in the form of non-financial legal terms and conditions incident to sale) or (b) in a transaction other than a bona fide arm's length transaction, the Net Sales price for the Product shall be deemed to be the average standard invoice price then being invoiced by MTPC in an arm's length transaction with similar customers in the same country within the Territory during the applicable Calendar Quarter.

1.1.84 "**Notice**" will have the meaning set forth in Section 17.5.

1.1.85 "**Ongoing Phase 1 Trial**" means Regeneron's Clinical Trial known as R475-PN-1516 "A Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study to Investigate the Safety, Tolerability and Pharmacokinetics of Fasinumab in Healthy Japanese and Caucasian Subjects."

1.1.86 "**Patents**" means any and all patents and patent applications, including any additions, divisions, continuations, continuations-in-part, substitutions, reissues, reexaminations, extensions, registrations, patent term extensions, supplementary protection certificates and renewals of any of the above, that are Controlled by Regeneron during the Term and cover or claim the Product in the Field in the Territory.

1.1.87 **"Payee Party"** will have the meaning set forth in Section 7.9.1.

1.1.88 "**Paying Party**" will have the meaning set forth in Section 7.9.1.

1.1.89 "**Person**" means any individual, corporation, association, partnership (general or limited), joint venture, trust, estate, limited liability company, limited liability partnership, unincorporated organization, government (or any agency or political subdivision thereof) or other legal entity or organization.

1.1.90 "**Phase 3 Clinical Trial**" means a registration or pivotal clinical trial performed in subjects with a particular disease or condition which is designed in a randomized, controlled fashion to establish the efficacy and safety of a Product given its intended use and to define warnings, precautions and adverse events that are associated with Product in the dosage range intended to be prescribed. For clarity, a Phase 3 Clinical Trial shall not include the long-term treatment or safety study primarily designed to fulfill the FDA's safety data requirement.

1.1.91 "**Phase 2b/3 Clinical Trial**" means a registration or pivotal clinical trial performed in subjects with a particular disease or condition which is designed in a randomized, controlled fashion to establish the dose, efficacy and safety of a product given its intended use and to define warnings, precautions and adverse events that are associated with product in the dosage range intended to be prescribed. This study may be conducted in lieu of conducting separate Phase 2 and 3 studies and may be bridged to larger studies, whether or not such trial is referred to as a "phase 2b clinical trial", "phase 2b/3 clinical trial" or "phase 3 clinical trial" in Regulatory Filings or other submissions, notifications, communications, correspondence, registrations or filings made to, received from or otherwise conducted with a Regulatory Authority.

1.1.92 "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency.

1.1.93 "**Post-Marketing Surveillance**" means post-marketing surveillance required by a Regulatory Authority in Japan to ensure the efficacy and safety of Products after Marketing Approval of such Products and to establish proper methods of use of Product, consisting of three systems: the adverse drug reactions and infections collection and reporting system, the reexamination system, and the reevaluation system in Japan.

1.1.94 "**Product**" means (a) the Anti-NGF Antibody Product known as of the Effective Date as fasinumab or REGN475, or (b) any Backup Product included as a Product after the Effective Date pursuant to Section 2.3.

1.1.95 "**Product Trademark**" means a Regeneron Product Trademark or MTPC Product Trademark, as context requires.

1.1.96 "**Publication**" will have the meaning set forth in Section 11.3.1.

1.1.97 "**Purchase Price**" will have the meaning set forth in Section 7.2.1.

1.1.98 "**Purchase Price Adjustment A**" will have the meaning set forth in in Section 7.2.1(b).

1.1.99 **"Purchase Price Adjustment B"** will have the meaning set forth in Section 7.2.1(c).

1.1.100 **"Purchase Price Adjustments"** will have the meaning set forth in Section 7.2.1(c).

1.1.101 "**Purchase Price Adjustment Report**" will have the meaning set forth in Section 7.2.1(c).

1.1.102 **"Purchase Price Tier Net Sales"** will have the meaning set forth in Section 7.2.2.

1.1.103 "**Quality Agreement**" will have the meaning set forth in Section 8.5.

1.1.104 "**Regeneron Clinical Data**" will have the meaning set forth in Section 4.5.2.

1.1.105 "**Regeneron Indemnitees**" will have the meaning set forth in Section 14.1.

1.1.106 "**Regeneron Invention**" means any invention or discovery that is conceived, made, generated or reduced to practice during the Term in the performance of activities undertaken pursuant to this Agreement by employees, agents, or independent contractors of Regeneron or its Affiliates and is not a Joint Invention.

1.1.107 "**Regeneron Product Trademark**" will have the meaning set forth in Section 10.8.3.

1.1.108 "**Regeneron Regulatory Data**" means all data associated with regulatory filings made by or on behalf of Regeneron or its Affiliates with respect to Products and all data generated by or on behalf of Regeneron or its Affiliates in the

performance of non-clinical and clinical development activities or regulatory activities with respect to the Products or other activities pursuant to this Agreement.

1.1.109 "**Regeneron Trademark**" means any trademark or trade name, including registrations and applications therefor, that is Controlled by Regeneron and that covers the corporate name and/or company logo of Regeneron or one of its Affiliates.

1.1.110 "**Regulatory Activities**" will have the meaning set forth in Section 5.1.1.

1.1.111 "**Regulatory Approvals**" means, with respect to any country or region in the Territory, any approval, product and establishment license, registration or authorization of any Regulatory Authority required for the use, storage, Development or Commercialization (but not manufacture) of a Product in such country or region.

1.1.112 "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the manufacture, Development, Commercialization, reimbursement and/or pricing of Product in the Territory. "Regulatory Authority" includes the PMDA in Japan or the applicable governmental regulatory authority for any other country in the Territory, or any successor agency of the foregoing having regulatory jurisdiction over the manufacture, distribution and sale of drugs in any country or region in the Territory.

1.1.113 "**Regulatory Filings**" means any document (including any electronic document) that may be required for any Regulatory Approval or otherwise filed or submitted to a Regulatory Authority in the Territory in an effort to comply with Applicable Laws with respect to the Development or Commercialization of Products in the Territory.

1.1.114 **"Representatives"** means, with respect to a Party and its Affiliates, such Party's and its Affiliates' respective officers, directors, employees, agents and other representatives, and with respect to a MTPC Distributor or MTPC Contractor and its respective affiliates, such Person's and its affiliates' respective officers, directors, employees, agents and other representatives.

1.1.115 "**Safety Agreement**" will have the meaning set forth in Section 5.4.

1.1.116 "**Sales and Marketing Activities**" will have the meaning set forth in Section 6.4.

1.1.117 "**SDNs**" will have the meaning set forth in Section 13.4(b).

1.1.118 "**Tax**" or "**Taxes**" means (i) any taxes, including income, profits, gross receipts, net proceeds, sales, alternative or add on minimum, ad valorem,

turnover, property, personal property (tangible and intangible), environmental, stamp, leasing, lease, user, duty, franchise, capital stock, transfer, registration, license, withholding, social security (or similar), unemployment, disability, payroll, employment, social contributions, fuel, excess profits, occupational, premium, windfall profit, severance, estimated, or other tax charges of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not and (ii) any liability of for the payment of any amounts of the type described in clause (i) as a result of the operation of law or any express obligation to indemnify any other person.

1.1.119 "**Term**" will have the meaning set forth in Section 15.1.

1.1.120 "**Territory**" means Japan, South Korea, Taiwan, Indonesia, Thailand, Philippines, Malaysia, Singapore, Vietnam, Myanmar and Sri Lanka.

1.1.121 **"Territory Benefited Activities"** means activities performed by Regeneron with respect to the Product outside of the Territory (other than Joint Development Studies or Regeneron's global development or commercialization of the Product as reflected in the Global Development Plan or Global Commercialization Plan). Such activities may include global branding, advisory boards and publications.

1.1.122 **"Territory Commercialization Plan**" means, with respect to a Product, the three (3) year rolling plan developed by the JCC and approved by the JSC for the Commercialization of such Product in the Territory, which shall include the following:

(a) the overall strategy for Commercializing such Product in the Territory, including target product profiles, branding, positioning, promotional materials, promotional activities, detailing strategies and core messages for such Product;

(b) all marketing related activities to support the Commercialization of such Product including advertising, market research, public relations, patient advocacy, KOL outreach and any other marketing programs for such Product in the Territory;

(c) the field force size and the number and position of details required to meet market and sales forecasts;

(d) anticipated launch dates for such Product for countries in the Territory;

(e) supply forecasts, in compliance with the Commercial Supply Agreement, for commercial supply of Products for the Territory;

(f) market and sales forecasts for Products for the Territory; and

(g) any medical affairs activities.

1.1.123 **"Territory Cooperation Activities"** means activities performed by or on behalf of Regeneron (whether required hereunder or otherwise agreed

to be performed by Regeneron) to cooperate with MTPC and/or assist MTPC for its Development (including obtaining Regulatory Approvals) and/or Commercialization of the Product in the Field in the Territory (e.g. regulatory inspections, preparation of regulatory submissions, etc.).

1.1.124 **"Territory Development Plan**" means, with respect to a Product, the three (3) year rolling plan developed by the JDC and approved by the JSC for the Development of Product in the Territory, which shall include the following:

(a) the overall strategies and timelines for Developing and obtaining Regulatory Approvals, including Marketing Approvals, for such Product in the Territory;

(b) the protocol synopses for clinical trials of such Product;

(c) the allocation of the Development activities and responsibilities between MTPC, its Affiliates and/or Third Party service providers; and

(d) a forecast for clinical supply of the Product, in compliance with the Clinical Supply Agreement.

A summary of MTPC's initial proposed Territory Development Plan is attached to this Agreement as the Summary of Initial Territory Development Plan Appendix.

1.1.125 **"Territory Product Changes"** means changes to the dose, formulation, delivery, Manufacturing or other changes to the form or Manufacturing of the Product in the Territory compared to the dose, formulation, delivery, form or Manufacturing of the Product that is being developed or commercialized by Regeneron outside the Territory, whether such changes are requested by MTPC or requested or required by a Regulatory Authority.

1.1.126 **"Territory Required Activities"** means activities requested or required by any Regulatory Authority in connection with MTPC's Development or Commercialization of the Product in the Territory that are not within MTPC's rights under this Agreement, including pre-clinical research or any change to manufacturing processes for the Product.

1.1.127 "**Third Party**" means a Person other than MTPC, Regeneron or their respective Affiliates.

1.1.128 "**Third Party Fill/Finish Provider**" means any Third Party engaged by Regeneron to perform filling, finishing, packaging and/or labeling of the Product for the Territory.

1.1.129 "**Trademark**" means all registered and unregistered trademarks (including all common law rights thereto), service marks, trade names, brand names, logos, taglines, slogans, certification marks, internet domain names, trade dress, corporate names, business names and other indicia of origin, together with the goodwill

associated with any of the foregoing and all applications, registrations, extensions and renewals thereof throughout the world, and all rights therein provided by international treaties and conventions, in each case, that are Controlled by the applicable Party during the Term.

1.1.130 "**Trademark License**" will have the meaning set forth in Section 10.8.3.

1.1.131 **"Upfront Payment"** will have the meaning set forth in Section 7.1.1.

1.1.132 "**Working Group**" will have the meaning set forth in Section 3.1.1.

ARTICLE II
EXCLUSIVE DEVELOPMENT AND COMMERCIALIZATION COLLABORATION

2.1 **MTPC as Exclusive Development and Commercialization Collaborator**. Subject to the terms and conditions of this Agreement (including without limitation Section 2.10), Regeneron hereby grants to MTPC during the Term the exclusive right to Develop and Commercialize Products in the Field in the Territory. Pursuant to such grant, subject to the terms and conditions of this Agreement, MTPC shall have the exclusive right during the Term to invoice and book all Product sales in the Field in the Territory and may exercise such right through its Affiliates and MTPC Distributors (subject to Section 2.6) at all times in compliance with the terms of this Agreement. For clarity, as between the Parties, Regeneron and its Affiliates shall retain exclusively all rights to Products, as described in detail in Section 2.10, other than the rights granted to MTPC in the Territory in the foregoing appointment or otherwise in this Agreement.

2.2 **Supply of Product for Development and Commercialization**. Regeneron shall supply (or have supplied) to MTPC (or at MTPC's request, any of MTPC's Affiliates and MTPC Distributors), and MTPC (or any such Affiliate or MTPC Distributor) shall purchase exclusively from Regeneron, Products for Development and Commercialization, subject to and under the provisions of this Agreement and, as applicable, the Clinical Supply Agreement and the Commercial Supply Agreement, including the forecasting and ordering mechanisms of such agreements.

2.3 **Backup Products and Additional Anti-NGF Antibody Products**. If Regeneron wishes to develop and commercialize a Backup Product inside or outside the Territory, it will notify MTPC. During the Term, Regeneron shall not develop and commercialize the Backup Product in the Territory without MTPC's prior written consent. If both Parties agree to Develop and Commercialize such Backup Product in the Territory, then such Backup Product shall be included in this Agreement as a "Product".

2.4 **Negative Covenants**.

2.4.1 **Exclusivity**.

(a) During the Term, except for the development of Products in the Field in the Territory as expressly contemplated in this Agreement, Regeneron will not, and shall ensure that its Affiliates and licensees of any Anti-NGF Antibody Product outside the Territory do not, develop, have developed, commercialize or have commercialized, or grant rights to a Third Party to develop, have developed, commercialize or have commercialized, any Anti-NGF Antibody Products, including any Backup Products (except under the circumstances described in Section 2.3), in the Field in the Territory.

(b) During the Term, except for the Development and Commercialization of Products in the Field in the Territory, as expressly contemplated in this Agreement, and solely using Product purchased from Regeneron pursuant to the Clinical Supply Agreement or Commercial Supply Agreement, MTPC will not, and shall ensure that its Affiliates and MTPC Distributors do not, manufacture, have manufactured, develop, have developed, commercialize or have commercialized any Anti-NGF Antibody Products in the Field in the Territory.

2.4.2 **Purchasing Product.** MTPC hereby covenants and agrees that during the Term it shall not, and it shall ensure that its Affiliates and MTPC Distributors do not, purchase, obtain or receive any Products or components thereof from any Third Party.

2.4.3 **Product Changes**. MTPC is not authorized to alter the Product without Regeneron's prior written consent. In the event that MTPC wishes to make any changes to the Product, the Parties shall discuss and resolve such matters in the JSC in accordance with Article III.

2.4.4 **Regeneron Sales**. During the Term, Regeneron will not, and shall ensure that its Affiliates and licensees do not, (a) provide any Product to any Third Party (except as instructed by MTPC) if Regeneron or its Affiliate, as applicable, has actual knowledge or reasonably believes that such Third Party, either directly or indirectly, is selling, or intends to sell such Product in the Territory; or (b) Develop or Commercialize any Product (except in accordance with this Agreement) in a manner intentionally directed for use of such Product in the Territory.

2.4.5 **MTPC Sales**. MTPC agrees it will Commercialize the Products solely within the Territory for use in the Field pursuant to the authority and rights granted to MTPC under this Agreement. During the Term, MTPC will not, and shall ensure that its Affiliates and MTPC Distributors do not, (a) provide any Product to any Third Party if MTPC or its Affiliate or MTPC Distributor, as applicable, has actual knowledge or reasonably believes that such Third Party, either directly or indirectly, is selling, or intends to sell such Product outside the Territory; or (b) Commercialize any Product in a manner intentionally directed for use of such Product outside the Field or outside the Territory.

2.4.6 **Regeneron Intellectual Property Rights.** The Parties acknowledge that [***].

2.5 **Diligence Obligations**. MTPC will use Commercially Reasonable Efforts to Develop and Commercialize the Product in the Territory in accordance with the terms of this

Agreement, the Territory Development Plan and the Territory Commercialization Plan, except to the extent and for so long as MTPC is reasonably unable to comply with any such plans due to (a) a delay in Regeneron's provision of clinical data arising from Regeneron's development of the Product outside of the Territory or (b) the requirements of the Regulatory Authorities in the Territory.

2.6 **MTPC Distributors and MTPC Contractors.** MTPC shall be responsible and liable under this Agreement for the acts and omissions of its MTPC Distributors and MTPC Contractors and its and their Representatives and compliance by MTPC Distributors and MTPC Contractors and such Representatives with the terms and conditions of this Agreement, to the same extent as MTPC would be responsible and liable hereunder if it performed the activities of MTPC Distributors, MTPC Contractors and/or Representatives itself. MTPC shall not (and shall ensure its Affiliates, MTPC Contractors and/or MTPC Distributors do not) engage or permit any Third Party to (a) distribute, sell or otherwise handle the Product in the Territory, (b) interact with any Government Official in connection with the activities contemplated under this Agreement or (c) perform a material portion of MTPC's Development or Commercialization of the Product in the Territory, in each case, other than MTPC Distributors or MTPC Contractors that possess the applicable rights under this Agreement to perform the activities in subsections (a), (b) and/or (c) and are listed on the Approved MTPC Distributor/Contractor Appendix or otherwise pre-approved in writing by Regeneron, which approval Regeneron will not unreasonably withhold, delay or condition. Notwithstanding the foregoing, Regeneron shall have the right to revoke its approval, including for a MTPC Distributor or MTPC Contractor listed on the Approved MTPC Distributor/Contractor Appendix, (i) within [***] from the Effective Date, in Regeneron's reasonable discretion or (ii) at any time, for any MTPC Distributor and/or MTPC Contractor that Regeneron has reason to believe (and has provided supporting evidence to MTPC) is conducting activities that materially violate MTPC's obligations under this Agreement. After such revocation, MTPC shall not be permitted to use such MTPC Distributor or MTPC Contractor in connection with Development or Commercialization of Product in the Territory, except if re-approved by Regeneron in writing.

2.7 **Know-How Disclosure.** At MTPC's reasonable request, Regeneron shall disclose the Know-How to MTPC. MTPC will use the Know-How only in connection with its activities under this Agreement, will not provide the Know-How to or for the benefit of any Third Party without the prior written consent of Regeneron and will use reasonable precautions to ensure the Know-How is secured and is shared only with those Persons who reasonably have a need to know such Know-How to assist MTPC in the exercise of its rights under this Agreement. For clarity, the Know-How and any tangible embodiments thereof are Confidential Information of Regeneron under this Agreement and subject to all provisions of Article XI. Any sharing of Know-How by MTPC shall be under confidentiality restrictions at least as stringent as those provided for in Article XI.

2.8 **Regeneron Activities.** Subject to MTPC's payment obligations under Article VII, Regeneron shall use Commercially Reasonable Efforts to perform or have performed (a) Territory Required Activities and Territory Cooperation Activities (b) Territory Product Changes approved by the JSC and (c) any Territory Product Change which is a change in dose of the Product required or requested by Regulatory Authority. Alternatively, Regeneron may elect for MTPC to perform Territory Required Activities, subject to Section 4.2.1 and other applicable provisions of this Agreement.

2.9 **Materials, Placebo and Comparator Product Transfer.**

2.9.1 At MTPC's reasonable request, Regeneron shall provide MTPC with any Materials and related information, as and to the extent (a) required by any Regulatory Authority or (b) otherwise mutually agreed by the Parties. MTPC shall pay Regeneron the [***] for such Materials and Regeneron shall supply such Materials pursuant to the Clinical Supply Agreement. Except as otherwise provided for under this Agreement or in a separate written agreement between the Parties, all Materials delivered to MTPC will remain the sole property of Regeneron.

2.9.2 MTPC shall and shall ensure that its Affiliates: (a) only use the Materials in furtherance of the testing and validation of Product supplied by Regeneron pursuant to the Clinical Supply Agreement or Commercial Supply Agreement, or otherwise for activities contemplated by this Agreement and in compliance with this Agreement, (b) only use Materials in compliance with Regeneron's protocols and instructions provided to MTPC, (c) not administer the Materials to any human, (d) not use or deliver any Materials to or for the benefit of any Third Party without the prior written consent of Regeneron and (e) use the Materials in compliance with all Applicable Laws. MTPC shall use the Materials provided under this Agreement with prudence and appropriate caution because not all of their characteristics may be known. Except as otherwise expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

2.9.3 Regeneron shall supply or have supplied to MTPC supplies of Product, placebo and comparator drugs for use in clinical trials in accordance with any Territory Development Plan, all pursuant to the Clinical Supply Agreement. MTPC will pay for such clinical materials [***], as provided in the Clinical Supply Agreement. The representations and other undertakings related to such clinical materials shall be as set forth in the Clinical Supply Agreement, and not in this Section 2.9.3.

2.10 **Reservation of Rights**. Except for the rights specifically granted in this Agreement, Regeneron reserves all rights in and does not grant to MTPC any licenses to any intellectual property, data, information, and regulatory filings and approvals owned, controlled or held by Regeneron. Except for the rights specifically granted in this Agreement, MTPC reserves all rights in and does not grant to Regeneron any licenses to any intellectual property, data, information, and regulatory filings and approvals owned, controlled or held by MTPC. For clarity, Regeneron retains the right to Manufacture or have Manufactured in the Territory, including without limitation Manufacturing rights with respect to the Product, placebo, comparator agent, other Anti-NGF Antibodies, or other products or technologies, and Regeneron retains the right to conduct or have conducted research, development and regulatory activities in the Territory relating to such Manufacture; provided, that Regeneron shall comply with Sections 2.3 and 2.4.1(a).

ARTICLE III
MANAGEMENT

3.1 **Management**.

3.1.1 **Committee Establishment**. The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "**JSC**"), a Joint Development Committee (the "**JDC**"), a Joint Commercialization Committee (the "**JCC**"), a Joint Manufacturing Committee (the "**JMC**") and such other committees or sub-committees as the Parties deem appropriate (collectively, with the JSC, JDC, JCC and JMC, "**Committees**"). The roles and responsibilities of the Committees are set forth in this Agreement and may be further designated by the Parties in writing. From time to time, the Committees may establish working groups (each, a "**Working Group**") to oversee particular projects or activities.

3.1.2 **Decision-making**. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.

3.1.3 **Membership**. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and MTPC, each of whom must be a senior executive, director or general manager, as applicable, from such Party. Each Party may replace its Committee members upon written notice (which may be via email) to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and MTPC. Each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue final minutes within thirty (30) days thereafter.

3.1.4 **Meetings**. Each Committee shall hold meetings at such times as the Parties shall jointly determine, but, except upon mutual agreement, in no event less frequently than (a) twice per year for the JSC, (b) once every Quarter for the JDC, (c) once every Quarter for the JCC, commencing, for the JCC, at the time mutually agreed by the Parties, and (d) once every Quarter for the JMC. If possible, the meetings shall be held in person at least once per year (to the extent practicable, alternating the site for such meetings between the Parties or their Affiliates) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, manufacture or Commercialization of any Product (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Days (but excluding any scheduled corporate holidays at either Party's head office) prior written notice (which may be via email), except that emergency meetings may be called with at least two (2) Business Days (excluding any scheduled corporate holidays at either Party's head office) prior written notice (which may be via email).

3.1.5 **Limited Powers**. None of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, to determine a Party's compliance with such terms or conditions or to waive compliance with this Agreement, other than by mutual agreement of the Parties.

3.1.6 **Standard of Performance**. The Committees shall exercise their decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Product in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field in the Territory by or through a Party or any of its Affiliates.

3.1.7 **Alliance Manager**. Each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and commercialization issues ("**Alliance Manager**") to facilitate ongoing communications and exchange of information between the Parties and to act as a liaison between the Parties. Each Party may replace its Alliance Manager at any time upon notice to the other Party.

3.2 **Joint Steering Committee.**

3.2.1 **Composition and Purpose**. The JSC shall have overall responsibility for the oversight and coordination of the Parties' activities related to Development and Commercialization of the Product in the Field in the Territory under this Agreement. The JSC shall be composed of at least three (3) senior executives, directors or general managers of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

3.2.2 **Specific Responsibilities**. The JSC shall in particular:

(a) annually review and approve the Territory Development Plan and the Territory Commercialization Plan;

(b) at least semi-annually review the efforts and progress of MTPC under the Territory Development Plan and Territory Commercialization Plan;

(c) review and approve the Development of the Product in the Field in the Territory in any new indications;

(d) discuss prospective launch dates and forecasts for the Commercialization of the Product in the Territory;

(e) review and approve any Territory Product Changes, other than changes in the dose of the Product in the Territory required or requested by a Regulatory Authority (subject at all times to Regeneron's final decision-making authority set forth in Section 3.6.2), and Territory Required Activities;

(f) oversee the other Committees and resolve matters referred by the other Committees to the JSC for decision-making and approval as set forth in this Agreement or otherwise, and to resolve matters on which such Committees are unable to reach consensus;

(g) consider and act upon such other matters as are specifically assigned to the JSC under this Agreement or otherwise agreed by the Parties;

(h) [***];

(i) discuss any Manufacturing Process Improvements requiring a material change in the Territory Development Plan or resulting in material supplementary Regulatory Activities by MTPC, its Affiliates or MTPC Distributors; and

(j) establish sub-committees of the JSC, as the JSC deems appropriate.

3.3 **Joint Development Committee.**

3.3.1 **Composition and Purpose**. The purpose of the JDC shall be to advise the JSC on the strategy for the Development of Products in the Field in the Territory. The JDC shall be initially composed of two (2) senior executives, directors or general managers of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

3.3.2 **Specific Responsibilities**. In particular, the JDC shall be responsible for:

(a) overseeing the development of, reviewing, commenting on and annually updating and presenting to the JSC for approval the Territory Development Plan;

(b) overseeing the implementation of the Territory Development Plan as directed by the JSC;

(c) reviewing, and proposing to the JSC for approval, Product labeling and proposed changes to Product labeling in the Territory;

(d) facilitating an exchange between the Parties of data, information and results relating to the Development of Products;

(e) formulating a life-cycle management strategy for Products in the Field in the Territory in concert with the JCC, including evaluating new opportunities for new formulations, delivery systems and improvements and presenting the same to the JSC for approval;

(f) overseeing, and coordinating the overall regulatory strategy for the Product in the Territory, the submission of Regulatory Filings (and any other submissions to Regulatory Authorities concerning the Product) in countries in the Territory, including

coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with Products;

(g) reviewing and approving protocols for all clinical trials for the Product in the Territory, including post-marketing non-approval trials, but excluding Post-Marketing Surveillance, and advising the JCC as to the acceptability of such protocols, including the right for the Regeneron representative(s) to the JDC to reject such protocols entirely;

(h) reviewing and approving all aspects of non-clinical activities to be performed by MTPC under Section 4.2.1; and

(i) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the JSC.

3.4 **Joint Commercialization Committee**.

3.4.1 **Composition and Purpose**. The purpose of the JCC shall be to advise the JSC on the strategy for the Commercialization of Products in the Field in the Territory. The JCC shall be initially composed of two (2) senior executives, directors or general managers of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

3.4.2 **JCC Responsibilities**. In particular, the JCC shall be responsible for:

(a) overseeing the development of, reviewing, commenting on and annually updating and presenting to the JSC for approval the Territory Commercialization Plan;

(b) overseeing the implementation of the Territory Commercialization Plan as directed by the JSC;

(c) to the extent described in Section 6.6, reviewing and approving marketing and promotional literature related to the Product in the Field in the Territory; developing and updating, as necessary, promotional guidelines for Product branding, positioning, core messages and promotional material messages, pricing and rebate/discount guidelines, and field force guidelines in the Field in the Territory and submitting material decisions with respect thereto for final approval by the JSC;

(d) defining target groups to be covered by overall marketing efforts in the applicable country in the Territory;

(e) establishing the trade dress for each Product, consistent with the guidelines established by the JSC, in the applicable country in the Territory and submitting material decisions with respect thereto for final approval by the JSC;

(f) reviewing and advising on Trademark usage for the Product in the Territory and submitting material decisions with respect thereto for final approval by the JSC;

(g) proposing the anticipated date of First Commercial Sale for the Product on a country-by-country basis in the Territory, to be submitted for JSC approval;

(h) [***];

(i) preparing short-term and long-term sales forecasts for each Product on a country-by-basis in local currency for countries in the Territory, in each case, to be submitted for JSC approval;

(j) reviewing protocols for all post-marketing non-approval trials, but excluding Post-Marketing Surveillance in the Territory and submitting the same to the JSC for final review;

(k) proposing the contents, design and layout of packaging for the Product in the Field in the Territory, to be submitted for JSC approval;

(l) in concert with the JDC, reviewing publications proposed by MTPC with respect to the Development of Product in the Territory, which shall be submitted to Regeneron for approval;

(m) formulating a life-cycle management strategy for the Product in the Territory and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC, each of which shall be submitted to the JSC for approval; and

(n) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement by the JSC.

3.5 **Joint Manufacturing Committee**. Working with the JSC, JDC and JCC, as appropriate, the Joint Manufacturing Committee shall be responsible for overseeing matters relating to the supply of Product to MTPC, its Affiliates and/or MTPC Distributors in the Territory, including supply forecasts, recalls, adoption of Manufacturing Process Improvements for the Product in the Territory, market withdrawals, and any other corrective actions related to the Product in the Territory, and for any other matters specifically assigned to the JMC by the JSC. The JMC shall be initially composed of two (2) senior executives, directors or general managers of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). The JMC shall review, discuss and approve all Territory Product Changes for final approval by the JSC; provided, however, no approval is required in the JMC, JDC or JSC in the event that any Territory Product Change requested or required by the Regulatory Authority is solely a change in dose of the Product. With respect to Manufacturing Process Improvements requiring a material change in the Territory Development Plan or any material supplementary Regulatory Activities by MTPC, its Affiliates or MTPC Distributors, the JMC shall discuss, but shall not have the authority to approve, whether MTPC will adopt such Manufacturing Process Improvements for the Product in the Territory, or whether Regeneron shall perform (or have performed) Alternate Manufacturing in accordance with Section 8.6.

3.6 **Resolution of Governance Disputes**. This Section 3.6 shall apply to the resolution of disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Article III ("**Governance Disputes**").

3.6.1 **Generally**. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible. In the case of any matter which cannot be resolved by the JCC, JDC or any Working Group, at the request of either Party, such matter shall promptly, and in any event within five (5) Business Days (but excluding any scheduled corporate holidays at either Party's head office) (or one (1) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution. In the event a unanimous vote on any matter cannot be obtained at the JSC within ten (10) Business Days (but excluding any scheduled corporate holidays at either Party's head office) after referral to it pursuant to this Section 3.6.1, then the Governance Dispute shall be referred as set forth in Section 3.6.2.

3.6.2 **Referral to Executive Officers**. In the event that the JSC is, after a period of ten (10) Business Days (but excluding any scheduled corporate holidays at either Party's head office) from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, then either Party may require that the matter be submitted to the CEO of Regeneron and MTPC (the "**Executive Officers**") for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within ten (10) Business Days (but excluding any corporate holidays at either Party's head office) of receiving such written notification. If the Executive Officers are unable to resolve such dispute in such period, then MTPC shall have the final decision-making authority with respect to any Governance Dispute that [***]; provided, however that at all times Regeneron shall have the final decision-making authority on any Governance Dispute [***] (i) that [***].

3.7 **Obligations of the Parties**. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

3.8 **Expenses**. Each Party will be responsible for all of its own travel and other costs and expenses for its respective members, designees and non-Committee invitees to attend meetings of, and otherwise participate on, the Committees.

3.9 **Relationship of Parties**. Nothing contained in this Agreement shall be deemed to make any Party or any member of the JSC or any other Committees a partner, agent or legal representative of the other Party. No member of the JSC or any other Committee shall have any authority to act for, or to assume any obligation or responsibility on behalf of, any other member of the JSC or any other Committee of the other Party. For the avoidance of doubt, this Agreement is not intended to create and may not be construed to create a partnership, joint venture, or entity of any kind between the Parties.

ARTICLE IV
PRODUCT DEVELOPMENT; DATA SHARING

4.1 **MTPC Development Activities**. MTPC shall have the exclusive right and responsibility to conduct or have conducted, or cause its Affiliates or MTPC Distributors to conduct or have conducted, in the Field in the Territory and in accordance with the terms of this Agreement, the Development activities set forth in the Territory Development Plan, at its sole expense. Subject to Section 2.2, MTPC will use Commercially Reasonable Efforts to conduct (or have conducted) Development of the Product in the Territory in a manner consistent with the Territory Development Plan, the terms and conditions of this Agreement and the requirements of all Applicable Laws. MTPC will provide all protocols for all clinical trials with respect to the Product in the Field in the Territory, including post-marketing non-approval trials, but excluding Post-Marketing Surveillance, to the JDC, within the timeframes and in the manner described in the Regulatory and Development Document Appendix. In any case where MTPC reasonably requests expedited review of protocols, Regeneron will use Commercially Reasonable Efforts to accommodate such request. Without limiting the applicability of the foregoing and the remainder of this ARTICLE IV, MTPC, through the JDC, will keep Regeneron informed of all material events and developments occurring in the course of the Development.

4.2 **Regeneron Development Activities.**

4.2.1 **Regeneron Non-Clinical Activities and Clinical Development Outside the Territory.** As between MTPC and Regeneron, Regeneron shall have the exclusive right and shall have sole discretion and control, at Regeneron's sole cost and expense (except as set forth herein with respect to Development Expenses Reimbursement and the MTPC Cost Share), over (a) all non-clinical activities with respect to Products both inside and outside of the Territory and (b) clinical and other development activities (including regulatory activities) with respect to Products outside of the Territory. Regeneron, through the JDC, will keep MTPC reasonably informed of all material events and developments occurring in the course of Regeneron's performance of such activities that are relevant to the Territory. Regeneron will also provide MTPC with all final protocols for all Regeneron sponsored clinical trials, and the investigator's brochures for such clinical trials, with respect to the Product in the Field outside of the Territory. Regeneron shall perform or have performed any mutually agreed non-clinical activities with respect to Product and Regeneron shall provide the data from such activities to MTPC for its use solely for the Development and/or Commercialization of the Product in the Territory. If Regeneron is unwilling or unable to perform any such non-clinical activities that are required by any Regulatory Authority, then upon mutual agreement of the Parties, MTPC may perform such activities; provided that all aspects of the performance of such activities, including the protocol and any Third Party engaged to perform such activities, are approved in advance by the JDC. Regeneron shall not unreasonably withhold consent for it (or, under the circumstances described above, MTPC) to perform any such non-clinical activities required by any Regulatory Authority.

4.2.2 **Regeneron Development Inside the Territory.** In addition to the foregoing, Regeneron and its Affiliates will have the right to develop the Product inside the Territory for the purpose of supporting marketing approval outside of the Territory, with the approval of the

JSC. Except as expressly set forth below in Section 4.3 for the sharing of costs for Joint Development Studies or elsewhere in this Agreement, Regeneron shall be responsible for the costs of such Product development activities in the Territory.

4.3 **Joint Development Studies**.

4.3.1 If Regeneron plans to develop the Product in any indication other than osteoarthritis and chronic low back pain in any global clinical trial both inside and outside of the Territory, then Regeneron shall provide MTPC with a development plan (including the proposed protocol) for such clinical trial, along with an estimated budget. Within [***] of delivery of such plan, protocol and budget, MTPC shall determine whether to participate in any such clinical trial. In the event that MTPC elects to participate in any such clinical trial, such clinical trial shall be deemed a "**Joint Development Study**", and Regeneron and MTPC shall mutually agree upon each Party's roles and responsibilities with respect to any such Joint Development Study. MTPC shall be responsible for bearing a portion of the Costs of any Joint Development Study (such portion, the "**MTPC Cost Share**"), which portion shall be calculated as follows: The MTPC Cost Share shall be equal to [***].

4.3.2 Within thirty (30) days after the end of each Calendar Quarter, (a) Regeneron shall provide MTPC with an accounting of the Costs that Regeneron and its Affiliates incurred in connection with the performance of each Joint Development Study and (b) MTPC shall provide Regeneron with an accounting of the Costs that MTPC and its Affiliates incurred in connection with the performance of each Joint Development Study. Regeneron shall calculate the payment due either to or from MTPC for the MTPC Cost Share (such payment, the "**MTPC Cost Share True Up Payment**"), as follows: (i) [***], less (ii) [***]. Regeneron shall provide its calculation of the MTPC Cost Share True Up Payment to MTPC within [***] after the end of each Calendar Quarter. If the MTPC Cost Share True Up Payment is a positive number, then MTPC shall pay such positive amount to Regeneron and if the MTPC Cost Share True Up Payment is a negative number, Regeneron shall pay such amount to MTPC. The Party to whom any payment is due under this Section 4.3.2 shall provide an invoice to the other Party for the applicable payment and such other Party shall make such payment within [***] after receipt of such invoice.

4.4 **Territory Development Plan**. No later than [***] from receipt of the Global Development Plan from Regeneron, MTPC shall prepare and submit to the JDC its first proposed Territory Development Plan, which shall be consistent with the Global Development Plan, except to the extent the Global Development Plan conflicts with Applicable Law or established practice in the Territory. The JDC shall promptly review such plan and confirm that the proposed Territory Development Plan complies with the Global Development Plan, and suggest any revisions to the proposed Territory Development Plan necessary for the JSC to approve such plan. Within [***] of such review, MTPC shall submit such proposed Territory Development Plan (as revised in accordance with the JDC review) to the JSC for review, comment and approval. Upon approval by the JSC, the revised plan shall be the Territory Development Plan. MTPC shall provide draft updates to the Territory Development Plan to the JDC at least four (4) months prior to the end of each Calendar Year, and the JDC will attempt to provide these updates to the JSC at least two (2) months before the end of the Calendar Year for review, comment and approval. Any updated Territory

Development Plan approved by the JSC shall replace the Territory Development Plan that was previously in effect.

4.5 **Clinical Development Data**.

4.5.1 **MTPC Clinical Data**. MTPC shall promptly, upon Regeneron's request (provided such request occurs no more than once per Calendar Quarter), provide Regeneron with copies (in such electronic form as may be reasonably requested by Regeneron) of the results of all Development for Products and any and all other information or data generated by or on behalf MTPC, its Affiliates, MTPC Contractors or MTPC Distributors with respect to the Development of the Product in the Field in the Territory, including all data collected or analyzed with respect thereto, and all study reports and documents summarizing or analyzing such data (collectively, "**MTPC Clinical Data**"). Certain documents, modules and other materials described in the Regulatory and Development Document Appendix that are within the definition of MTPC Clinical Data (including any key results memorandum or clinical study report), shall be provided in English at least to the extent specified in the Regulatory and Development Document Appendix. Regeneron and its Affiliates may use MTPC Clinical Data for the performance of Regeneron's obligations and exercise of its rights under this Agreement and are hereby granted a right of reference to and the right to use and incorporate some or all MTPC Clinical Data in any regulatory filings for Products outside the Territory or for other uses with respect to the development and commercialization of Products outside the Territory in accordance with Applicable Laws. For the avoidance of doubt, Regeneron and its Affiliates may provide MTPC Clinical Data (and extend the foregoing rights) to its and their subcontractors, licensees and development partners for the Product outside of the Territory.

4.5.2 **Regeneron Clinical Data**. During the Term, subject to Applicable Laws (and, with respect to any Joint Development Study, subject to MTPC paying to Regeneron the MTPC Cost Share), Regeneron will promptly (in such electronic form as may be reasonably requested by MTPC) provide the top line results and clinical study reports and pre-clinical study reports generated by or on behalf of Regeneron or its Affiliates from the development of the Product in the Field outside of the Territory, including for the Ongoing Phase 1 Trial, Phase 2b/3 Clinical Trials for osteoarthritis or chronic low back pain, any long-term treatment or safety study primarily designed to fulfill the FDA's safety data requirement for the Product and any Joint Development Studies (collectively "**Regeneron Clinical Data**"). If a Regulatory Authority in the Territory requires any other data Controlled by Regeneron or a further analysis of the data, Regeneron shall provide such data to MTPC or perform such analysis on the raw data and provide the analysis to MTPC, and if a Regulatory Authority requires raw data, then Regeneron will provide such raw data to MTPC, and in each case, such provided analysis or raw data may be provided to the Regulatory Authority, but only for the jurisdiction and Regulatory Authority request for which it was provided. If MTPC requests that Regeneron perform such analysis on an expedited basis, Regeneron will use good faith efforts to accommodate such request. MTPC and its Affiliates may only use Regeneron Clinical Data (and supplemental data described above in this Section 4.5.2) for seeking or maintaining Regulatory Approval for Products in accordance with Applicable Laws and this Agreement in the Field in the Territory. For the avoidance of doubt, MTPC may provide the foregoing

information (and extend the foregoing rights) to its Affiliates and MTPC Distributors for such use described in this Section.

4.6 **Quality Control Standards**. Each Party shall use its standard operating procedures and quality control procedures as necessary and appropriate for the conduct and analysis of clinical trials to be conducted by each Party for the Product, including the collection and processing of data. Upon reasonable prior notice and during normal business hours (and no more than once per year without cause), each Party shall have the right to review the other Party's internal processes and procedures for such clinical trials, and each Party will give appropriate attention to any comments, questions or concerns the other Party may have with respect to such processes and procedures.

4.7 **No Debarred Personnel**. In performing Development, MTPC will not, and shall ensure that its Affiliates and MTPC Distributors and MTPC Contractors do not, use the services of any employee or consultant who has been debarred by the FDA or any Regulatory Authority, or, to the best of MTPC's knowledge, is the subject of debarment proceedings by the FDA or any other Regulatory Authority. In performing the global development of the Product, Regeneron will not use the services of any employee or consultant who has been debarred by the FDA or any Regulatory Authority, or, to the best of Regeneron's knowledge, is the subject of debarment proceedings by the FDA or any other Regulatory Authority.

ARTICLE V
REGULATORY MATTERS

5.1 **Regulatory Activities**.

5.1.1 **Regulatory Activities**. Subject to, and in accordance with, the terms and conditions of this Agreement and the requirements of all Applicable Laws, MTPC, at its sole cost and expense, will use Commercially Reasonable Efforts to (a) take (or have taken) all actions necessary to prepare and file (or have filed) all Regulatory Filings with respect to the Product required to obtain Marketing Approvals in each country in the Territory; (b) respond in a timely fashion to requests for data and information from Regulatory Authorities with respect to the Product; and (c) meet with officials of Regulatory Authorities at such times as may be requested by such Regulatory Authorities with respect to the Product ("**Regulatory Activities**"). MTPC will have final decision-making authority over (and the right to control) all Regulatory Activities in the Territory; provided that all such Regulatory Activities will be conducted in a manner consistent with the Territory Development Plan and overseen by the JSC in accordance with Article III. Without limiting the applicability of the foregoing and the remainder of this ARTICLE V, MTPC, through the JSC, will keep Regeneron reasonably informed of all material events and developments occurring in the course of the Regulatory Activities, including scheduled MTPC regulatory strategy discussions and meetings with Regulatory Authorities in the Territory relating to the Product.

5.1.2 **Regeneron Assistance**. Upon written request of MTPC, Regeneron will use Commercially Reasonable Efforts to assist MTPC at MPTC's expense in connection with any meetings with, or requests from, Regulatory Authorities in the Territory related to the Product.

5.2 **MTPC Regulatory Data and Regulatory Approvals**.

5.2.1 **Regulatory Filings**.

(a) **Review**. The JDC shall coordinate communication and the exchange of information between the Parties with respect to Key Regulatory Filings to be prepared and submitted by or for MTPC in the Territory. MTPC shall provide Regeneron with copies of Key Regulatory Filings and summaries of other Regulatory Filings in the manner and within the timeframes set forth in the Regulatory and Development Document Appendix, and will allow Regeneron the time for review and comment on such Regulatory Filings set forth therein, prior to filing or submission of the applicable Regulatory Filing. All Regeneron comments to such Regulatory Filings shall be considered by MTPC in good faith. In any case where MTPC reasonably requests expedited review of Regulatory Filings, Regeneron will use Commercially Reasonable Efforts to accommodate such request. MTPC shall provide copies of all final Regulatory Filings in the original language to Regeneron promptly after its submissions of Regulatory Filings in the Territory.

(b) **Accelerated Reporting**. In the event that Applicable Laws require MTPC to report information to any Regulatory Authority on an accelerated basis such that MTPC is unable to comply with Section 5.2.1(a), MTPC will nonetheless comply with Section 5.2.1(a) to the fullest extent practicable and provide to Regeneron a prompt and reasonably detailed description of the event that triggered the accelerated reporting obligation as soon as reasonably practicable, but in no event later than three (3) Business Days (but excluding any scheduled corporate holidays at MTPC's head office) after MTPC obtains actual knowledge of such triggering event.

(c) **Copies**. Subject to Applicable Laws, MTPC will provide to Regeneron electronic copies of each Regulatory Filing as submitted to Regulatory Authorities (in the original language in which it was filed) and all MTPC Regulatory Data relevant thereto promptly following such submission in accordance with the Regulatory and Development Document Appendix. Regeneron will have a right of access, a right of reference and the right to use and incorporate all MTPC Regulatory Data in connection with any regulatory filings for Products outside the Territory or for other uses with respect to the development and commercialization of Products outside the Territory in accordance with Applicable Laws. For the avoidance of doubt, Regeneron may provide copies of Regulatory Filings (and extend its right of access, right of reference and the right to use and incorporate all MTPC Regulatory Data in connection with Products into regulatory submissions outside of the Territory) to its licensees and development partners.

(d) **Translations**. Those documents and information listed in the Regulatory and Development Document Appendix shall be provided to Regeneron by MTPC in the language and format and on the timeline set forth therein.

5.2.2 **Regulatory Meetings in the Territory**. MTPC will provide Regeneron (through the JDC) with advance notice of pre-scheduled meetings, teleconferences and other interactions to the extent reasonably practicable, regarding the Product with any Regulatory Authority in the Territory, and MTPC will provide (a) a copy of the applicable meeting request or request for advice or (b) a brief description of the topics to be presented or discussed at that meeting.

Subject to Applicable Laws, MTPC shall allow Regeneron to attend at its own cost and expense any such meeting as an observer (without any obligation on Regeneron to do so). MTPC will provide summaries of all meetings, discussions and correspondence with Regulatory Authorities in the manner and within the timeframes set forth in the Regulatory and Development Document Appendix.

5.2.3 **Ownership of Regulatory Filings and Regulatory Approvals**. MTPC will hold title to all Regulatory Filings and Regulatory Approvals (except with respect to data supplied by Regeneron and incorporated therein); provided, that, MTPC will file for and obtain Regulatory Filings and Regulatory Approvals in such manner as may be required under (but solely to the extent reasonably practicable under) the Applicable Laws of the applicable countries within the Territory to allow for the expeditious transfer thereof to Regeneron or Regeneron's designee pursuant to Section 15.9.2(a) upon termination of this Agreement.

5.3 **Provision of Regulatory Assistance to MTPC**. Regeneron will use Commercially Reasonable Efforts, at MTPC's request and expense, to assist MTPC in connection with its conduct of all Regulatory Activities in the Territory. Without limiting the foregoing, Regeneron shall provide MTPC with copies of any United States and European Medicines Agency regulatory filings, which includes biologics license applications, marketing authorization application dossiers and investigational new drug applications for Product filed by or on behalf of Regeneron for the Product and chemistry, manufacturing and control information for the Product and any material communications with applicable United States and European Union regulatory authorities, which includes any request for scientific advice, formal meeting minutes, and other material written communications between Regeneron and such regulatory authority including any minutes of inquiry generated by Regeneron, for Product, filed by or on behalf of Regeneron or its Affiliates, as necessary for MTPC to make Regulatory Filings for Product in the Territory, and all Regeneron Regulatory Data relevant thereto. MTPC will have a right of access, a right of reference and the right to use and incorporate all regulatory filings and Regeneron Regulatory Data provided to it pursuant to this Section 5.3 solely to support MTPC's Regulatory Activities, Development and Commercialization of Product in the Field in the Territory in accordance with the terms of this Agreement, including the Territory Development Plan and Territory Commercialization Plan. For the avoidance of doubt, MTPC may provide copies of the foregoing regulatory filings and Regeneron Regulatory Data (and extend the foregoing rights) to its Affiliates and MTPC Distributors.

5.4 **Safety; Adverse Event Reporting**. MTPC will be responsible, at its sole cost and expense, for: (a) collecting all pharmacovigilance and other drug safety data for the Product in the Territory as required by Applicable Laws; and (b) reporting any such data, including Adverse Events in the Territory, to the applicable Regulatory Authorities in the Territory, as appropriate to be in compliance with all Applicable Laws and (c) reporting all such data to Regeneron as set forth in the Safety Agreement. Without limitation to the foregoing, the Parties shall within ninety (90) days of the Effective Date execute a safety agreement setting forth the specific procedures to be used by the Parties to coordinate the investigation of safety issues and the exchange of necessary safety and pharmacovigilance information including reports of adverse drug experiences and Product complaints to ensure timely communication to Regulatory Authorities and compliance with

Applicable Laws (the "**Safety Agreement**"). The Safety Agreement will permit either Party to audit the other Party's safety-related activities, procedures and records applicable to the Product.

5.5 **Recalls**.

5.5.1 For each country in the Territory, MTPC and Regeneron will, through the JSC, confer and coordinate regarding their respective internal standard operating procedures (and any changes thereto) regarding Product recalls and the treatment of and response to Product complaints and inquiries as to safety, quality or efficacy of Products.

5.5.2 If either Party becomes aware of information about a Product indicating that it may not conform to the specifications of the Product set forth in the Clinical Supply Agreement or Commercial Supply Agreement, as applicable, or that there are potential adulterations, misbranding and/or other material adverse issues regarding safety of a Product (or otherwise that a recall or withdrawal of a Product is potentially at issue), it will as soon as practical (but in any event within such period as the Parties may mutually establish to ensure their respective compliance with Applicable Law) so notify the other Party. With respect to the Territory, the Parties will promptly meet to discuss such circumstances and to consider appropriate courses of action, including Product recalls. MTPC will consult with Regeneron regarding any decisions involving a potential recall, and shall not conduct any recall without mutual agreement of the Parties, except if required to do so by Regulatory Authorities or Governmental Authorities. MTPC shall implement and be responsible, at its sole expense (except as provided below), for all recalls of Product in the Territory, and will maintain complete and accurate records of any Product recall for such periods as may be required by legal requirements.

5.6 **Inspection Rights**. Not more than once per year, without cause, or at any time, with reasonable cause, Regeneron will have the right, at Regeneron's expense and on not less than thirty (30) days prior notice, to inspect the facilities where MTPC or its Affiliates, MTPC Contractors or MTPC Distributors store or handle, or have stored or handled, any Products and to audit the procedures of MTPC or its Affiliates, MTPC Contractors or MTPC Distributors for the storage and handling of Products for purposes of quality control. The Quality Agreement shall set forth MTPC's review and access rights with respect to Regeneron's manufacturing facilities to be used for the supply of Product to MTPC and its Affiliates and MTPC Distributors.

5.7 **Governmental Inspections and Inquiries**. MTPC will advise Regeneron promptly, but in no event later than five (5) Business Days after MTPC's receipt of notice thereof, of any planned Regulatory Authority visit to the portion of the facilities of MTPC or its Affiliates, MTPC Contractors or MTPC Distributors where Product is stored or handled or any material written inquiries by a Regulatory Authority concerning such facilities, the procedures of MTPC or its Affiliates, MTPC Contractors or MTPC Distributors for the storage or handling of Products, or the Development or Commercialization of Product in the Territory. If the Regulatory Authority makes an unannounced or unplanned visit to such facility(ies), or if MTPC does not have at least five (5) Business Days' notice of the visit, MTPC will inform Regeneron of the visit as soon as reasonably practicable, but in no event later than three (3) Business Days after MTPC obtains actual knowledge of the visit. MTPC will inform Regeneron, as soon as practicable, regarding the purpose and result of such visit or inquiry, and will provide to Regeneron copies of any minutes of the inspection

generated by MTPC or its Affiliates, MTPC Contractors or MTPC Distributors (as set forth in the Regulatory and Development Document Appendix) promptly following such inspection and any report or correspondence (as set forth in the Regulatory and Development Document Appendix) provided by MTPC, or its Affiliate, MTPC Contractor or MTPC Distributor, as the case may be, to the Regulatory Authority or issued by or provided by the Regulatory Authority to MTPC, or its Affiliate, MTPC Contractor or MTPC Distributor as the case may be, in connection with such visit or inquiry. If requested by MTPC, at MTPC's expense, Regeneron shall reasonably cooperate with MTPC to generate and provide any reports or correspondences required by any Regulatory Authority in connection with any such Regulatory Authority's inquiry into Manufacturing activities conducted for Product supplied by Regeneron.

ARTICLE VI
COMMERCIALIZATION; SALES AND MARKETING

6.1 **Regeneron Commercialization.** As between MTPC and Regeneron, Regeneron shall have the exclusive right and shall have sole discretion and control (at Regeneron's sole cost and expense) for all commercialization activities with respect to Products outside the Territory.

6.2 **MTPC Commercialization Activities**. MTPC shall have the exclusive right and responsibility to conduct or have conducted, or cause its Affiliates or MTPC Distributors to conduct or have conducted, in the Field in the Territory and in accordance with the terms of this Agreement, the Commercialization activities set forth in the applicable Territory Commercialization Plan, at MTPC's, its Affiliates' or MTPC Distributors' sole expense. MTPC will use Commercially Reasonable Efforts to Commercialize the Product in the Field in each country in the Territory.

6.3 **Territory Commercialization Plan**. No later than [***] prior to the anticipated First Commercial Sale of a Product in a country in the Territory, or within such other timeframe as mutually agreed (but in any event no earlier than [***] following the date that Regeneron provides the Global Commercialization Plan to MTPC), MTPC shall prepare and submit to the JCC its first proposed Territory Commercialization Plan, which shall be consistent with the Global Commercialization Plan, except to the extent the Global Commercialization Plan conflicts with Applicable Law or established practice in the Territory. The JCC shall promptly review such plan and confirm that the proposed Territory Commercialization Plan complies with the Global Commercialization Plan, and suggest any other revisions to the proposed Territory Commercialization Plan necessary for the JSC to approve such plan. Within [***] of such review, MTPC shall submit such proposed Territory Commercialization Plan (as revised in accordance with the JCC review) to the JSC for review, comment and approval (which the JSC shall endeavor to accomplish within [***] from receipt of the plan). Upon such approval by the JSC, the revised plan shall be the Territory Commercialization Plan. MTPC shall provide draft updates to the Territory Commercialization Plan to the JCC at least [***] prior to the end of each of MTPC's fiscal years, and the JCC will attempt to provide such updates to the JSC at least [***] before the end of MTPC's fiscal year for review, comment and approval. Any updated Territory Commercialization Plan approved by the JSC shall replace the Territory Commercialization Plan that was previously in effect.

6.4 **Sales and Marketing Activities**. Subject to, and in accordance with, the terms and conditions of this Agreement, the Territory Commercialization Plan, and the requirements of all Applicable Laws, MTPC, at its sole cost and expense, will have the sole responsibility, and will use Commercially Reasonable Efforts to, establish (or have established) a sales force and to market and sell (or have marketed and sold) the Product in each country in the Territory ("**Sales and Marketing Activities**"). Subject to Applicable Laws, MTPC will initiate Sales and Marketing Activities within the timeframes reasonably necessary to achieve the First Commercial Sale in each country in the Territory as soon as practically possible after obtaining Marketing Approval for Product in such country. MTPC will include proposed Sales and Marketing Activities in the Territory Commercialization Plan. MTPC shall not use the services of a sales representative employed by a Third Party without Regeneron's prior written consent and, upon such consent, any such sales representative shall be deemed a MTPC Contractor hereunder. MTPC will be responsible for (a) ensuring that all sales force personnel (including personnel from MTPC's own sales force and any sales force of any MTPC Distributor) comply with all Applicable Laws and (b) ensuring that sales representatives in such sales forces have minimum skill levels customary for sales representatives in the Field at major pharmaceutical companies in the applicable countries in the Territory.

6.5 **Pricing**. [***].

6.6 **Marketing and Promotional Literature**. MTPC shall submit to the JCC an English translation of all core marketing materials (e.g., master visual aids, speaker slide decks, convention panels) for the Product in the Territory, once before Product launch and then subsequently every Calendar Year prior to any sales force plan of action meeting for such year, and the JCC shall approve such materials and all core messages contained therein. All marketing and promotional literature related to the Product and used in the Territory by MTPC will be consistent with JCC-approved core messaging and Applicable Laws. All marketing materials (including print, convention panels, presentations, websites or other media) prepared by MTPC to be used at global conventions or medical education symposia that have attendees from regions outside the Territory (which conventions and symposia shall be mutually agreed by the JCC) shall be reviewed and approved by JCC for compliance with Applicable Laws and alignment with Regeneron's global positioning of the Product.

6.7 **Medical and Consumer Inquiries**. MTPC shall be responsible for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Products in the Field in the Territory. The Parties will work together to formulate responses to the major inquiries, which shall be used, if possible, by MTPC in the Territory and which may be used by Regeneron outside of the Territory. If Regeneron receives questions about Products in the Field in a country in the Territory, it shall refer such questions to MTPC, and MTPC shall be responsible for responding thereto. If MTPC receives a question about Products in the Field in a country outside of the Territory, it shall refer such questions to Regeneron, and Regeneron shall be responsible for responding thereto.

6.8 **Restriction on Bundling in the Territory**. If MTPC or its Affiliates or MTPC Distributors sell a Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, MTPC agrees not to, and to require its Affiliates and

MTPC Distributors not to, bundle or include any Product as part of any multiple product offering or discount or price the Products in a manner that is reasonably likely to disadvantage a Product in order to benefit sales or prices of other products offered for sale by a MTPC or its Affiliates or MTPC Distributors to such customer.

6.9 **Restriction on Commercialization Activities.** MTPC further agrees that it shall refrain from pursuing a policy of directly or indirectly selling, advertising, promoting or marketing Products for sale outside of the Territory. Regeneron will use reasonable efforts to monitor and prevent the unauthorized importation of Products into the Territory and MTPC will use reasonable efforts to monitor and prevent the unauthorized importation of Products outside of the Territory. Each Party shall notify the other Party promptly if it becomes aware of, or reasonably suspects that, Product sold by the other Party is being diverted into or outside of the Territory, as the case may be.

ARTICLE VII
FINANCIAL TERMS

7.1 **Payments for Development and Commercialization Rights**. MTPC shall make the following payments to Regeneron at the times, in the manner and for the purposes described in this Section 7.1:

7.1.1 **Upfront Payment.** In consideration of MTPC's exclusive right to Develop the Product in the Territory, within fifteen (15) days of the Effective Date, MTPC shall pay a one-time, non-refundable, non-creditable payment of [***] United States Dollars (US$[***]) to Regeneron (such payment, the "**Upfront Payment**").

7.1.2 **Payment for Distribution Rights**. In consideration of MTPC's exclusive rights to Commercialize the Product in the Territory, within thirty (30) days of the date [***], MTPC shall make a one-time, non-refundable, non-creditable payment to Regeneron of [***] United States Dollars (US$[***]) (such payment, the "**Distribution Rights Payment**").

The Parties acknowledge that the Distribution Rights Payment is made as consideration for MTPC's exclusive rights to Commercialize the Product in the Territory.

7.1.3 **Reimbursement of Development Expenses.** The Parties acknowledge that Regeneron is currently developing the Product outside the Territory and MTPC will be Developing the Product inside the Territory under MTPC's exclusive right to Develop the Product in the Territory pursuant to this Agreement. The Parties intend to share clinical data from such activities in the manner described in this Agreement for promoting the development and regulatory activities by MTPC and Regeneron in and outside the Territory. The Parties intend to [***]. MTPC shall pay Regeneron [***] United States Dollars (US$[***]), as follows (such payment, the "**Development Expenses Reimbursement**"):

(a) within thirty (30) days of [***], a one-time, non-refundable, non-creditable payment to Regeneron of [***] United States Dollars (US$[***]);

(b) within thirty (30) days of [***], a one-time, non-refundable, non-creditable payment to Regeneron of [***] United States Dollars (US$[***]); and

(c) within thirty (30) days of [***], a one-time, non-refundable, non-creditable payment to Regeneron of [***] United States Dollars (US$[***]).

With respect to any Development Expenses Reimbursement, Regeneron shall provide to MTPC, [***], a report, the format and terms of which shall be mutually agreed by the Parties, describing [***].

7.1.4 **Development Milestone Payments**. In consideration of the know-how and other rights granted by Regeneron to MTPC hereunder, MTPC shall make one-time, non-refundable payments to Regeneron within thirty (30) days after the first achievement by MTPC, its Affiliates, MTPC Contractors or MTPC Distributors of each of the following milestone events for a Product (each a "**Development Milestone Payment**"):

	Development Milestone Event	**Development Milestone Payment (US$)**
(A)	[***]	$[***]
(B)	[***]	$[***]
(C)	[***]	$[***]
(D)	[***]	$[***]
(E)	[***]	$[***]
(F)	[***]	$[***]
(G)	[***]	$[***]

Each Development Milestone Payment shall only be payable once, regardless of the number of times a milestone is achieved by the Product. If any given Development Milestone Payment is due and one or more previous Development Milestone Payments for events that would reasonably have been anticipated to precede such Development Milestone Payment has not been paid for any reason, then payment of all such preceding unpaid Development Milestone Payments will be due at such time as well. For example, if Development Milestone Payment [***] were to become due, and the Development Milestone Payment [***] has not been paid, then the Development Milestone Payment [***]. Similarly, the achievement of milestone [***], if not previously paid; the achievement of milestone [***], if not previously paid; the achievement of milestone [***], if not previously paid; and the achievement of milestone [***], if not previously paid.

[***]

7.2 **Product Purchase Price**. The purchase price for the Product supplied under the Commercial Supply Agreement shall be paid in the manner and in the amount set forth in this Section 7.2:

7.2.1 MTPC will pay to Regeneron the purchase price (the "**Purchase Price**") for Product supplied under the Commercial Supply Agreement in three (3) parts.

(a) First, MTPC shall pay [***] ("**Initial Purchase Price**"), by multiplying (i) the number of units shipped, by (ii) the Initial Purchase Price per unit, calculated in accordance with Section 7.2.5, which shall be payable within [***] of the date of the invoice provided by Regeneron to MTPC for such Product.

(b) Second, MTPC will pay to Regeneron, following the end of each Calendar Quarter, the following payment adjustment ("**Purchase Price Adjustment A**") for Product supplied under the Commercial Supply Agreement, based on the aggregate annual Net Sales of the Product in the Territory in the applicable Calendar Year at the rates set forth below; provided, however, that previously paid amounts of Initial Purchase Price for the units of Product that were sold in such Calendar Year (i.e., excluding units of Product used for charitable purposes, clinical studies, regulatory or promotional use, or lost through expiration or otherwise) shall be fully creditable against the Purchase Price Adjustment A:

Annual Net Sales in Territory	**Purchase Price (% of Net Sales)**
On the portion of annual Net Sales of the Product in the Territory up to and including [***]	30%
On the portion of annual Net Sales of the Product in the Territory [***]	[***]%
On the portion of annual Net Sales of the Product in the Territory [***]	[***]%
On the portion of annual Net Sales of the Product in the Territory [***]	[***]%
On the portion of annual Net Sales of the Product in the Territory [***]	50%

(c) Third, MTPC will pay to Regeneron the following one-time, non-refundable, non-creditable payments ("**Purchase Price Adjustment B**," together with any Purchase Price Adjustment A, the "**Purchase Price Adjustments**") following the end of the Calendar Quarter in which the sales amounts described in the table below is first achieved:

	Sales Amounts	**Payment (US$)**
A)	First achievement of [***] of annual Net Sales of the Product in the Territory	$[***]
B)	First achievement of [***] of annual Net Sales of the Product in the Territory	$[***]
C)	First achievement of [***] of annual Net Sales of the Product in the Territory	$[***]
D)	First achievement of [***] of annual Net Sales of the Product in the Territory	$[***]
E)	First achievement of [***] of annual Net Sales of the Product in the Territory	$[***]

For purposes of the foregoing table, references to "annual Net Sales" shall mean [***]. Each Purchase Price Adjustment B shall only be payable once, regardless of the number of times the sales amounts described in the table above is achieved by the Product in subsequent Calendar Quarters.

All Purchase Price Adjustment payments made will be non-refundable and non-creditable against any other payments due hereunder or under the Commercial Supply Agreement, but will be adjustable as set forth in Sections 7.2.2, 7.2.3, 7.2.4 and 7.2.5.

[***]

MTPC will make Purchase Price Adjustment payments to Regeneron hereunder in arrears, within [***] from the end of each Calendar Quarter in which the underlying Net Sales occur.

Within [***] after the end of each Calendar Quarter, commencing with the first Calendar Quarter in which Net Sales occur, MTPC shall provide an inventory report (the **"Inventory Report"**) specifying a reconciliation of inventory of Product held by MTPC and its Affiliates and MTPC Distributors, including (a) such inventory balance at the beginning of such Calendar Quarter, (b) additions to such inventory during such Calendar Quarter, (c) the number of units of Product sold during such Calendar Quarter, (d) the number of units lost, destroyed or expired during such Calendar Quarter and (e) the inventory balance of Product at the end of such Calendar Quarter. The Inventory Report shall provide such information broken out by lot numbers for units of Product contained in such report. An example of the Inventory Report is set forth on the Inventory Report Appendix.

Within [***] after the end of each Calendar Quarter, commencing with the first Calendar Quarter in which Net Sales occur, MTPC shall provide a report (the "**Purchase Price Adjustment Report**"), for each country in the Territory in which sales of any Product occurred in the Calendar Quarter, specifying: (a) the gross sales (if available) and Net Sales (including a statement of the aggregate deductions taken from gross sales in the calculation of Net Sales) on a country-by-country basis, in each country's currency during such Calendar Quarter; (b) units sold per country in such Calendar Quarter, which in total will agree to the units sold in the Inventory Report for such Calendar Quarter; (c) the applicable Purchase Price Adjustment A percentage rate(s) under this Agreement for Product

sold during such Calendar Quarter, calculated as set forth above; (d) the Purchase Price Adjustments (including any Purchase Price Adjustment B) payable in the country's currency where such Net Sales occurred; (e) the applicable exchange rate to convert from each country's currency to United States dollars under Section 7.7; and (f) all credits applied against the Purchase Price Adjustment, and the final net Purchase Price Adjustment payable in United States dollars. An example of the Purchase Price Adjustment Report and a Purchase Price Adjustment calculation is set forth in the Purchase Price Adjustment Appendix.

7.2.2 Subject to Section 7.2.4, the Purchase Price Adjustment A for the Product as calculated pursuant to Section 7.2.1(b) will be [***]. For example, if the condition described in this Section 7.2.2 has occurred in any country, then [***].

7.2.3 Subject to Section 7.2.4, if MTPC is required to obtain a license from a Third Party under such Third Party's patents in order to Develop or Commercialize the Product in any country in the Territory (i.e., because the Commercialization of the Product in such country infringes upon a valid claim of such Third Party's patent), MTPC shall be entitled to deduct from the Purchase Price Adjustments of the Product as calculated pursuant to Section 7.2.1 [***], but in no event will such deduction, when combined with any reduction applied pursuant to Section 7.2.2, exceed the following amount in any Calendar Quarter: [***].

7.2.4 If the Purchase Price for the Product (calculated as the Purchase Price Adjustment that would be paid pursuant to Section 7.2.1, after any adjustments made pursuant to Sections 7.2.2 and 7.2.3, *plus* the Initial Purchase Price attributable to such units of Product in accordance with Accounting Standards) would be [***]. In the event MTPC is required to make an additional payment under this Section 7.2.4, then all credits that would otherwise have been applicable under Section 7.2.3 shall be reversed to the extent of the additional payments under this Section 7.2.4 (and MTPC shall retain such credits for possible application in future periods), and any reductions that would have been allowed under Section 7.2.2 shall be inapplicable to the extent necessary to provide for the payment required under this Section 7.2.4.

7.2.5 No later than [***] prior to the anticipated first delivery of Product to MTPC and [***] prior to the start of each Calendar Year thereafter, Regeneron will provide MTPC with the Fully Burdened Manufacturing Cost for each unit of Product for the upcoming Calendar Year, calculated in accordance with its customary cost accounting procedures, for purposes of the Initial Purchase Price payments under Section 7.2.1(a).

7.3 **Failed Lots**. During the Term, Regeneron shall provide MTPC reasonable documentation to support that a specific lot or batch was Manufactured for supply in the Territory pursuant to the Clinical Supply Agreement or Commercial Supply Agreement. Within thirty (30) days after the end of each Calendar Year, Regeneron shall provide to MTPC a report describing any Failed Lots of Product that was to be supplied to MTPC pursuant to the Clinical Supply Agreement or Commercial Supply Agreement during such Calendar Year. [***]. As used in this Section, "**Failed Lots**" means any Products, or raw materials, drug substances or intermediates thereof, which fail to meet specifications agreed by the Parties in separate agreements in accordance with Sections 8.2 and 8.3, identified by any quality or release tests conducted prior to delivery of the Product to MTPC (or at MTPC's request, any of MTPC's Affiliates or MTPC Distributors).

7.4 **Territory Product Changes Payments**. In the event that [***]. These payments shall be in addition to all other payments provided for in this Article VII; provided, however, that MTPC shall have no obligation to pay such additional amounts [***].

7.5 **Territory Required Activities and Territory Cooperation Activities Payments.** If Regeneron performs or has performed any Territory Required Activities or Territory Cooperation Activities at MTPC's request in order to support MTPC's Development or Commercialization of the Product in the Territory, then MTPC will reimburse Regeneron [***].

7.6 **Territory Benefited Activities**. If Regeneron performs any Territory Benefitted Activities and MTPC requests any data, information, results or materials from such Territory Benefitted Activities or otherwise to participate in or benefit from such Territory Benefitted Activities, then [***]. If [***], then Regeneron shall allow MTPC to otherwise participate in or benefit from the applicable Territory Benefitted Activities as mutually agreed.

7.7 **Payment Method and Currency**. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. Unless otherwise expressly set forth in this Agreement, all payments may be invoiced after becoming due under this Agreement and shall be made within [***] after receipt of such invoice. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due is calculated based upon sales made or amounts incurred in one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars at the average rate of exchange for the Calendar Quarter to which such payment relates using the arithmetic mean of the daily rate of exchange, as reported in Thomson Reuters Eikon as the Mid Price Close, or in the event that Thomson Reuters Eikon does not have data available for the Quarter, then in *The Wall Street Journal*.

7.8 **Interest on Overdue Payments**. Any amounts not paid by either Party when due under this Agreement will be subject to interest from and after the date payment is due through and including the date upon which such Party makes such payment in immediately available funds at a rate equal to the one (1) month London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in Thomson Reuters Eikon (or any other source agreed to by the Parties) effective for the date on which the payment was due, [***] or if lower, the maximum rate permitted by Applicable Law.

7.9 **Taxes**.

7.9.1 **Withholdings**. The Party making the payment under this Agreement (the "**Paying Party**") will make all payments to the Party receiving the payment under this Agreement (the "**Payee Party**") [***].

7.9.2 **Other Tax Liability**. Except as provided to the contrary in this Agreement, each Party shall be solely responsible for all federal, state and local Tax liability arising from this Agreement imposed on such Party by the taxing authority of a jurisdiction in which such Party is resident or is otherwise subject to such Tax liability. In the case of value added, goods and services, consumption or similar taxes incurred by a Party with respect to payments made to a Party hereunder or the activities underlying such payments ("**Indirect Taxes**"), each Party and their

Affiliates will use Commercially Reasonable Efforts to secure available exemption(s) from Indirect Taxes and/or to cooperate with the other Party's efforts to obtain maximum recovery of Indirect Taxes paid or incurred by such Party or any Affiliate, to the extent permitted by Applicable Law.

7.10 **Prohibited Payments**. Notwithstanding any of the provisions of this Agreement, if MTPC is prevented from paying any payments by virtue of the statutes, laws, codes or governmental regulations of the country from which the payment is to be made, then such payment may be paid by depositing funds in the currency in which it accrued to Regeneron's account in a bank reasonably acceptable to Regeneron in the country whose currency is involved.

ARTICLE VIII
REGENERON SUPPLY OF PRODUCT

8.1 **Regeneron Supply of Product**. Regeneron agrees to manufacture or have manufactured and supply or have supplied exclusively to MTPC Product for Development and Commercialization in the Territory, in exchange for the payments described herein and pursuant to the other terms and conditions of this Agreement, the Clinical Supply Agreement and Commercial Supply Agreement, as applicable. As of the Effective Date, Regeneron manufactures the Product in its own facilities. In its discretion, Regeneron may transfer a portion or all of such Manufacturing activities to one or more Third Parties, provided that in such case Regeneron shall remain responsible for the performance of such Third Parties.

8.2 **Clinical Supply Agreement**. Within [***] following the Effective Date (or such other mutually agreed timeframe), the Parties shall execute a definitive clinical supply agreement ("**Clinical Supply Agreement**") for the supply of Product and placebo to MTPC, its Affiliates and/or MTPC Distributors solely for use in Development in the Field in the Territory, at the Fully-Burdened Manufacturing Cost. Product supplied under the Clinical Supply Agreement shall meet the specifications set forth therein.

8.3 **Commercial Supply Agreement**. At least [***] prior to the expected date the first Marketing Approval is anticipated to be obtained, the Parties shall negotiate and execute a definitive commercial supply agreement ("**Commercial Supply Agreement**") for the supply of Product to MTPC for Commercialization in the Territory. The Commercial Supply Agreement shall conform in all material respects to the terms set forth in this Agreement. Regeneron may designate an Affiliate to enter into the Commercial Supply Agreement. Except as otherwise mutually agreed by the Parties and set forth in the Commercial Supply Agreement, Product supplied under the Commercial Supply Agreement shall be in filled, packaged and labeled form and shall meet the specifications set forth therein.

8.4 **Cost of Product under Commercial Supply Agreement**. The price for Product provided by Regeneron to MTPC under the Commercial Supply Agreement shall be the Purchase Price as provided in Section 7.2, plus applicable sales tax (if any).

8.5 **Quality Agreement**. Within [***] following the Effective Date (or such other mutually agreed timeframe) but in any event prior to the commencement of the first human clinical trials for the Product in the Territory, the Parties shall enter into a reasonable and customary GMP

quality agreement with respect to Product to be manufactured by or for Regeneron and supplied to MTPC under the Clinical Supply Agreement (the "**Quality Agreement**") and, at least [***] prior to the expected date the first Marketing Approval is anticipated to be obtained, the Parties shall review and, if applicable, amend such Quality Agreement, as the case may be, with respect to Product to be supplied to MTPC under the Commercial Supply Agreement for use in the Commercialization of the Product in the Territory.

8.6 **Manufacturing Process Improvements**. Notwithstanding anything to the contrary in this Agreement, the Commercial Supply Agreement, the Clinical Supply Agreement and/or the Quality Agreement, Regeneron shall have the right, in its discretion, to make improvements to and otherwise modify the Manufacture of the Product from time to time ("**Manufacturing Process Improvements**"). Regeneron will make all Manufacturing Process Improvements applicable to the Product in the Territory available to MTPC and Regeneron shall be solely responsible for its Costs in making any Manufacturing Process Improvement. Prior to adopting any Manufacturing Process Improvements for the Product in the Territory requiring a change in the Territory Development Plan or any supplementary Regulatory Activities by MTPC, its Affiliates, or MTPC Distributors, Regeneron shall provide sufficient information for MTPC to determine whether to adopt such Manufacturing Process Improvements. The Parties shall, at the JMC, and, if requested by MTPC, at any other Committees, discuss and mutually agree upon whether to adopt such Manufacturing Process Improvements and if so, the appropriate timing to adopt such Manufacturing Process Improvements. For clarity, MTPC shall be responsible for any Costs relating to Development or Regulatory Activities for the Product resulting from any Manufacturing Process Improvement. If MTPC elects not to adopt any such Manufacturing Process Improvement for the Product in the Territory, such that at any time the Product would need to be Manufactured in any manner other than Regeneron's method of Manufacturing of the Product with such Manufacturing Process Improvement (such requested manner, the "**Alternate Manufacturing**"), then Regeneron may, in its discretion, (a) perform such Alternate Manufacturing or (b) transfer a portion or all of such Alternate Manufacturing activities to one or more Third Parties at MTPC's cost, provided that in such case Regeneron shall remain responsible for the performance of such Third Parties.

ARTICLE IX
RECORDS AND REPORTING

9.1 **Reports**. In addition to the reports required to be provided pursuant to Article VII, MTPC will provide reports to Regeneron within thirty (30) days of the end of each Calendar Quarter during the Term summarizing MTPC's Development and Commercialization activities under this Agreement during such Calendar Quarter, including a general description of any clinical development activities, Regulatory Activities, and Sales and Marketing Activities by MTPC during such Calendar Quarter, and the date of the First Commercial Sale in a country (if applicable), if such activities occurred during such Calendar Quarter.

9.2 **Purchase Price Records**. MTPC will keep and maintain, and shall cause its Affiliates and MTPC Distributors to maintain, for five (5) years after the applicable book or record was created, or such longer period as may be required by Applicable Law, complete and accurate

books and records necessary to permit calculation and verification of the Purchase Price Adjustments due under Article VII.

9.3 **Audits**.

9.3.1 Upon not less than thirty (30) days prior written Notice to MTPC and not more often than once each Calendar Year, Regeneron may have an independent certified public accountant selected by Regeneron and reasonably acceptable to MTPC, examine during regular business hours the books and records required to be maintained under Section 9.2 and/or books and records of the Costs under Section 4.3.2(b), at Regeneron's expense, for the sole purpose of verifying the accuracy of the Purchase Price Adjustments payable to Regeneron hereunder and the associated reports furnished by MTPC with respect thereto, and/or the MTPC Cost Share, and solely for prior periods covering, for any particular audit, no more than the three (3) full Calendar Years prior to the date of such audit. Any amounts shown to be owed but unpaid as a result of such audit shall be paid within thirty (30) days from the accountant's report (plus interest on such amounts pursuant to Section 7.8), unless challenged as provided below. Any amounts shown to have been overpaid shall be refunded to MTPC within thirty (30) days from the accountant's report. Regeneron shall bear the full cost of such audit unless such audit discloses an underpayment of more than [***] of the amounts paid during such audit period, in which case MTPC shall bear the full reasonable out-of-pocket, external cost of such audit.

9.3.2 If MTPC challenges the results of the audit in good faith, MTPC shall be entitled at its own cost and expense to obtain a second independent certified public accountant to confirm the accuracy of the first audit. If the results of the confirmatory audit are substantially similar to the results of the first audit, any amounts owed or overpaid by MTPC shall be paid or refunded in accordance with the procedures above. If the results of the confirmatory audit are not substantially similar to the results of the first audit, each Party shall cause its respective auditors to identify the discrepancy and to agree on a final amount owed or overpaid (as the case may be) by MTPC that shall be final and binding on the Parties. If the auditors cannot resolve the discrepancy, the Parties shall submit the matter to the JSC. In the event that the JSC is unable to resolve such discrepancy within ten (10) Business Days (but excluding any scheduled corporate holidays at either Party's head office) of receipt by a Party of Notice of such dispute, either Party may submit the dispute to the Executive Officers for resolution, with neither Party's Executive Officers having the final right to decide the resolution of the dispute.

ARTICLE X
INTELLECTUAL PROPERTY PROVISIONS

10.1 **Inventions**.

10.1.1 Regeneron will retain sole ownership of all Regeneron Inventions and MTPC shall retain sole ownership of all MTPC Inventions. Each Party shall retain joint ownership of any Joint Inventions. During the Term, each Party shall have full rights to exploit and license such Joint Inventions (and any patent rights or other intellectual property rights therein or thereto), without the consent of the other Party or any obligation or requirement of an accounting to the other Party, (a) in the case of MTPC, solely in the Territory (subject to Regeneron's reservation

of rights under Section 2.10), and (b) in the case of Regeneron, solely outside the Territory. During the Term, neither Party shall exploit and/or license any such Joint Inventions (and any patent rights or other intellectual property rights therein or thereto), without the consent of the other Party, (x) in the case of MTPC, outside the Territory, and (y) in the case of Regeneron, in the Territory. Following the Term, each Party shall have full rights to exploit and license any Joint Invention (and any patent rights or other intellectual property rights therein or thereto) anywhere in the world, without the consent of the other Party or any obligation or requirement of an accounting to the other Party, and each Party hereby grants to the other Party any consents necessary to exploit and license any Joint Invention in accordance with this sentence, without prejudice to the need for such consents to be separately and expressly granted under this Section 10.1.1 or Section 10.1.3. The Parties shall mutually determine, on a case-by-case basis, which Party shall have primary responsibility for the preparation, filing, prosecution and maintenance of any patents or patent applications claiming or covering Joint Inventions. MTPC shall bear all external fees and costs incurred with respect to preparation, filing, prosecution and maintenance of such patents or patent applications for Joint Inventions in the Territory and Regeneron shall bear all fees and costs incurred with respect to preparation, filing, prosecution and maintenance of such patents or patent applications for Joint Inventions outside of the Territory. The Party who is responsible for filing any such patent applications for the Joint Inventions will be termed the "**Lead Party**". The Lead Party shall confer with and keep the non-Lead Party reasonably informed regarding the status of such activities, including by providing the non-Lead Party a reasonable opportunity to review and comment on in advance any material filings and correspondence with applicable patent offices. The Lead Party and non-Lead Party shall agree in advance on a general patent prosecution strategy for Joint Inventions addressing, among other things, the scope of claims to be pursued and the countries in which patents covering Joint Inventions will be filed and prosecuted. If the Parties do not agree in advance on such strategy or on the content of any such filings, the Lead Party shall have the right to make the decision using its reasonable judgment as necessary to obtain appropriately broad coverage for the applicable Joint Invention; provided that Lead Party shall reflect any reasonable comments offered by non-Lead Party in any final filings submitted to Governmental Authority to the extent such comments are intended to prevent any detrimental effect on the prosecution, maintenance and enforcement of patents owned or Controlled by such non-Lead Party for the Product, unless the Lead Party reasonably determines such comments to be detrimental to the prosecution, maintenance or enforcement of any patents owned or Controlled by Lead Party for the Product. In the event that the Lead Party desires to abandon or cease prosecution or maintenance of any patent or patent application claiming or covering any Joint Invention, such Party shall provide prompt notice to the non-Lead Party of such intention. In such case, no later than thirty (30) days after such notice from the Lead Party intending to abandon or cease prosecution or maintenance, upon the non-Lead Party's written election, such non-Lead Party shall have the right to assume prosecution and maintenance of such patent or patent application at its' own expense.

10.1.2 Each Party will cause all Persons who perform clinical development activities or regulatory activities for such Party or its Affiliates, MTPC Contractors or MTPC Distributors under this Agreement to be under an obligation to assign their rights in any inventions resulting therefrom to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions which have standard

policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained).

10.1.3 Each Party will promptly disclose to the other Party, in writing, and will cause its Affiliates, MTPC Contractors, MTPC Distributors, agents, and independent contractors to so disclose to the other Party, any Regeneron Invention relating to Development or Commercialization of the Product in the Territory, Joint Inventions or MTPC Inventions conceived, made or generated by such Party which are, in such Party's reasonable judgment, potentially patentable. MTPC will have the option but not the obligation to prepare, file, prosecute and maintain MTPC Inventions on a worldwide basis, at MTPC's sole cost and expense. MTPC will consider in good faith any requests and suggestions of Regeneron with respect to strategies for filing and prosecuting MTPC Inventions outside of the Territory and will keep Regeneron informed of progress with regard to the preparation, filing, prosecution and maintenance of MTPC Inventions. For clarity, all MTPC Inventions preparation, filing, prosecution and maintenance in the Territory shall be in MTPC's sole discretion. MTPC hereby grants to Regeneron, a non-exclusive, fully paid, irrevocable, fully sublicensable (through multiple tiers) license, under the MTPC Inventions and Joint Inventions (and any patents or other intellectual property rights therein or thereto), to research, develop, use, make, have made, import, offer for sale, sell and otherwise commercialize Products outside the Territory during the Term. Following the Term, the license in the previous sentence shall automatically become perpetual and worldwide, except in the cases of termination pursuant to Section 15.5 by MTPC upon Regeneron's material breach, or by Regeneron under Section 15.6. If MTPC wants to exploit or license any Joint Invention or MTPC Invention outside the Territory, MTPC shall obtain Regeneron's prior written consent. In the event that MTPC desires to abandon or cease prosecution or maintenance of any patent or patent application claiming or covering any MTPC Invention outside Territory, MTPC shall provide prompt notice to the Regeneron of such intention. In such case, no later than thirty (30) days after such notice from MTPC intending to abandon or cease prosecution or maintenance, upon Regeneron's written election, Regeneron shall have the right to assume prosecution and maintenance of such patent or patent application at its' own expense. In such case, Regeneron shall keep MTPC reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such patent for such MTPC Invention, including content, timing and jurisdiction of the filing of such patent for such MTPC Invention. Regeneron will provide MTPC with copies of, and an opportunity to review and provide comment on, any material filings and correspondence with applicable patent offices. The Parties will discuss in good faith the incorporation of MTPC's proposed comments to avoid any inconsistency with MTPC's global patent strategy. If Regeneron does not provide such election within thirty (30) days after such notice from MTPC, MTPC may, at its sole discretion, continue prosecution and maintenance of such patent for the MTPC Invention or discontinue prosecution and maintenance of such patent for the MTPC Invention.

10.2 **Patent Prosecution and Maintenance**. Regeneron will use Commercially Reasonable Efforts to prepare, file, prosecute and maintain (a) the Patents and (b) any patent or patent application claiming or covering a Regeneron Invention directed to the use or planned use of the Product in the Field in the Territory under this Agreement, in each case, at Regeneron's sole cost and expense. Regeneron will consider in good faith any requests and suggestions of MTPC with respect to strategies for filing and prosecuting the Patents in the Territory and will keep MTPC

informed of progress with regard to the preparation, filing, prosecution and maintenance of such Patents. In the event that Regeneron desires to abandon or cease prosecution or maintenance of any Patents in the Territory, Regeneron shall provide prompt notice to MTPC of such intention. In such case, no later than thirty (30) days after such notice from Regeneron, upon MTPC's written election, MTPC shall have the right to assume prosecution and maintenance of such Patent at MTPC's expense; provided however that MTPC shall have no right to assume prosecution and maintenance of such Patent unless abandonment of such Patent causes substantial loss of patent rights for the Product in the Territory. In such case, MTPC shall keep Regeneron reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Patent, including content, timing and jurisdiction of the filing of such Patent. MTPC will provide Regeneron with copies of, and an opportunity to review and provide comment on, any material filings and correspondence with applicable patent offices. The Parties will discuss in good faith the incorporation of Regeneron's proposed comments to avoid any inconsistency with Regeneron's global Patent strategy. If MTPC does not provide such election within thirty (30) days after such notice from Regeneron, Regeneron may, at its sole discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent.

10.3 **Enforcement of Patents against Infringement in the Territory**.

10.3.1 **Initiation**. MTPC and Regeneron will each promptly notify the other in writing of any alleged or threatened infringement of the Patents by a Third Party, or any alleged or threatened assertion of invalidity of any of the Patents by a Third Party wherein such infringement is based upon the development, commercialization or an application to market any Anti-NGF Antibody Product by a Third Party in the Field in the Territory and of which such Party becomes aware. The notifying Party shall provide all relevant evidence of such infringement of which they are aware. Regeneron will have the first right, but not the obligation, to prosecute any such infringement at its own expense. MTPC shall have the right to join as a party to such suit, if permitted by Applicable Law, to recover its damages and participate with its own counsel; provided that Regeneron shall retain control of the prosecution of such suit. If Regeneron (i) does not commence an infringement action against such alleged or threatened infringement prior to the first to occur of (a) the expiration of the [***] following the first notice provided above with respect to such alleged infringement, or (b) if such [***] period would exceed the time limit set forth in appropriate laws and regulations for filing of such actions, the beginning of the [***] period before such time limit; or (ii) notifies MTPC in writing that it has no intention of commencing an infringement action against such alleged or threatened infringement, whichever comes first, then [***].

10.3.2 **Cooperation**.

(a) In the event Regeneron brings an infringement action in the Territory of [***] pursuant to this Section 10.3, MTPC will cooperate fully, including, the furnishing of a power of attorney solely for such purpose or to join or be named as a party to such action if permitted by Applicable Laws. Regeneron shall have the sole and exclusive right to, and shall use Commercially Reasonable Efforts to, initiate, defend and/or settle and to take other actions that Regeneron, in its sole discretion, deems to be proper, justified or necessary in any such infringement

action, including any proceeding involving the infringement, suspected infringement or validity of the Patents; provided, however, that Regeneron shall not have the right to settle such patent infringement litigation in a manner that imposes any costs or liability on, or involves any admission by, MTPC without the express written consent of MTPC, not to be unreasonably withheld, delayed or conditioned. Regeneron will provide MTPC with copies of all pleadings and other documents filed with the court and will consider reasonable input from MTPC during the course of the proceedings.

(b) [***].

10.3.3 **Recovery**. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in Section 10.3.1 (whether by way of settlement or otherwise) will be (a) first, allocated to reimbursement of unreimbursed legal fees and expenses incurred by the Party paying for the proceeding, then toward reimbursement of any of unreimbursed legal fees and expenses (if any) of the other Party reasonably incurred in connection with such proceeding, and (b) second, the remainder will be divided between the Parties as follows: [***].

10.4 **Invalidity or Unenforceability Defenses or Actions.** If a Third Party asserts, as a defense or as a counterclaim in any action or proceeding with respect to an infringement action under Section 10.3, that any Patent is invalid or unenforceable, then Regeneron, through the counsel engaged by Regeneron pursuant to Section 10.3, shall respond to such defense or defend against such counterclaim (as applicable); provided, that the Parties shall fully discuss and seek to agree on the strategy of such response, considering and accommodating MTPC's and Regeneron's global intellectual property litigation positions in all such decisions that may impact such global positions. The Parties' reasonable and documented out-of-pocket costs and expenses of conducting any such action or proceeding shall be entirely borne by the Party that is paying for such infringement action under Section 10.3.

10.5 **Administrative Patent Proceedings**. Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any reissue, post-grant review, inter partes review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding relating to Patents in the Territory. The Party controlling the prosecution of the respective Patents shall control the course of action with respect to any such proceeding, but the Parties will reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms. Notwithstanding the foregoing, if any proceeding under this Section 10.5 involves Patents involved in an infringement action under Section 10.3, any decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding shall be made by the Party controlling such Third Party infringement action in consultation with the other Party. All costs incurred in connection with any proceeding under this Section 10.5 relating to the Patents shall be borne solely by the Party that is controlling such activities.

10.6 **Joint Inventions.** If a Third Party asserts, as a defense or counterclaim in any action or proceeding with respect to patent rights in a Joint Invention, that any such patent right is invalid or unenforceable, then Regeneron shall respond to such defense or defend against such counterclaim (as applicable) if the proceeding is with respect to patent rights outside the Territory, and MTPC shall do so if the proceeding is with respect to patent rights inside the Territory. If either party wishes to initiate an infringement or other action with respect to patent rights in a Joint Invention, the Parties will review and confer as to the appropriate strategy before commencing such action.

10.7 **Third Party Infringement Claims.** In the event that a Third Party makes any claim, gives notice, or brings any suit or other inter partes proceeding against MTPC, its Affiliates, MTPC Contractors or MTPC Distributors, that the Development or Commercialization of the Product in the Territory infringes or misappropriates any intellectual property rights of such Third Party ("**Third Party Infringement Claim**"), in each case, Regeneron will cooperate with MTPC as to potential strategies to defend against any Third Party Infringement Claim, consistent with the overall goals of this Agreement, including by being joined as a party and/or asserting any Know-How or Patents against such Third Party. Regeneron shall reasonably cooperate with MTPC in connection with any such defense. In such event, MTPC shall not enter into settlement, consent judgment, or other voluntary final disposition of such claim without consent of Regeneron, if such settlement imposes any costs or liability on, or involves any admission by Regeneron, such consent shall not be unreasonably withheld, delayed or conditioned. In the event that a Third Party makes any claim, gives notice, or brings any suit or other inter partes proceeding in the Territory against Regeneron or its Affiliates, that the Manufacture of the Product inside or outside the Territory infringes or misappropriates any intellectual property rights of such Third Party in the Territory, Regeneron will defend against such claim, consistent with the overall goals of this Agreement. In such event, Regeneron shall not enter into settlement, consent judgment, or other voluntary final disposition of such claim without consent of MTPC, if such settlement imposes any costs or liability on, or involves any admission by MTPC, such consent shall not be unreasonably withheld, delayed or conditioned.

10.8 **Trademarks**.

10.8.1 **Global Brand and Trademarks**. The goal of the Parties is to obtain and maintain consistent global branding and Trademarks for the Product. Through the JSC, Regeneron shall consider recommendations provided by MTPC to Regeneron regarding the selection of the names, marks and logos to be used for Products outside the Territory for purposes of selecting such names, marks and logos that can also be used within the Territory as part of a global brand, but Regeneron is under no obligation to adopt or use any such recommendations. Regeneron shall be free to select any Trademarks that it Controls for use in the Field with the Product outside of the Territory in its sole discretion.

10.8.2 **Potential Trademark License**. In the event that the Regeneron decides to offer MTPC the right to use, in the Territory and the Field with respect to the Commercialization of the Product, any Trademark Controlled by Regeneron or its Affiliates, Regeneron will offer a license to such Trademark in a Notice under this Agreement naming the relevant Trademark. Nothing in this Agreement shall obligate Regeneron to offer or grant such a Trademark license.

10.8.3 **Trademark License**. Following such Notice from Regeneron, and effective immediately upon MTPC's provision of Notice that it accepts such license from Regeneron naming the relevant Trademark, Regeneron hereby grants to MTPC an exclusive, royalty-free license to use such Trademark solely in connection with MTPC's Development and Commercialization of Product in the Field in the Territory in compliance with this Agreement (the "**Trademark License**") and quality standards required by Regeneron. Such Trademark Controlled by Regeneron or its Affiliates shall be considered, solely with respect to the Territory, a "**Regeneron Product Trademark**." Any and all goodwill derived from the use of such Trademark Controlled by Regeneron or its Affiliates shall inure solely to the benefit of Regeneron or its Affiliates. Unless otherwise mutually agreed between the Parties, Regeneron (or its Affiliate, as appropriate) shall own and retain all right, title and interest, and all goodwill, in and to such Trademark Controlled by Regeneron (or such Affiliate). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the Trademark License.

10.8.4 **MTPC Selected Trademark**. If MTPC does not accept the foregoing offer of a license to a Trademark Controlled by Regeneron or its Affiliates from Regeneron, or if Regeneron does not make such a license offer, including if MTPC reasonably determines that it is not appropriate, due to local considerations in the Territory, to use such Trademark in connection with MTPC's Development and Commercialization of Product in compliance with this Agreement, then MTPC will select, considering the global positioning for the Product, other Trademark(s) for sale of the Product in such country in the Territory, subject to Regeneron's prior approval at its reasonable discretion, such approval shall not be unreasonably withheld, conditioned or delayed. If approved, each such Trademark selected by MTPC shall be an "**MTPC Product Trademark**."

10.8.5 **Trademark Usage.** MTPC agrees that its and its Affiliates', MTPC Contractors and MTPC Distributors' use of any Product Trademarks and Regeneron Trademarks shall comply with this Agreement, all Applicable Law and Regeneron's Trademark policies. MTPC will refrain from any use of Product Trademarks and Regeneron Trademarks in a manner that threatens to damage the goodwill associated with the respective Trademarks or which threatens to tarnish the reputation or otherwise reflect unfavorably upon the owner of the Trademarks. MTPC shall not during or after the term of the Agreement, anywhere in the world, take any action that in Regeneron's sole and absolute discretion impairs or contests or is likely to impair or contest the validity of the Regeneron's right, title and interest in and to any Product Trademarks or Regeneron Trademarks including, but not limited to, using, or filing an application to register, any word, mark, symbol or device, or any combination thereof, that is confusingly similar to or dilutes the distinctiveness of any of Product Trademarks or Regeneron Trademarks. If MTPC takes any such action, then Regeneron has the right to terminate the Trademark License immediately upon notice to MTPC.

10.8.6 **Ownership, Filing, Prosecution and Maintenance for Product Trademarks**. MTPC will coordinate and collaborate with Regeneron to secure all rights to Regeneron or MTPC (taking into account Applicable Law, the requirements of applicable Regulatory Authorities, and the interests of the then-current owner of the Product Trademark as between the Parties), in the Product Trademarks for use in connection with the Commercialization

of Products in the Territory for use in the Field. The Party that owns Product Trademarks will be responsible for (and shall control) the filing, prosecution, maintenance, enforcement and defense of all registrations of the Product Trademarks in the Territory, and will be responsible for the payment of any costs incurred by such Party relating to filing, prosecution, maintenance, defense and enforcement of the Product Trademarks in the Territory; provided, however, that the non-owning Party may elect at its expense to participate in the defense or enforcement of the Product Trademarks in the Territory (and shall have the right to lead such defense or enforcement in the event the owning Party fails to do so). In any event, each Party will provide to the other Party prompt written Notice of any actual or threatened infringement of Product Trademarks in the Territory.

10.8.7 **Product Labeling and Patent Rights Marking**. Subject to Applicable Law, MTPC will identify Regeneron as the manufacturer of the Product (including on package inserts, packaging and trade packaging for, and samples of, Product), using the Regeneron Trademarks designated by Regeneron for such use, in a manner approved in advance in writing by both Parties and in accordance with (and subject to) the Trademark License. To the extent reasonable and customary in the industry for such Products, MTPC will mark all Products sold by MTPC with appropriate Product Trademarks and patent numbers to the extent permitted by Applicable Law in the country within the Territory where such Product is sold. Any and all goodwill derived from the use of the Regeneron Trademarks shall inure solely to the benefit of Regeneron. MTPC may, in its sole discretion, include any MTPC Trademarks on the Product, and on the labels, packaging, promotional materials and other materials therefor. Any and all goodwill derived from the use of the MTPC Trademarks shall inure solely to the benefit of MTPC.

10.8.8 **Quality Control**. All use by MTPC, its Affiliates, MTPC Contractors and MTPC Distributors of the Product Trademarks and Regeneron Trademarks shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademarks and Regeneron Trademarks. During the Term, MTPC shall submit samples of promotional materials, Product-related materials, package inserts, packaging, trade packaging, and the like to Regeneron for its prior approval, including approval of the usage of any Product Trademarks or Regeneron Trademarks, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of Regeneron to object within such thirty (30) day period shall constitute approval of such MTPC materials. If Regeneron objects within such thirty (30) day period, then the Parties shall discuss changes to such MTPC materials in good faith and shall resolve any dispute regarding such changes through the dispute resolution procedures applicable to a Legal Dispute in Article XVI.

ARTICLE XI
CONFIDENTIALITY, PUBLICATION AND PUBLICITY

11.1 **Confidentiality**. All Confidential Information disclosed by or on behalf of one Party to the other Party hereunder will be maintained in confidence by the receiving Party and will not be disclosed to a Third Party or used for any purpose other than for purposes of exercising a such Party's rights or performing such Party's obligations hereunder pursuant to the terms of this Agreement, except as follows:

11.1.1 If a Party reasonably believes that the Confidential Information of the other Party is required to be disclosed to any Regulatory Authority or governmental or other regulatory agency in order to obtain patents, Regulatory Approval, Marketing Approval or any other approval to conduct clinical trials or to market a Product (or to otherwise perform a Party's obligations hereunder), or to comply with applicable NASDAQ, Securities Exchange or Securities and Exchange Commission regulations (or the regulations of counterpart agencies within the Territory, or in other countries worldwide in which the Parties or their Affiliates are subject to such rules or regulations), then such disclosure may be made only to the extent reasonably necessary to obtain patents or approval, to perform such Party's obligations or to comply with rules or regulations as appropriate, and such receiving Party shall seek confidential treatment to the extent reasonably practicable. When a Party seeks confidential treatment, such Party must provide to the other Party a copy of, and an opportunity for review and comment by such other Party on, the confidential treatment request, and consider all such comments in good faith, allowing a practicable period to review in compliance with Applicable Law or other applicable rules or regulations;

11.1.2 If a Party reasonably believes it is necessary or useful to be disclosed to employees, agents, consultants, Affiliates, MTPC Distributors, MTPC Contractors, and/or other Third Parties for the purpose of conducting activities permitted or required under this Agreement in accordance with this Agreement, Confidential Information of the other Party may be disclosed to such employees, agents, consultants, Affiliates, MTPC Distributors, MTPC Contractors, and/or other Third Parties only to the extent necessary, and only if such Persons are bound by confidentiality obligations at least as protective of such Confidential Information as the terms herein;

11.1.3 If a Party reasonably believes Confidential Information of the other Party is necessary to be disclosed to actual or prospective investors, lenders, real estate or equipment lessors or acquirers or other potential or current financing sources of a Party (collectively "**Financing Sources**"), such Confidential Information may be disclosed to such Financing Sources provided that the Financing Sources agree to be bound by confidentiality obligations at least as protective of such Confidential Information as the terms herein; or

11.1.4 If a Party reasonably believes that Confidential Information of the other Party is required to be disclosed by law or court order, then provided that, to the extent reasonably practicable, Notice of such disclosure is promptly delivered to the disclosing Party in order to provide an opportunity to challenge or limit the disclosure obligations, and provided further that the receiving Party works in good faith with the disclosing Party to seek confidential treatment of such disclosure and to disclose only to the extent reasonably necessary to comply with the applicable law or court order, such Confidential Information may be disclosed to the extent legally required.

11.2 **Disclosure of this Agreement**. Neither Party will release to any Third Party or publish in any way any non-public information regarding the existence, terms and conditions of this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned or delayed, except for the disclosure to Financing Sources who are subject to a signed confidentiality agreement, and except pursuant to Section 11.3, 11.4 and

except to the extent required to comply with Applicable Laws or with applicable NASDAQ, Securities Exchange or Securities and Exchange Commission regulations (or the regulations of counterpart agencies within the Territory, or in other countries worldwide in which the Parties or their Affiliates are subject to such rules or regulations); provided that such disclosure may be made only to the extent reasonably necessary to comply with rules or regulations as appropriate, and such receiving Party shall seek confidential treatment to the extent reasonably practicable. When a Party seeks confidential treatment, such Party must provide to the other Party a copy of, and an opportunity for review and comment by such other Party on, the confidential treatment request, and consider all such comments in good faith, allowing a practicable period to review in compliance with Applicable Law or other applicable rules or regulations.

11.3 **Publications**.

11.3.1 **Peer Reviewed Journal Submissions**. Both Parties will submit any proposed publication or presentation containing material information regarding clinical or non-clinical trial results for, or similar information regarding, the safety or efficacy of the Products (a "**Publication**") to the other Party at least forty-five (45) days prior to submitting it to any Third Party for publication in a peer reviewed journal, which shall be provided in English; provided, that Regeneron shall only be required under this Agreement to provide Publications to MTPC in connection with studies conducted at least in part in the Territory plus the Ongoing Phase 1 Trial. For the avoidance of doubt, Publications exclude marketing materials.

(a) The other Party will have thirty (30) days after receipt of the draft Publication to review and comment on such draft. The publishing Party will consider such other Party's comments in good faith.

(b) Upon Notice within such thirty (30) day period by the other Party that it reasonably believes the Publication would amount to the public disclosure of such other Party's Confidential Information and/or negatively impact such other Party's intellectual property position, submission of the concerned Publication to Third Parties will be delayed for a thirty-five (35) day period from the date of said Notice for appropriately deleting Confidential Information from the proposed Publication or drafting and filing a patent application with respect to any subject matter to be made public in such Publication. Notwithstanding the foregoing, neither Party shall be restricted hereunder from making any publication or disclosure to extent required to comply with Applicable Law.

11.3.2 **Other Publications**. For all other Publications, including but not limited to poster presentations, abstract submissions, investor presentations and the like, both Parties will submit such proposed Publications at least twenty (20) Business Days prior to submitting it to any Third Party for publication or disclosure. For the avoidance of doubt, Publications exclude marketing materials.

(a) The other Party will have ten (10) Business Days after receipt of the draft Publication to review and comment on such draft.

(b) Upon Notice within such ten (10) Business Day period by the other Party that it reasonably believes the Publication would amount to the public disclosure of such other Party's Confidential Information and/or negatively impact such other Party's intellectual property position, submission of the concerned Publication to Third Parties will be delayed for a thirty five (35) day period from the date of said Notice for appropriately deleting Confidential Information from the proposed Publication or drafting and filing a patent application with respect to any subject matter to be made public in such Publication. Notwithstanding the foregoing, neither Party shall be restricted hereunder from making any publication or disclosure to extent required to comply with Applicable Law.

(c) For all proposed Publications, each Party will cooperate in good faith with the other Party to achieve the business objectives of the proposed Publication and the publishing Party will in good faith take into account reasonable comments from the other Party.

11.4 **Publicity**. Regeneron and MTPC will issue a press release in a form mutually agreed to by the Parties within three (3) Business Days of the execution of this Agreement. Any other news release or other public announcement regarding this Agreement or the Development or Commercialization of Product in the Territory that either Party wishes to release will first be provided to the other Party for review at least seven (7) Business Days in advance, and the submitting Party will in good faith take into account reasonable comments from the other Party. Notwithstanding any other provision of this Agreement, (a) each Party will have the right, without consent of the other Party, to make disclosures regarding any matter related to this Agreement that such Party reasonably believes is required to comply with Applicable Law, and (b) the requirement that a publication, news release or other public announcement be provided to the other Party for review seven (7) Business Days in advance will not apply if such Party reasonably believes that Applicable Law requires the issuance thereof sooner than seven (7) Business Days; provided, that if Applicable Law does not permit such seven (7) Business Days' notice, the disclosing Party will provide the other Party prior notice, and such time to comment, as Applicable Law permits.

11.5 **Employees and Consultants**. Each Party hereby agrees and covenants that all of its employees and consultants and all of the employees and consultants of its Affiliates who participate in any activities under this Agreement or have access to any Confidential Information are or will, prior to their participation or access, be bound by written obligations to maintain such Confidential Information in confidence and not to use or transfer such information or materials except as expressly permitted hereunder. Each Party agrees to use, and to cause its Affiliates to use, reasonable commercial efforts to enforce such obligations.

ARTICLE XII
REPRESENTATIONS AND WARRANTIES

12.1 **Mutual Representations and Warranties**. Each Party hereby represents, warrants and covenants to the other Party that, as of the Effective Date:

12.1.1 **Corporate Existence and Power**. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its

property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

12.1.2 **Authority and Binding Agreement**. (a) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

12.1.3 **Execution of this Agreement.** The individuals executing this Agreement for each Party have been duly authorized to execute and deliver this Agreement on behalf of each Party.

12.1.4 **Certification.** During the term of this Agreement, each Party shall, upon the other Party's reasonable request, certify in writing from time to time its compliance with the representations, warranties, covenants and certifications contained in Sections 13.3 and 13.4.

12.1.5 **No Conflict**. To the each Party's knowledge, it has not entered into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise conflict with or adversely affect the rights granted to the other Party under this Agreement, and its performance and execution of this Agreement will not result in a breach of any other contract to which it is a Party.

12.1.6 **No Litigation**. It is aware of no action, suit, inquiry or investigation instituted by any Third Party which questions or threatens the validity or enforceability of this Agreement.

12.1.7 **Consents**. All necessary consents, approvals and authorizations of all Governmental Authorities and other persons or entities required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained.

12.2 **MTPC's Representations and Warranties**. MTPC hereby represents and warrants to Regeneron that as of the Effective Date MTPC has no knowledge of any pending filing, complaint, matter or action against or involving either MTPC or its Affiliates with any Regulatory Authority that could be reasonably anticipated to have a material adverse effect on its ability to obtain Regulatory Approvals for a Product in any country or region of the Territory.

12.3 **Regeneron's Representations and Warranties**. Regeneron hereby represents and warrants to MTPC as of the Effective Date:

12.3.1 **Patents, Know-How and Materials**. Regeneron Controls the Patents, Know-How and Materials. To the best of Regeneron's knowledge, Regeneron has taken commercially reasonable measures consistent with industry practice, to conduct the filing, prosecution and maintenance of the Patents in accordance with respective Applicable Laws to ensure

that such Patents are either issued or pending with the applicable governmental agency, and any and all maintenance fees, annuity fees and renewal fees with respect to any of the Patents that are due and payable have been paid.

12.3.2 **Title; Encumbrances.** Regeneron has sufficient legal and/or beneficial title, ownership or license, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind, as necessary to sell and transfer the Products to MTPC as contemplated by this Agreement, the Clinical Supply Agreement and the Commercial Supply Agreement.

12.3.3 **No Conflict.** Regeneron has not granted any assignment, license, covenant not to sue, or other similar interest or benefit, exclusive or otherwise, to any Third Party relating to any Patent, Know-How or Material that conflicts with or limits the rights granted to MTPC hereunder.

12.3.4 **Confidentiality.** Regeneron and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Know-How that constitutes trade secrets under Applicable Laws (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring such employees, consultants and independent contractors to maintain the confidentiality of such Know-How) and, to Regeneron's knowledge, such Know-How has not been used, disclosed to or discovered by any Third Party except pursuant to such confidentiality agreements and there has not been a breach by any party to such confidentiality agreements.

12.3.5 **No Claims of Third Party Rights.** Regeneron has not received any written notice, claim or demand from any person or entity (a) asserting that the research, development, manufacture, use and sale of any Product in the Field in the Territory infringes a Third Party patent or misappropriates any trade secrets or any other intellectual property of a Third Party, or (b) challenging the validity, enforceability or ownership of any Patents.

12.3.6 **No Exercise of Patent Rights and Know-How.** Except as otherwise expressly provided in this Agreement, Regeneron shall not conduct any activities, including any license, assignment, or other transfer to any Third Party any Patents, Know-How, Regeneron Inventions, Regeneron's interest in any Joint Inventions or Regeneron Product Trademark, in each case, in a manner that would conflict with any rights granted to MTPC hereunder, including rights granted to MTPC under Article 2, regardless of whether a specific country in the Territory recognizes a general principle of patent exhaustion doctrine applicable to MTPC's import of the Product into such country in accordance with the terms of this Agreement.

12.3.7 **Material Agreement.** Regeneron and its Affiliates shall be fully responsible for any obligations under any agreements of Regeneron or its Affiliates with any Third Party relating to any of the activities to be performed under this Agreement, including any payments owed to Sanofi or any of its Affiliates as a result of the sale of the Product in the Territory under that certain Amended and Restated License and Collaboration Agreement dated November 10, 2009, by and between Aventis Pharmaceuticals Inc., Sanofi-Aventis Amerique Du Nord and Regeneron

Pharmaceuticals, Inc., and Regeneron represents that no such obligation conflicts with any rights granted to MTPC hereunder.

12.4 **Limitation on Warranties; No Implied Warranties**. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY MAKES NO AND EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES WITH RESPECT TO PRODUCTS, THE PATENTS, THE KNOW-HOW, THE MATERIALS, OR ANY OTHER SUBJECT MATTER OF THIS AGREEMENT, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. EXCEPT TO THE EXTENT EXPRESSLY PROVIDED FOR HEREIN, NOTHING IN THIS AGREEMENT WILL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY REGENERON THAT THE PATENTS AND KNOW-HOW ARE NOT INFRINGED BY ANY THIRD PARTY OR THAT THE PRACTICE OF THE PATENTS OR KNOW-HOW DOES NOT INFRINGE ANY INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

ARTICLE XIII
OTHER COVENANTS AND AGREEMENTS

13.1 **Compliance with Law**.

13.1.1 MTPC will comply with all Applicable Laws related to its Development and Commercialization of the Products. Without limiting the generality of the foregoing, MTPC will not promote any of the Products in a manner that would conflict with Applicable Law.

13.1.2 MTPC will conduct all post-marketing non-approval clinical trials in a manner consistent with Product labeling, including all package inserts for Product, except to the extent otherwise required by Applicable Law, and will conduct all such trials in accordance with Applicable Law.

13.1.3 Regeneron will comply with all Applicable Laws related to its development in the event of Joint Development Studies. Without limiting the generality of the foregoing, Regeneron shall Manufacture or have Manufactured the Products in compliance with the Applicable Laws.

13.1.4 Each Party shall comply with Japanese tax laws in connection with the activities to be performed under this Agreement.

13.2 **Performance Through Affiliates**. Each Party may discharge any obligation and exercise any right hereunder through any of its Affiliates (without an assignment of this Agreement) with prior written notice to the other Party.

13.3 **Anti-Corruption Compliance**. With respect to its performance under this Agreement, the Parties hereby represent, warrant, covenant and certify the following:

(a) Neither Party nor its Representatives has caused nor shall cause the other Party or its Affiliates to be in violation of the Anti-Corruption Laws, the U.S. Travel Act, or any other Applicable Law.

(b) Each Party and its Representatives shall not with a corrupt intent directly or indirectly offer, promise, authorize, pay, or give any money, favor, advantage, bribe, kickback, or anything else of value to a Government Official (as defined below) or to any other individual or entity for purposes of obtaining, retaining, or directing business or any other improper advantage.

(c) Each Party understands that "**Government Official**" means (i) a director, officer, employee, agent or representative of any government, military, or state-owned or affiliated entity or organization; (ii) any department, agency, corporate entity, instrumentality or political subdivision of any government or military; (iii) any person or commercial entity acting in an official capacity for or on behalf of any government or military; (iv) any candidate for political office, any political party or any official of a political party; (v) any officer, employee, agent or representative of any public international organization such as the United Nations or the World Bank; (vi) any member of a royal family that may be influential in advancing such Party's business interests; and/or (vii) any family member of any Government Officials described in this definition.

(d) Neither Party, nor, its officers, directors or shareholders owning five percent (5%) or more of such Party's or Affiliate's fully diluted equity (collectively, "**Interested Persons**") is a Government Official in the Territory. Each Party shall notify the other Party promptly if it becomes aware that (i) an Interested Person becomes such a Government Official or (ii) such a Government Official becomes an Interested Person or acquires a personal interest in the income of such Party.

(e) Each Party will in good faith provide to the other Party and/or its Representatives and advisors, all documents and information of the character and type requested by the other Party in writing in the course of the other Party's due diligence review relating to anti-corruption compliance; provided such review is reasonably related to the activities to be performed by such Party under this Agreement.

(f) Each Party shall respond to the other Party's requests for information, to the extent reasonable and related to each Party's efforts to ensure compliance with the Anti-Corruption Laws, Export Control Laws, and any other Applicable Law.

(g) Each Party shall and shall cause its Representatives to adequately and appropriately maintain books, records and related material documents, including but not limited to (i) invoices, receipts, financial documents, evidence of cash payments and (ii) copies of policies, procedures, controls, and records of compliance training and audits with respect to the Product (collectively "**Compliance Records**") that reflect completely and in reasonable detail its transactions and other expenses related to the performance of its obligations and exercise its of rights under this Agreement and its compliance with the requirements under this Agreement and the compliance efforts discussed in the Committees. Each Party may in its sole discretion audit (either itself or using a Third Party retained by such Party) such Compliance Records of the other

Party at any time during business hours upon reasonable notification, if such Party reasonably suspects that a material issue or a violation has or will occur with respect to the Anti-Corruption Laws, Export Control Laws, or any other Applicable Law. Each Party shall provide the other Party and its Representatives reasonable access to Compliance Records, with regard to the material documents described in (i) above, for ten (10) years, and with regard to the items described in (ii) above, for three (3) years after the creation of the applicable Compliance Record. Each Party may also reasonably suspend any payments owed to the other Party pursuant to this Agreement until such time that such Party has reasonably determined that such payment will not cause a violation of the Anti-Corruption Laws, Export Control Laws, or any other Applicable Law.

(h) Each Party shall maintain and shall reasonably cause its Representatives to comply with policies and procedures which are (i) substantially consistent with the foregoing representations, warranties, covenants and certifications and (ii) in compliance with all Applicable Law applicable to each Party and their respective Representatives.

13.4 **Export Control Laws**.

(a) **Export Control Laws**. In exercising its rights under this Agreement, each Party agrees to comply strictly and fully with U.S. export control laws, including the Arms Export Controls Act (22 U.S.C. Ch. 39), the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 et seq.), the Trading With the Enemy Act (50 U.S.C. app. §§ 1 et seq.), the Export Administration Act of 1979 (50 U.S.C. app. §§ 2401 et seq.), International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, and all rules, regulations and executive orders relating to any of the foregoing, including but not limited to the International Traffic in Arms Regulations (22 C.F.R. §§ 120 et seq.), the Export Administration Regulations (15 C.F.R. §§ 730 et. seq.), and the regulations administered by the Office of Foreign Assets Controls of the United States Department of the Treasury, and all export controls imposed on the Products by any country or organization or nations within whose jurisdiction each Party operates or does business (collectively, "**Export Control Laws**"). MTPC will not export or permit exportation of any part of the Products or any related technical data or any direct product of any related technical data, outside of the Territory or the United States without obtaining Regeneron's prior written consent and any required written permission, license, or approval to do so from any Governmental Authority from whom Regeneron determines consent is required.

(b) **Restricted Destinations and End-Users**. MTPC shall not (i) export, reexport or transfer any Products to any country that is subject to an embargo by the U.S. government (currently, Cuba, Iran, North Korea, Sudan, Syria, or the Crimea region of Ukraine) (collectively, the "**Embargoed Countries**"); (ii) export, reexport or transfer any Products to any instrumentality, agent, entity, or individual that is acting on behalf of, or directly or indirectly owned or controlled by, any governmental entity of any Embargoed Country; (iii) export, reexport or transfer any Products to a national of an Embargoed Country; or (iv) engage in any transactions or dealings with any organization, entity, or individual identified on the List of Specially Designated Nationals and Blocked Persons ("**SDNs**") or the Foreign Sanctions Evaders List, which are both maintained by the Office of Foreign Assets Control of the U.S. Treasury Department, or the Entity List, Denied

Persons List, or Unverified List, which are maintained by the Bureau of Industry and Security of the U.S. Commerce Department.

13.5 **Obligation to Report**. Each Party will immediately report to the other Party (i) any concerns, suspicions, or actual knowledge of violations of Anti-Corruption Laws, Export Control Laws or any other Applicable Law in connection with this Agreement, or (ii) if such Party becomes the subject of any formal or informal investigation, prosecution, or government or judicial determination related to such a violation of Anti-Corruption Laws, Export Control Laws, or any other Applicable Laws.

13.6 **Obligation to Cooperate**. Each Party will fully cooperate and cause its Representatives to cooperate with the other Party in such other Party's review or investigation in relation to an actual or potential violation of any Applicable Law in connection with this Agreement. Each Party shall reasonably cooperate with the other Party in regard to any matter, dispute or controversy related to this Agreement and in which each Party may become involved and of which the other Party may have knowledge, and such obligation shall continue after the expiration or termination of this Agreement.

13.7 **Termination for Non-Compliance**. Each Party understands and acknowledges that, notwithstanding any provision contained herein, a violation of the foregoing Sections 13.3 or 13.4 by the other Party or any of its Representatives shall be deemed a material breach of this Agreement and will entitle such Party to (i) terminate this Agreement immediately for cause pursuant to Section 15.5 (for clarity, without the applicable cure period), and (ii) be indemnified for and held harmless against any and all damages, fines, penalties, disgorgements, settlements, determinations, or claims faced by or imposed on such Party or its respective Representatives to the extent attributable to the material breach of the foregoing Sections 13.3 or 13.4 by the other Party or any of its Representatives.

ARTICLE XIV
INDEMNIFICATION AND INSURANCE

14.1 **Indemnity By MTPC**. MTPC hereby agrees to defend, hold harmless and indemnify Regeneron and its Affiliates, licensees and development partners, and its and their agents, directors, officers and employees (the "**Regeneron Indemnitees**") from and against any and all Third Party suits, claims, actions and proceedings and associated expenses (including court costs, legal expenses and attorneys' fees) and damages and recoveries awarded with respect thereto (collectively "**Losses**") incurred by a Regeneron Indemnitee in connection with any and all Third Party claims arising or resulting from: (a) any breach (or alleged breach) of any of the representations, warranties, covenants or agreements made by MTPC or obligations of MTPC under this Agreement, or (b) the Development or Commercialization of any Product in the Field in the Territory by or on behalf of MTPC or its Affiliates, MTPC Contractors or MTPC Distributors, or the use of any Regeneron Trademarks in connection therewith, except, in the case of either (a) or (b), to the extent such Losses arise from negligence, gross negligence or willful misconduct of a Regeneron Indemnitee.

14.2 **Indemnity by Regeneron**. Regeneron hereby agrees to defend, hold harmless and indemnify MTPC and its Affiliates, MTPC Contractors and MTPC Distributors and its and their agents, directors, officers and employees (the "**MTPC Indemnitees**") from and against any and all

Losses incurred by a MTPC Indemnitee in connection with any and all Third Party claims arising or resulting from (a) any breach (or alleged breach) of any of the representations, warranties, covenants or agreements made by or obligations of Regeneron under this Agreement, (b) the development or commercialization of the Product by or on behalf of Regeneron or its Affiliates or licensees outside the Territory, (c) any product liability caused by a defect in Manufacture caused by Regeneron (but not any Third Party Fill/Finish Provider) or (d) any product liability caused by a defect in Manufacture caused by a Third Party Fill/Finish Provider, except, in the case of (a) to (d), to the extent such Losses arise from negligence, gross negligence or willful misconduct of a MTPC Indemnitee; provided that, Regeneron's indemnity obligation under clause (d) shall be limited to [***].

14.3 **Procedure for Indemnification**. If a Regeneron Indemnitee or a MTPC Indemnitee (as the case may be, an "**Indemnitee**") wishes to seek indemnification hereunder, such Indemnitee will provide Notice to the Party obligated to indemnify the Indemnitee hereunder (the "**Indemnifying Party**") of the Third Party claim giving rise to the obligation to indemnify as soon as reasonably practicable after receiving notice of such Third Party claim. The Indemnifying Party will have the right to assume and control the defense of any such Third Party claim for which it is obligated to indemnify the Indemnitee under this Agreement. The Indemnitee will cooperate with the Indemnifying Party (and its insurer) as the Indemnifying Party may reasonably request, and at the sole cost and expense of the Indemnifying Party. The Indemnitee will have the right to retain its own counsel, at the expense of the Indemnifying Party, if representation of such Indemnitee by the counsel retained by the Indemnifying Party would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other Party represented by such counsel. In all other cases, the Indemnitee will have the right to participate in such defense, subject to the Indemnifying Party's control, using its own counsel at its own expense. The Indemnifying Party will have no obligation to indemnify any Indemnitee in connection with any settlement made without the Indemnifying Party's prior written consent; provided, that the Indemnifying Party does not unreasonably withhold, condition or delay any such written consent. The Indemnifying Party shall seek the prior written consent of the Indemnified Party for any settlement of a Third Party claim subject to indemnification hereunder (such consent to not be unreasonably withheld, delayed or conditioned) if such settlement would materially diminish or materially adversely affect the scope, exclusivity or duration of the Patents or Know-How, would require any payment by such Indemnified Party, would require an admission of legal wrongdoing in any way on the part of an Indemnified Party, or would effect an amendment of this Agreement (otherwise, no such consent shall be required). If the Indemnifying Party does not assume and conduct the defense of the Third Party claim as provided above, (a) the Indemnitee may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the claim in any manner the Indemnitee may deem reasonably appropriate (and the Indemnitee need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnitee as provided in this ARTICLE XIV.

14.4 **Insurance**. During the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by Applicable Law, each of Regeneron and MTPC will (i) use Commercially Reasonable Efforts to procure and maintain appropriate commercial general liability and product liability insurance in an amount not less than [***] United

States Dollars ($[***]) per occurrence and in the annual aggregate or (ii) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or MTPC, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. Any insurance proceeds received by a Party in connection with any Losses shall be retained by such Party and shall not reduce any obligation of the other Party.

ARTICLE XV
TERM AND TERMINATION

15.1 **Term**. The term ("**Term**") of this Agreement will commence on the Effective Date and, unless earlier terminated as expressly provided below in this ARTICLE XV, will expire on the date that MTPC has ceased Developing Products and/or Commercializing the Product in all countries in the Territory.

15.2 **Termination by Regeneron for Non-Payment**. Regeneron may terminate this Agreement upon the failure of MTPC to pay any amount due hereunder, but solely in the event and after such failure continues for thirty (30) days after Regeneron has provided MTPC with written Notice of such failure (but no such termination shall occur if MTPC cures such failure prior to the end of such thirty (30) day period), and in any event subject to Section 15.7.

15.3 **Termination by MTPC**. MTPC shall have the right to terminate this Agreement in its entirety upon twelve (12) months' prior written Notice to Regeneron. Each Party shall continue to meet its obligations under this Agreement during such twelve (12) month period. If, prior to any termination under this Section, Regeneron has entered into any non-cancellable and reasonable commitments, the Costs of which would be payable by MTPC had this Agreement continued beyond such termination, then MTPC shall pay Regeneron's Costs associated with such commitments.

15.4 **Termination by Regeneron for Change of Control.** In the event of a Change of Control of MTPC, MTPC (or the applicable surviving entity) shall deliver to Regeneron written Notice of the closing of such transaction within five (5) days following such closing. Regeneron shall have the right, exercisable [***], to terminate this Agreement in its entirety upon Notice to MTPC (or such surviving entity); provided that, Regeneron shall not have the right to terminate this Agreement if [***].

15.5 **Termination by Either Party for Breach or Insolvency**. Either Party will have the right to terminate this Agreement prior to the expiration of the Term upon the occurrence of any of the following:

15.5.1 Upon the material breach of any representations, warranties, covenants or obligations by the other Party if the breaching Party has not cured such breach within ninety (90) days after written Notice thereof (describing such breach in reasonable detail) by the non-breaching Party; and

15.5.2 Immediately upon written Notice, if the other Party has filed a petition in bankruptcy, or if an involuntary petition in bankruptcy has been filed against the other Party and such petition will not be dismissed within sixty (60) days, or if a receiver or guardian has been appointed for the other Party, or upon or after the cessations of operations of the other Party.

15.6 **Termination by Regeneron** [***]**.** Regeneron shall have the right to terminate this Agreement in its entirety upon [***] prior written Notice to MTPC following the occurrence of either of the following:

15.6.1 [***]; or

15.6.2 [***].

Each Party shall continue to meet its obligations under this Agreement during such [***] period. If Regeneron terminates this Agreement pursuant to this Section 15.6, Regeneron shall upon the written request of MTPC delivered within [***] following such Notice of termination, [***].

15.7 **Disputes Over Right to Terminate**. With respect to efforts to terminate this Agreement for non-payment or breach under Sections 15.2 or 15.5, if the alleged breaching Party disputes in good faith the existence of a breach specified in a Notice provided by the other Party and/or the right to terminate this Agreement, then the non-breaching Party shall not have the right to terminate this Agreement hereunder unless and until such Dispute is resolved in accordance with ARTICLE XVI, and it has been determined that the alleged breaching Party has materially breached this Agreement and such Party fails to cure such breach within ninety (90) days following such decision (except to the extent such breach involves the failure to make a payment when due, which breach must be cured within fifteen (15) days following such determination), and it is understood and agreed that during the pendency of such Dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder; provided, however, under no circumstance shall either Party be required to continue to conduct any activities under this Agreement if in the reasonable judgment of such Party, doing so would constitute a violation of Applicable Law or would raise material safety concerns.

15.8 **Effect of Expiration or Termination of this Agreement for MTPC's Cause**. Upon (i) the expiration of this Agreement or (ii) termination of this Agreement by Regeneron pursuant to Section 15.2, by MTPC pursuant to Section 15.3, by Regeneron pursuant to Section 15.4, or by Regeneron for breach or insolvency by MTPC pursuant to Section 15.5, the following provisions of this Section 15.8 will apply:

15.8.1 Each Party will return the originals and any copies of the other Party's Confidential Information; provided, that, each Party may retain copies of any Confidential Information that is subject to continuing rights hereunder and one copy of the other Party's Confidential Information for the purposes of legal archive and monitoring its obligations hereunder and exercising any surviving rights and complying with Applicable Laws;

15.8.2 Neither Party will be relieved of any liability or obligation of such Party that accrued, or which arose during or relates to any period, prior to the effective date of such expiration or termination, including any payment obligations; and

15.8.3 MTPC will grant to Regeneron as of the effective date of the expiration of this Agreement an exclusive, fully paid, perpetual, irrevocable, fully sublicensable (through multiple tiers) license to use the MTPC Product Trademarks that were actually used during the Term in the Commercialization of Product in the Territory (and Regeneron shall thereupon be fully responsible for all costs and expenses of, and shall have the right to control, the prosecution, maintenance, defense and enforcement of such MTPC Product Trademarks). If MTPC desires after the effective date of the expiration of this Agreement, MTPC may assign and transfer the right to the MTPC Product Trademarks to Regeneron at Regeneron's expense.

15.9 **Effect of Certain Terminations of this Agreement for MTPC's Cause**. Upon the termination of this Agreement by Regeneron pursuant to Section 15.2, by MTPC pursuant to Section 15.3, by Regeneron pursuant to Section 15.4, or by Regeneron for breach or insolvency by MTPC pursuant to Section 15.5, the following provisions of this Section 15.9 will apply (in addition to the provisions of Section 15.8):

15.9.1 MTPC will, in the manner and within the timeframes requested by Regeneron, (i) cease conducting any Development and Commercialization activities with respect to Product and (ii) discontinue making any representation regarding its status as a Development and Commercialization collaborator with the ability to distribute the Product in the Field in the Territory, subject, in either such case, to requirements of Applicable Laws and to a reasonable wind-down and transition period (not to exceed ninety (90) days);

15.9.2 MTPC will promptly (but in any event subject to Applicable Laws):

(a) transfer to Regeneron or Regeneron's designee all Regulatory Filings, Regulatory Approvals and Marketing Approvals, if such transfer is possible, or, if such transfer is not possible, then at Regeneron's discretion (i) withdraw any such Regulatory Filings, Regulatory Approvals and Marketing Approvals for the Products and take all actions necessary or useful to support Regeneron's or Regeneron's designee's submission and procurement of substitute regulatory filings and the achievement of substitute regulatory approvals or (ii) provide Regeneron with access to, and grant Regeneron the right and license to use and to reference, such Regulatory Filings, Regulatory Approvals and Marketing Approvals;

(b) provide Regeneron with copies of (i) all material correspondence between MTPC and Regulatory Authorities with respect to Regulatory Filings, Regulatory Approvals and Marketing Approvals for Products and (ii) all other clinical and non-clinical data, records and tabulations, in all such cases with respect to Products, that MTPC holds as of the date of termination with respect to Products;

(c) assign to Regeneron all agreements specific to the conduct of clinical trials for Product (to the extent assignable and excluding any such agreements that also involve clinical trials for other MTPC products that are not Products), including agreements or

contracts with contract research organizations, clinical sites and investigators, between MTPC and any Third Party, subject to any consent required by such Third Party, which consent MTPC will use Commercially Reasonable Efforts to obtain on behalf of Regeneron; and

(d) provide Regeneron with copies of all reports and data obtained by MTPC or its Affiliates pursuant to this Agreement regarding the Development or Commercialization of Products, including any MTPC Clinical Data. MTPC hereby acknowledges and agrees that Regeneron will not be obligated to treat any information received pursuant to this Section 15.9.2(d) as MTPC Confidential Information and may use such information, data and Know-How for any purpose at Regeneron's discretion.

As promptly as possible after any such termination, MTPC will execute any and all documents of any Regulatory Authorities, so as to allow Regeneron to make immediate use of any data, records, and Regulatory Filings, Regulatory Approvals and Marketing Approvals transferred by MTPC to Regeneron pursuant to this Section 15.9.2.

15.10 **Effect of Certain Terminations of this Agreement for Regeneron's Cause**. Upon the termination of this Agreement by MTPC for breach or insolvency by Regeneron pursuant to Section 15.5, the following provisions of this Section 15.10 will apply:

15.10.1 Regeneron will return the originals and any copies of MTPC's Confidential Information; provided, that, Regeneron may retain copies of any Confidential Information that is subject to continuing rights hereunder and one copy of MTPC's Confidential Information for the purposes of legal archives and monitoring its obligations hereunder and exercising any surviving rights and complying with Applicable Laws;

15.10.2 Regeneron will not be relieved of any liability or obligation of Regeneron that accrued, or which arose during or relates to any period, prior to the effective date of such expiration or termination, including any payment obligations; and

15.10.3 MTPC will, in the manner and within the timeframes requested by Regeneron, (i) cease conducting any Development and Commercialization activities with respect to Product and (ii) discontinue making any representation regarding its status as a Development and Commercialization collaborator with the ability to distribute the Product in the Field in the Territory, subject, in either such case, to requirements of Applicable Laws and to a reasonable wind-down and transition period (not to exceed ninety (90) days).

15.11 **Remedies Cumulative and Nonexclusive**. All of the non-breaching Party's remedies will be cumulative, and the exercise of one remedy hereunder by the non-breaching Party will not be deemed to be an election of remedies.

15.12 **Survival**. The Sections 2.6, 2.7 (excluding the first sentence), 2.9.2, 2.10, 3.9, 4.5.1, 5.2.1(c), 7.7, 7.8, 9.2, 9.3, 10.1, 12.4, 13.3(g), 13.5, 13.6, 13.7, and Articles XI, XIV, XV, XVI and XVII, will survive any expiration or termination of this Agreement and remain in full force and effect in accordance with their terms.

ARTICLE XVI
DISPUTE RESOLUTION

16.1 **Resolution of Disputes**. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

16.1.1 **Governance Disputes and Audit Disputes**. Governance Disputes shall be resolved pursuant to Article III and disputes referred to in Section 9.3 shall be resolved in accordance therewith.

16.1.2 **Legal Disputes**.

(a) "**Legal Dispute**" shall mean any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement.

(b) The Parties agree that they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion.

(c) In the event that the JSC is unable to resolve any such Legal Dispute within ten (10) Business Days (but excluding any scheduled corporate holidays at either Party's head office) of receipt by a Party of Notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within ten (10) Business Days (but excluding any scheduled corporate holidays at either Party's head office), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 16.4 and Section 17.2.

16.2 **No Waiver**. Nothing in this Article XVI or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

16.3 **Continued Performance**. Pending resolution of any Dispute covered by this Article XVI, both Parties will continue their performance under this Agreement of any obligations (including payment obligations) that are not the subject of such Dispute.

16.4 **Governing Law; Jurisdiction; Venue**. This Agreement shall be governed by and construed under the substantive laws of the State of New York, U.S.A., without reference to any choice of law principles thereof that would cause the application of the laws of a different jurisdiction. Without limiting the exclusivity of the alternative dispute resolution provisions of Sections 16.1 through 16.3 the Parties consent to the non-exclusive personal jurisdiction and venue of the courts located in the Federal District of Hawaii.

ARTICLE XVII
OTHER PROVISIONS

17.1 **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement, other than the obligation to make monetary payments, and neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides Notice thereof to the other Party. Such excuse will be continued so long as the condition constituting a force majeure event continues and the nonperforming Party uses reasonable efforts to remove the condition. For purposes of this Agreement, a force majeure event will include conditions beyond the reasonable control and without the fault of a Party, such as an act of God, voluntary or involuntary compliance with any regulation, law or order of any government, war, an act of terrorism, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, inability to procure necessary raw materials in a commercially reasonable manner or default of suppliers or sub-contractors; provided, however, the payment of invoices due and owing hereunder may not be delayed by the payor because of a force majeure affecting the payor.

17.2 **Exclusions of Consequential Damages**. EXCEPT IN THE CASE OF BREACH OF SUCH PARTY'S OBLIGATIONS UNDER ARTICLE XI OR INDEMNIFICATION OF THIRD PARTY CLAIMS PURSUANT TO ARTICLE XIV, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES OF THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY, AND WHETHER OR NOT SUCH PARTY HAD PRIOR NOTICE THEREOF.

17.3 **Assignment**. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the prior written consent of the other Party; provided, however, that subject to Section 15.4, either Party may assign this Agreement in its entirety without such consent, to any of its Affiliates, to any purchaser of all, or substantially all, of its assets for the business to which this Agreement relates or to any successor corporation resulting from any merger, consolidation, share exchange, or other similar transaction, and provided further that either Party may assign or sell its rights to receive any amounts due hereunder. This Agreement will inure to the benefit of MTPC and Regeneron and their respective successors and permitted assigns. Any assignment of this Agreement that is not made in accordance with this Section 17.3 shall be null and void and of no legal force or effect.

17.4 **Severability**. In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) frustrates the purpose of this Agreement (in which case the Parties will attempt to replace such invalidated provision with an

enforceable provision that most clearly implements such purpose). The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) that, insofar as practical, implement the purposes of this Agreement.

17.5 **Notices**. All notices, consents, approvals and other legally operative communications that are required or permitted hereunder ("**Notice**") will be in writing in the English language and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

Regeneron Ireland
Europa House
Block 9 Harcourt Street
Harcourt Street
Dublin 2
Ireland
Attention: Director
Copy: Secretary
Tel: +353 1 411 2207
Fax: +353 (0) 1 686 4924

Mitsubishi Tanabe Pharma Corporation
3-2-10, Dosho-machi, Chuo-ku,
Osaka 541-8505, Japan
Attention: General Manager, Business Development Department
Tel: +81-6-6205-5321
Fax: +81-6-6205-5289

or to such other address as the Party to whom Notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed delivered (i) if sent by mail, as aforesaid, on the date upon which the return receipt is signed or delivery is refused or the Notice is designated by the postal authorities as not deliverable, as the case may be, (ii) if sent by facsimile, as aforesaid, when sent (with confirmation of receipt), and (iii) if sent by courier or hand delivered, as aforesaid, when received. The cost of any translation into English of any communication, document or Notice will be borne solely by the Party providing such communication, document or Notice.

17.6 **Entire Agreement; Amendments**. This Agreement, the Clinical Supply Agreement (when executed), the Commercial Supply Agreement (when executed), the Quality Agreement (when executed) and the Safety Agreement (when executed) contain the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded by this Agreement, the Clinical Supply Agreement, the Commercial Supply Agreement, the Quality Agreement and the

Safety Agreement. Except as expressly set forth in this Agreement, this Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

17.7 **Headings**. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

17.8 **Independent Contractors**. It is expressly agreed that Regeneron and MTPC will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Regeneron nor MTPC will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior consent of the other Party.

17.9 **Waiver**. The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

17.10 **Counterparts**. This Agreement may be executed in identical duplicate copies exchanged by facsimile or e-mail (in PDF format) transmission. Each identical counterpart will be deemed an original, but all of which together will constitute one and the same instrument.

17.11 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

17.12 **Third Party Beneficiaries**. Except as otherwise expressly provided in this Agreement, nothing herein expressed or implied is intended or will be construed to confer upon or to give to any Third Party any rights or remedies by reason of this Agreement. Except as otherwise expressly provided in this Agreement, there are no intended Third Party beneficiaries under or by reason of this Agreement.

17.13 **Further Assurances**. Upon the other Party's request hereunder, each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

17.14 **Construction of Agreement.** Unless context otherwise clearly requires, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "day" or "year" means a calendar day or calendar year unless otherwise specified; (iii) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other legally operative communications contemplated under this Agreement; (iv) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including all Appendices); (v) the word "or" shall be construed as the inclusive meaning identified with the phrase "and/or;" (vi) provisions that require that a Party, the Parties or any committee or team hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific

and in writing, whether by written agreement, letter, approved minutes or otherwise; (vii) words of any gender include the other gender; (viii) references to any specific Applicable Law or article, section or other division thereof shall be deemed to include the then-current amendments thereto or any replacement Applicable Law thereof; and (ix) references to either Party include the successors and permitted assigns of that Party. If the terms of this Agreement conflict with the terms of any Appendix, then the terms of this Agreement will govern.

[Remainder of this page is intentionally left blank.]

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

IN WITNESS WHEREOF, the Parties have executed this Collaboration Agreement to be effective as of the Effective Date.

MITSUBISHI TANABE PHARMA CORPORATION		REGENERON IRELAND	
By:	/s/ Masayuki Mitsuka	By:	/s/ Niall O'Leary
Name:	Masayuki Mitsuka, Ph.D.	Name:	Niall O'Leary
Title:	President & Representative Director Chief Executive Officer	Title:	Executive Director - Site Head

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

Approved MTPC Distributor/Contractor Appendix

1. MTPC Distributors

Name	Registered office
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

2. MTPC Contractors

Name	Registered office
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Regulatory and Development Document Appendix

A) The following documents, modules and materials, "Time Sensitive Regulatory Documents", are to be provided to Regeneron in English, [***], but in no event later than [***] Business Days prior to submission to the applicable Regulatory Authority. Regeneron shall use good faith efforts to respond within no more than [***] Business Days of receipt of such materials and MTPC will use good faith efforts to incorporate Regeneron's comments.

Time Sensitive Regulatory Documents include:

[***]

B) The following documents and materials are to be provided to Regeneron in English, [***].

[***]

C) The following documents and materials are to be provided in English at each meeting of the JDC: [***]

Additional documents or materials may be added to this list upon mutual agreement of the Parties or the approval of any Committee.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

Summary of Initial Territory Development Plan Appendix

[***]

118946190 v36

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

Inventory Report Appendix

[***]

118946190 v36

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and three asterisks [***], have been separately filed with the Commission.

Purchase Price Adjustment Appendix

[***]

118946190 v36

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2015

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert E. Landry, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2015

/s/ Robert E. Landry
Robert E. Landry
Senior Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
November 4, 2015

/s/ Robert E. Landry
Robert E. Landry
Senior Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
November 4, 2015