

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 **March 31, 2014**

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  
(State or other jurisdiction of  
incorporation or organization)

13-3444607  
(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York  
(Address of principal executive offices)

10591-6707  
(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  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  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  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

Number of shares outstanding of each of the registrant's classes of common stock as of April 17, 2014:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
Class A Stock, \$.001 par value	2,000,781
Common Stock, \$.001 par value	98,879,794

**REGENERON PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
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"ARCALYST<sup>®</sup>", "EYLEA<sup>®</sup>", "ZALTRAP<sup>®</sup>", "VelocImmune<sup>®</sup>", "VelociGene<sup>®</sup>", "VelociMouse<sup>®</sup>", "VelociMab<sup>®</sup>", and "VelociSuite<sup>®</sup>" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2014</b>	<b>2013</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 461,858	\$ 535,608
Marketable securities	186,275	158,376
Accounts receivable - trade, net	801,773	787,071
Accounts receivable from Sanofi	118,003	104,707
Accounts receivable from Bayer HealthCare	127,720	63,189
Inventories	86,545	70,354
Deferred tax assets	36,623	44,677
Prepaid expenses and other current assets	52,252	32,952
<b>Total current assets</b>	<b>1,871,049</b>	<b>1,796,934</b>
Marketable securities	534,689	389,891
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	600,864	526,983
Deferred tax assets	248,454	231,878
Other assets	5,340	5,327
<b>Total assets</b>	<b>\$ 3,260,396</b>	<b>\$ 2,951,013</b>
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 237,935	\$ 250,896
Deferred revenue from Sanofi, current portion	12,980	12,815
Deferred revenue - other, current portion	53,093	34,185
Facility lease obligations, current portion	1,060	939
<b>Total current liabilities</b>	<b>305,068</b>	<b>298,835</b>
Deferred revenue from Sanofi	73,694	76,522
Deferred revenue - other	128,539	107,677
Facility lease obligations	203,380	184,258
Convertible senior notes	326,673	320,315
Other long-term liabilities	11,794	11,330
<b>Total liabilities</b>	<b>1,049,148</b>	<b>998,937</b>
<b>Stockholders' equity:</b>		
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 - 2,000,781 at March 31, 2014 and 2,020,481 at December 31, 2013	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 98,847,729 at March 31, 2014 and 97,666,814 at December 31, 2013	99	97
Additional paid-in capital	2,236,931	2,045,857
Accumulated deficit	(27,249)	(92,692)
Accumulated other comprehensive income (loss)	1,465	(1,188)
<b>Total stockholders' equity</b>	<b>2,211,248</b>	<b>1,952,076</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 3,260,396</b>	<b>\$ 2,951,013</b>

**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 March 31,	
	2014	2013
<b>Statements of Operations</b>		
Revenues:		
Net product sales	\$ 362,378	\$ 318,740
Sanofi collaboration revenue	130,508	99,273
Bayer HealthCare collaboration revenue	125,312	14,907
Technology licensing and other revenue	7,542	6,744
	<u>625,740</u>	<u>439,664</u>
Expenses:		
Research and development	287,379	180,299
Selling, general, and administrative	108,850	77,260
Cost of goods sold	27,473	28,021
Cost of collaboration manufacturing	16,099	1,034
	<u>439,801</u>	<u>286,614</u>
Income from operations	<u>185,939</u>	<u>153,050</u>
Other income (expense):		
Investment income	937	456
Interest expense	(11,613)	(11,675)
	<u>(10,676)</u>	<u>(11,219)</u>
Income before income taxes	175,263	141,831
Income tax expense	<u>(109,820)</u>	<u>(42,957)</u>
Net income	<u>\$ 65,443</u>	<u>\$ 98,874</u>
Net income per share - basic	\$ 0.66	\$ 1.02
Net income per share - diluted	\$ 0.58	\$ 0.90
Weighted average shares outstanding - basic	98,709	96,878
Weighted average shares outstanding - diluted	112,151	109,369
<b>Statements of Comprehensive Income</b>		
Net income	\$ 65,443	\$ 98,874
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	2,653	(478)
Comprehensive income	<u>\$ 68,096</u>	<u>\$ 98,396</u>

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

**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)**  
**For the three months ended March 31, 2014 and 2013**  
*(In thousands)*

	Class A Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance, December 31, 2013</b>	2,020	\$ 2	97,667	\$ 97	\$2,045,857	\$ (92,692)	\$ (1,188)	\$ 1,952,076
Issuance of Common Stock in connection with exercise of stock options	—	—	1,338	2	53,918	—	—	53,920
Common Stock tendered upon exercise of stock options in connection with employee tax obligations	—	—	(198)	—	(63,086)	—	—	(63,086)
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	—	—	21	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(20)	—	20	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	82,982	—	—	82,982
Excess tax benefit from stock-based compensation	—	—	—	—	117,260	—	—	117,260
Net income	—	—	—	—	—	65,443	—	65,443
Other comprehensive income	—	—	—	—	—	—	2,653	2,653
<b>Balance, March 31, 2014</b>	<u>2,000</u>	<u>\$ 2</u>	<u>98,848</u>	<u>\$ 99</u>	<u>\$2,236,931</u>	<u>\$ (27,249)</u>	<u>\$ 1,465</u>	<u>\$ 2,211,248</u>
<b>Balance, December 31, 2012</b>	2,069	\$ 2	95,223	\$ 95	\$1,763,508	\$ (517,054)	\$ (1,166)	\$ 1,245,385
Issuance of Common Stock in connection with exercise of stock options	—	—	396	—	9,804	—	—	9,804
Common Stock tendered upon exercise of stock options in connection with employee tax obligations	—	—	(17)	—	(3,085)	—	—	(3,085)
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	—	—	38	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(11)	—	11	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	53,555	—	—	53,555
Excess tax benefit from stock-based compensation	—	—	—	—	2,293	—	—	2,293
Net income	—	—	—	—	—	98,874	—	98,874
Other comprehensive loss	—	—	—	—	—	—	(478)	(478)
<b>Balance, March 31, 2013</b>	<u>2,058</u>	<u>\$ 2</u>	<u>95,651</u>	<u>\$ 95</u>	<u>\$1,826,075</u>	<u>\$ (418,180)</u>	<u>\$ (1,644)</u>	<u>\$ 1,406,348</u>

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

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

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 65,443	\$ 98,874
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>		
Depreciation and amortization	11,530	9,407
Non-cash compensation expense	81,408	53,030
Non-cash interest expense	5,916	5,781
Other non-cash charges and expenses, net	3,761	7,174
Deferred taxes	(8,522)	39,525
<b>Changes in assets and liabilities:</b>		
Increase in Sanofi, Bayer HealthCare, and trade accounts receivable	(92,529)	(117,782)
Increase in inventories	(15,550)	(17,581)
Increase in prepaid expenses and other assets	(20,898)	(17,815)
Increase (decrease) in deferred revenue	37,107	(6,470)
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(14,139)	32,105
Total adjustments	(11,916)	(12,626)
Net cash provided by operating activities	53,527	86,248
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(253,878)	(181,236)
Sales or maturities of marketable securities	82,469	54,754
Capital expenditures	(64,822)	(21,203)
Net cash used in investing activities	(236,231)	(147,685)
<b>Cash flows from financing activities:</b>		
Payments in connection with facility and capital lease obligations	(262)	(649)
Proceeds from issuance of Common Stock	55,042	12,964
Payments in connection with Common Stock tendered for employee tax obligations	(63,086)	(3,085)
Excess tax benefit from stock-based compensation	117,260	2,293
Net cash provided by financing activities	108,954	11,523
Net decrease in cash and cash equivalents	(73,750)	(49,914)
Cash and cash equivalents at beginning of period	535,608	230,276
Cash and cash equivalents at end of period	\$ 461,858	\$ 180,362

**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. ("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, 2013 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, 2013.

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

**2. Net Product Sales**

EYLEA<sup>®</sup> net product sales in the United States totaled \$359.0 million and \$313.9 million for the three months ended March 31, 2014 and 2013, respectively. In addition, ARCALYST<sup>®</sup> net product sales totaled \$3.4 million and \$4.8 million for the three months ended March 31, 2014 and 2013, respectively.

For the three months ended March 31, 2014 and 2013, the Company recorded 79% and 77%, respectively, of its 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 (including Medicaid), distribution-related fees, prompt pay discounts, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the three months ended March 31, 2014.

	<b>Rebates &amp; Chargebacks</b>	<b>Distribution- Related Fees</b>	<b>Other Sales- Related Deductions</b>	<b>Total</b>
Balance as of December 31, 2013	\$ 4,400	\$ 19,663	\$ 538	\$ 24,601
Provision related to current period sales	6,886	16,858	448	24,192
Credits/payments	(6,664)	(16,310)	(454)	(23,428)
Balance as of March 31, 2014	<u>\$ 4,622</u>	<u>\$ 20,211</u>	<u>\$ 532</u>	<u>\$ 25,365</u>

**3. Collaboration Agreements***Sanofi*

The collaboration revenue the Company earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses that the Company incurred, the Company's share of losses in connection with Sanofi's commercialization of ZALTRAP<sup>®</sup>, and revenue related to non-refundable up-front payments.

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

<b>Sanofi Collaboration Revenue</b>	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>ZALTRAP:</b>		
Regeneron's share of losses in connection with commercialization of ZALTRAP	\$ (3,212)	\$ (7,789)
Reimbursement of Regeneron research and development expenses	1,092	2,089
Other	2,177	1,858
<b>Total ZALTRAP</b>	<b>57</b>	<b>(3,842)</b>
<b>Antibody:</b>		
Reimbursement of Regeneron research and development expenses	126,822	99,623
Other	3,629	3,492
<b>Total Antibody</b>	<b>130,451</b>	<b>103,115</b>
<b>Total Sanofi collaboration revenue</b>	<b>\$ 130,508</b>	<b>\$ 99,273</b>

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 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. The Company and Sanofi globally collaborate on the development and commercialization of ZALTRAP. Under the terms of the companies' September 2003 collaboration agreement, as amended, Regeneron and Sanofi share co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan. The Company is entitled to receive a percentage of sales of ZALTRAP in Japan.

Under the Company's antibody collaboration agreement with Sanofi, agreed upon worldwide 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, which first occurred in the fourth quarter of 2013, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. Consequently, in the first quarter of 2014, the Company recognized as additional research and development expense \$23.8 million of antibody development expenses that the Company was obligated to reimburse to Sanofi related to alirocumab and sarilumab.

In May 2013, the Company acquired from Sanofi full exclusive rights to antibodies targeting the platelet derived growth factor (PDGF) family of receptors. At the time of acquisition, antibodies to the PDGF receptor were in preclinical development for use 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, which were recorded in the Company's Statements of Operations as research and development expense, and is obligated to pay up to \$30.0 million in additional potential development milestones as well as royalties on any future sales.

*Bayer HealthCare LLC*

The Company and Bayer HealthCare globally collaborate on the development and commercialization of EYLEA outside of the United States. Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in the fourth quarter of 2012 and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013. 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).



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

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

<b><u>Bayer HealthCare Collaboration Revenue</u></b>	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>EYLEA:</b>		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$ 61,159	\$ 6,362
Sales milestones	30,000	—
Cost-sharing of Regeneron EYLEA development expenses	20,347	5,888
Other	10,932	2,657
Total EYLEA	122,438	14,907
<b>PDGFR-beta antibody:</b>		
Cost-sharing of REGN2176-3 development expenses	513	—
Other	2,361	—
Total PDGFR-beta	2,874	—
Total Bayer HealthCare collaboration revenue	\$ 125,312	\$ 14,907

**EYLEA**

In the first quarter of 2014, the Company earned, and recorded as revenue, two \$15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding \$500 million and \$600 million, respectively, over a twelve-month period. The Company is eligible to receive up to \$60.0 million in additional sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels up to \$1 billion. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of the Company's EYLEA clinical data for a regulatory filing, the Company became eligible to receive up to \$30.0 million in additional sales milestone payments if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels up to \$200 million.

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 will be 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 will also be shared (for countries other than Japan). The Company is entitled to receive a tiered percentage of EYLEA net sales in Japan.

**PDGFR-beta Antibody**

In January 2014, the Company also 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, the Company 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.

**REGENERON PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

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

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. In addition, Bayer HealthCare is 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). Further, in connection with the Company's initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, the Company is eligible to receive up to \$15.0 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.

From inception of the agreement until Bayer HealthCare has the right to opt-in to the collaboration, the Company's sole significant deliverable is research and development services provided in accordance with the agreement. Therefore, the \$25.5 million upfront payment was allocated to this deliverable, initially recorded as deferred revenue, and will be recognized as revenue over the related performance period. In addition, the two \$2.5 million non-substantive development milestone payments from Bayer HealthCare were also initially recorded as deferred revenue and will be recognized over the same performance period as the upfront payment.

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 the Company, pay a \$20.0 million development milestone to the Company upon receipt of the first marketing approval in the European Union or Japan, share profits and losses from sales outside the United States equally with the Company, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

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

The Company also has the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If the Company opts-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.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing a PDGFR-beta antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both the Company and Bayer HealthCare in writing.

**REGENERON PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)***(Unless otherwise noted, dollars in thousands, except per share data)***4. 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:

	<b>Three months ended March</b>	
	<b>31,</b>	
	<b>2014</b>	<b>2013</b>
Net income - basic and diluted	\$ 65,443	\$ 98,874
<i>(Shares in thousands)</i>		
Weighted average shares - basic	98,709	96,878
Effect of dilutive securities:		
Stock options	9,879	10,276
Restricted stock	401	325
Warrants	3,162	1,890
Dilutive potential shares	13,442	12,491
Weighted average shares - diluted	112,151	109,369
Net income per share - basic	\$ 0.66	\$ 1.02
Net income per share - diluted	\$ 0.58	\$ 0.90

Shares which have been excluded from the March 31, 2014 and 2013 diluted per share amounts because their effect would have been antidilutive, include the following:

<i>(Shares in thousands)</i>	<b>Three months ended March</b>	
	<b>31,</b>	
	<b>2014</b>	<b>2013</b>
Stock options	3,646	3,868
Convertible senior notes	4,761	4,761

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

**5. Marketable Securities**

Marketable securities at March 31, 2014 and December 31, 2013 consist of both debt securities issued by investment grade institutions as well as equity securities. The following tables summarize the Company's investments in marketable securities at March 31, 2014 and December 31, 2013.

<b>At March 31, 2014</b>	<b>Amortized</b>	<b>Unrealized</b>		<b>Fair</b>
	<b>Cost Basis</b>	<b>Gains</b>	<b>Losses</b>	<b>Value</b>
U.S. government and government agency obligations	\$ 78,196	\$ 82	\$ (13)	\$ 78,265
Corporate bonds	579,600	517	(489)	579,628
Municipal bonds	43,276	138	(13)	43,401
International government agency obligations	8,214	3	—	8,217
Certificates of deposit	7,914	4	—	7,918
Equity securities	1,166	2,369	—	3,535
<b>Total marketable securities</b>	<b>\$ 718,366</b>	<b>\$ 3,113</b>	<b>\$ (515)</b>	<b>\$ 720,964</b>

<b>At December 31, 2013</b>				
U.S. government and government agency obligations	\$ 107,493	\$ 55	\$ (27)	\$ 107,521
Corporate bonds	369,321	233	(361)	369,193
Commercial paper	23,891	53	—	23,944
Municipal bonds	36,935	45	(59)	36,921
International government agency obligations	2,007	1	—	2,008
Certificates of deposit	7,509	5	—	7,514
Equity securities	1,166	—	—	1,166
<b>Total marketable securities</b>	<b>\$ 548,322</b>	<b>\$ 392</b>	<b>\$ (447)</b>	<b>\$ 548,267</b>

The Company classifies its debt securities based on their contractual maturity dates. The debt securities listed at March 31, 2014 mature at various dates through August 2024. The fair values of debt security investments by contractual maturity as of March 31, 2014 and December 31, 2013 consist of the following:

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
Maturities within one year	\$ 186,275	\$ 158,376
Maturities after one year through five years	525,961	383,410
Maturities after five years through ten years	4,042	4,138
Maturities after ten years	1,151	1,177
	<b>\$ 717,429</b>	<b>\$ 547,101</b>

**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, at March 31, 2014 and December 31, 2013.

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
<b>At March 31, 2014</b>						
U.S. government and government agency obligations	\$ 5,983	\$ (13)	—	—	\$ 5,983	\$ (13)
Corporate bonds	268,174	(489)	—	—	268,174	(489)
Municipal bonds	12,187	(13)	—	—	12,187	(13)
	<u>\$ 286,344</u>	<u>\$ (515)</u>	<u>—</u>	<u>—</u>	<u>\$ 286,344</u>	<u>\$ (515)</u>
<b>At December 31, 2013</b>						
U.S. government and government agency obligations	\$ 49,241	\$ (27)	—	—	\$ 49,241	\$ (27)
Corporate bonds	176,140	(361)	—	—	176,140	(361)
Municipal bonds	14,431	(59)	—	—	14,431	(59)
	<u>\$ 239,812</u>	<u>\$ (447)</u>	<u>—</u>	<u>—</u>	<u>\$ 239,812</u>	<u>\$ (447)</u>

Realized gains and losses are included as a component of investment income. For the three months ended March 31, 2014 and 2013, 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 months ended March 31, 2014 and 2013 related to unrealized gains and losses on available-for-sale marketable securities. For the three months ended March 31, 2014 and 2013, 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)*

**6. Fair Value Measurements**

The Company's assets that are measured at fair value on a recurring basis, at March 31, 2014 and December 31, 2013, consist of the following:

	Fair Value	Fair Value Measurements at Reporting Date Using	
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
<b>At March 31, 2014</b>			
Available-for-sale marketable securities:			
U.S. government and government agency obligations	\$ 78,265	—	\$ 78,265
Corporate bonds	579,628	—	579,628
Municipal bonds	43,401	—	43,401
International government agency obligations	8,217	—	8,217
Certificates of deposit	7,918	—	7,918
Equity securities	3,535	\$ 3,535	—
	<u>\$ 720,964</u>	<u>\$ 3,535</u>	<u>\$ 717,429</u>
<b>At December 31, 2013</b>			
Available-for-sale marketable securities:			
U.S. government and government agency obligations	\$ 107,521	—	\$ 107,521
Corporate bonds	369,193	—	369,193
Commercial paper	23,944	—	23,944
Municipal bonds	36,921	—	36,921
International government agency obligations	2,008	—	2,008
Certificates of deposit	7,514	—	7,514
Equity securities	1,166	\$ 1,166	—
	<u>\$ 548,267</u>	<u>\$ 1,166</u>	<u>\$ 547,101</u>

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks, and default rates, generated by market transactions involving identical or comparable assets. 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 months ended March 31, 2014 and 2013.

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 months ended March 31, 2014 and 2013. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2014 and 2013.

As of March 31, 2014 and December 31, 2013, the Company had \$400.0 million in aggregate principal amount of 1.875% convertible senior notes that will mature on October 1, 2016 unless earlier converted or repurchased. The fair value of the outstanding convertible senior notes was estimated to be \$1,437.7 million and \$1,327.2 million as of March 31, 2014 and December 31, 2013, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

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

## 7. Inventories

Inventories consist of the following:

	March 31, 2014	December 31, 2013
Raw materials	\$ 6,792	\$ 9,120
Work-in-process	47,858	35,868
Finished goods	13,230	14,352
Deferred costs	18,665	11,014
	<u>\$ 86,545</u>	<u>\$ 70,354</u>

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 March 31, 2014 and 2013, cost of goods sold included inventory write-downs and reserves totaling \$1.1 million and \$3.2 million, respectively.

## 8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2014	December 31, 2013
Accounts payable	\$ 32,692	\$ 61,936
Accrued payroll and related costs	41,754	69,429
Accrued clinical trial expense	30,828	23,654
Accrued sales-related charges, deductions, and royalties	94,554	66,855
Other accrued expenses and liabilities	38,107	29,022
	<u>\$ 237,935</u>	<u>\$ 250,896</u>

## 9. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. For the three months ended March 31, 2014 and 2013, the Company recorded an income tax provision of \$109.8 million and \$43.0 million, respectively. The Company's effective tax rate for the three months ended March 31, 2014 and 2013 was 62.7% and 30.3%, respectively. The Company's effective tax rate for the three months ended March 31, 2014 was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, and (iii) recently enacted New York State tax legislation. 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 10.4% for the first quarter of 2014.

The Company's effective tax rate for the three months ended March 31, 2013 included, as a discrete item, the favorable impact of the enactment of The American Taxpayer Relief Act in January 2013. The American Taxpayer Relief Act included a provision to extend the income tax credit for increased research activities retroactively to the tax year ended December 31, 2012, as well as for 2013. As a result, the Company's 2012 research tax credit reduced its effective tax rate for the three months ended March 31, 2013 by 12.3%.

Tax years subsequent to 2009 remain open to examination by federal tax authorities. The Company's 2011 federal income tax return is currently under audit by the Internal Revenue Service. In addition, the Company's 2009, 2010, and 2011 New York State returns are currently under audit by state tax authorities.

**REGENERON PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

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

**10. Statement of Cash Flows**

Supplemental disclosure of non-cash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2014 and December 31, 2013 were \$17.6 million and \$16.1 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2013 and December 31, 2012 were \$10.1 million and \$8.6 million, respectively, of accrued capital expenditures.

Pursuant to the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York, the Company recognized a facility lease obligation of \$19.4 million during the three months ended March 31, 2014 in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased. The Company did not recognize any such facility lease obligation during the three months ended March 31, 2013.

**11. Legal Matters**

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. 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 (the "'287 Patent") and its 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. 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).

As the '287 Patent Infringement Litigation and '018 Patent Infringement Litigation proceedings are at an early stage, at this time the Company is not able to predict the outcome of, or an estimate of gain, if any, related to, these proceedings.

**12. Subsequent Events**

In April 2014, the Company received notification that \$61.1 million principal amount of the Company's 1.875% convertible senior notes were surrendered for conversion, and settlement is anticipated during the second quarter of 2014. In accordance with the terms of the notes, the Company elected to settle these conversion obligations through a combination of cash, in an amount up to the principal amount of the converted notes, and shares in respect of any excess thereof (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 May 2014, the Company entered into a research collaboration and license agreement with Avalanche Biotechnologies, Inc., a privately held company, to discover, develop, and commercialize novel gene therapy products for the treatment of ophthalmologic diseases. In connection with the agreement, the Company is required to make a \$2.0 million upfront payment and a \$6.0 million pre-payment of collaboration research costs, and is obligated to pay potential additional research costs, potential development and regulatory milestones (for products directed to as many as eight therapeutic targets), and royalties on any future sales of such products. The Company has also purchased an aggregate of \$5.0 million of Avalanche preferred stock. Under the agreement, the Company will collaborate with Avalanche to conduct research for the discovery of novel gene therapy vectors. Subsequent to the filing of an Investigational New Drug application ("IND") with the FDA for a product candidate, Regeneron may exercise its right to obtain exclusive worldwide rights to further research, develop, and commercialize such product candidates directed to the applicable therapeutic target. In addition, Avalanche has the option to share in development costs and profits for products directed toward up to two therapeutic targets of its choice.



## 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 Regeneron's human genetics initiative; 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 EYLEA<sup>®</sup>, sarilumab, alirocumab, and dupilumab; ongoing regulatory obligations and oversight impacting our 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 third party intellectual property 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, colorectal cancer, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis (RA), asthma, and atopic dermatitis.

Our total revenues were \$625.7 million in the first quarter of 2014, compared to \$439.7 million in the first quarter of 2013. Our net income was \$65.4 million, or \$0.58 per diluted share, in the first quarter of 2014, compared to net income of \$98.9 million, or \$0.90 per diluted share, in the first quarter of 2013. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have three marketed products:

- **EYLEA (afibercept) Injection**, known in the scientific literature as VEGF Trap-Eye, which 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) and macular edema following central retinal vein occlusion (CRVO). We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States.
- **ZALTRAP<sup>®</sup> (ziv-afibercept) Injection for Intravenous Infusion**, known in the scientific literature as VEGF Trap, which is 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. Regulatory applications for marketing authorization of ZALTRAP for the treatment of previously treated mCRC patients in other countries have also been submitted and are currently under review by the respective regulatory agencies. We and Sanofi globally collaborate on the development and commercialization of ZALTRAP.
- **ARCALYST<sup>®</sup> (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.

We have 17 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of two Trap-based clinical programs and 15 fully human monoclonal antibody product candidates, as summarized below:

**Trap-based Clinical Programs**

**EYLEA**

In Phase 3 clinical development for the treatment of diabetic macular edema (DME), macular edema following branch retinal vein occlusion (BRVO), and myopic choroidal neovascularization (mCNV), in collaboration with Bayer HealthCare.

**ZALTRAP**

In Phase 1b clinical development with angiopoietin-2 inhibitor (nesvacumab) in oncology in collaboration with Sanofi.

**Antibody-based Clinical Programs**

**In Collaboration with Sanofi**

**Developed Independently**

***Sarilumab (REGN88)***

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

***REGN1400***

Antibody to ErbB3.  
In Phase 1 clinical development in oncology.

***Alirocumab (REGN727)***

Antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9).  
In Phase 3 clinical development for low-density lipoprotein (LDL) cholesterol reduction.

***REGN1154***

Antibody in Phase 1 clinical development against an undisclosed target.

***Dupilumab (REGN668)***

Antibody to the interleukin-4 receptor alpha (IL-4R).  
In clinical development in atopic dermatitis (Phase 2b), asthma (Phase 2b), and nasal polyposis (Phase 2).

***REGN1500***

Antibody in Phase 1 clinical development against an undisclosed target.

***Enoticumab (REGN421)***

Antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target.  
In Phase 1 clinical development in oncology.

***REGN1193***

Antibody in Phase 1 clinical development against an undisclosed target.

***Nesvacumab (REGN910)***

Antibody to angiopoietin-2 (Ang2), a novel angiogenesis target.  
In Phase 1 clinical development in oncology.

***REGN1908-1909***

Antibody combination in Phase 1 clinical development against an undisclosed target.

***REGN1033***

Antibody to myostatin (GDF8).  
In Phase 2 clinical development in skeletal muscle disorders.

***Fasinumab (REGN475)***

Antibody to Nerve Growth Factor (NGF).  
In development for the treatment of pain; currently on clinical hold by the Food and Drug Administration (FDA).

***REGN2009***

Antibody in Phase 1 clinical development against an undisclosed target.

***REGN2222***

Antibody in Phase 1 clinical development against an undisclosed target.

**In Collaboration with Bayer HealthCare**

***REGN2176-3***

Combination product comprised of an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta) co-formulated with EYLEA for use in ophthalmology.

In Phase 1 clinical development for the treatment of wet AMD.

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. Our long-term objective is 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*<sup>®</sup> 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*<sup>®</sup> technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*<sup>®</sup>) and cell line expression technologies (*VelociMab*<sup>®</sup>) 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.

We recently launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC will perform 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 intends to pursue both large population-based efforts as well as family-based approaches.

## Marketed Products

### ***EYLEA (afibercept) Injection***

Net product sales of EYLEA in the United States were \$359.0 million in the first quarter of 2014, compared to \$313.9 million in the first quarter of 2013. Bayer HealthCare records revenue from sales of EYLEA outside the United States, which were \$218.1 million in the first quarter of 2014 and \$62.0 million in the first quarter of 2013.

We commenced sales of EYLEA for the treatment of wet AMD in November 2011 and for the treatment of macular edema following CRVO in September 2012, following receipt of regulatory approval in the United States. Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals outside the United States, and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013 following receipt of regulatory approvals in the EU and Japan. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD and macular edema secondary to CRVO pending in other countries.

In August 2013, we and Bayer HealthCare announced positive week 52 results from the Phase 3 VISTA-DME and VIVID-DME trials of EYLEA for the treatment of DME, as described below under "Trap-based and Late-Stage Antibody-based Clinical Programs: *EYLEA - Ophthalmologic Diseases*." Based on the positive results of these studies, we submitted a supplemental Biologics License Application (BLA) for U.S. regulatory approval of EYLEA in DME in the fourth quarter of 2013; the target date for an FDA decision on the supplemental BLA is August 18, 2014. Applications for marketing approval for the treatment of DME in the EU and Japan have also been submitted by Bayer HealthCare. In addition, in February 2014, we and Bayer HealthCare announced positive week 100 results from the Phase 3 VISTA-DME trial, as described below under "Trap-based Clinical Programs: *EYLEA - Ophthalmologic Diseases*." In October 2013, we announced positive week 24 results from the Phase 3 VIBRANT trial of EYLEA for the treatment of macular edema following BRVO, as described below under "Trap-based Clinical Programs: *EYLEA - Ophthalmologic Diseases*." Based on the positive results of this study, a supplemental BLA for U.S. regulatory approval of EYLEA in macular edema following BRVO was submitted, and the target date for an FDA decision on the supplemental BLA is October 23, 2014.

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.

### ***ZALTRAP (ziv-afibercept) Injection for Intravenous Infusion***

We and Sanofi globally collaborate on the development and commercialization of ZALTRAP, and share profits and losses from commercialization of ZALTRAP, except for Japan, where we are entitled to receive a percentage of the sales of ZALTRAP. ZALTRAP net product sales, which are recorded by Sanofi, commenced in the United States in August 2012 and in Europe in the first quarter of 2013, and were \$21.6 million in the first quarter of 2014 and \$14.1 million in the first quarter of 2013. Regulatory applications for marketing authorization of ZALTRAP for the treatment of previously treated mCRC patients in other countries have also been submitted and are currently under review by the respective regulatory agencies.

## **ARCALYST (rilonacept) Injection for Subcutaneous Use**

ARCALYST (rilonacept) Injection for Subcutaneous Use 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 totaled \$3.4 million in the first quarter of 2014 and \$4.8 million in the first quarter of 2013.

## **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. In CRVO and BRVO, a blockage occurs in the main blood vessel that transports deoxygenated blood away from the retina. VEGF levels are elevated in response, contributing to macular edema. For clinically significant DME, VEGF-mediated leakage of fluid from blood vessels in the eye results in interference with vision.

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.

EYLEA is being evaluated in Phase 3 programs in patients with DME and macular edema following BRVO. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion 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.

#### Wet AMD

*Phase 3 SIGHT Trial.* In the fourth quarter of 2011, we and Bayer HealthCare initiated a Phase 3 trial in China evaluating the efficacy and safety of EYLEA in wet AMD (SIGHT). The trial is fully enrolled.

*RE-VIEW Study.* In the fourth quarter of 2012, we initiated a study (RE-VIEW) to fulfill a post-marketing requirement by the FDA, which is evaluating the effect of EYLEA on corneal endothelium. The trial is fully enrolled.

#### DME

*Phase 3 VISTA-DME and VIVID-DME Trials.* In August 2013, we and Bayer HealthCare announced that in the Phase 3 VISTA-DME and VIVID-DME trials of EYLEA for the treatment of DME, EYLEA 2 milligrams (mg) dosed monthly and EYLEA 2 mg dosed every two months (after 5 initial monthly injections) achieved the primary endpoint of a significantly greater improvement in best-corrected visual acuity (BCVA) from baseline compared to laser photocoagulation at 52 weeks. Both EYLEA treatment arms demonstrated similar improvements in BCVA. Based on the positive results of these studies, during the fourth quarter of 2013, we submitted a supplemental BLA for U.S. regulatory approval of EYLEA in DME; the target date for an FDA decision on the supplemental BLA is August 18, 2014. Bayer HealthCare also submitted applications for marketing approval for the treatment of DME in the EU in the fourth quarter of 2013 and Japan in the first quarter of 2014. Both the VISTA-DME and VIVID-DME trials are planned to continue up to 148 weeks.

We are conducting the VISTA-DME study in the United States. Bayer HealthCare is conducting the VIVID-DME study in Europe, Japan, and Australia. Patients in both trials were randomized to receive either EYLEA 2 mg monthly, EYLEA 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation. Previously, we reported that both trials achieved their primary endpoint of a statistically significant mean improvement in BCVA at 12 months versus baseline for EYLEA at both dosing schedules versus laser photocoagulation.

In addition, in February 2014, we and Bayer HealthCare announced that in the Phase 3 VISTA-DME trial of EYLEA for the treatment of DME, EYLEA 2 mg dosed monthly and EYLEA 2 mg dosed every two months (after 5 initial monthly injections) showed a sustained improvement from baseline in BCVA at week 100, compared to laser photocoagulation. After two years, patients receiving EYLEA 2 mg monthly had a mean change from baseline in BCVA of 11.5 letters and patients receiving EYLEA

2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 11.1 letters, compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 0.9 letters.

In these trials, EYLEA was generally well tolerated with a similar overall incidence of adverse events (AEs), ocular serious AEs, and non-ocular serious AEs across the treatment groups and the laser control group. The most frequent ocular treatment emergent AEs (TEAEs) observed included conjunctival hemorrhage, eye pain, and vitreous floaters. The most frequent non-ocular TEAEs included hypertension, nasopharyngitis, anemia, and urinary tract infection, which occurred with similar frequency in the treatment groups and the laser control group.

*Phase 3 VIVID-Japan and VIVID EAST-DME Studies.* An additional Phase 3 safety study in Japan (VIVID-Japan) was initiated in the first quarter of 2012 and is required for approval in Japan. Bayer HealthCare recently reported positive results from the VIVID-Japan study, which did not change the overall safety profile for EYLEA in DME, and submitted an application for marketing authorization of EYLEA for the treatment of DME in Japan. In February 2013, we and Bayer HealthCare also initiated another Phase 3 study to evaluate the efficacy and safety of EYLEA in DME in Russia, China, and other Asian countries (VIVID EAST-DME). This trial is fully enrolled.

#### Macular Edema Following BRVO

*Phase 3 VIBRANT Study.* In October 2013, we reported positive top-line results from the VIBRANT trial. The study achieved its primary endpoint of a statistically significant difference for EYLEA dose 2 mg monthly versus laser in proportion of patients who gained at least 15 letters of visual acuity at 24 weeks versus baseline. The incidence of serious AEs (SAEs) was similar in both study arms. The most common ocular AEs in the EYLEA treated patients were conjunctival hemorrhage and eye pain. There were no cases of intraocular inflammation. There was one ocular SAE in a patient in the EYLEA group, which was a traumatic cataract. Based on the positive results of the VIBRANT study, a supplemental BLA for U.S. regulatory approval of EYLEA in BRVO was submitted; the target date for an FDA decision on the supplemental BLA is October 23, 2014.

In January 2014, Bayer HealthCare exercised its right to opt-in to the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO as described below under "Collaborations with Bayer HealthCare - EYLEA outside the United States."

#### Other

*Phase 3 MYRROR Study.* In June 2013, we and Bayer HealthCare announced positive top-line results for EYLEA from the Phase 3 MYRROR study in myopic choroidal neovascularization (mCNV). In this trial, patients receiving EYLEA at an initial dose of 2 mg, followed by treatment on an as-needed (PRN) basis, achieved a statistically significant mean improvement in BCVA from baseline to week 24 versus the sham control. The most common adverse events observed in the MYRROR trial that occurred with a frequency of 2% or more were conjunctival hemorrhage, dry eye, eye pain, headache, and nasopharyngitis. Bayer HealthCare submitted an application for regulatory approval for this indication in Japan in the fourth quarter of 2013.

#### **ZALTRAP (ziv-aflibercept) - Oncology**

ZALTRAP is a fusion protein that is designed to bind all forms of VEGF-A, VEGF-B, and PlGF, and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for angiogenesis that is needed for tumors to grow.

During the third quarter of 2012, we and Sanofi initiated a Phase 1b study of a combination of ZALTRAP and our angiopoietin-2 inhibitor (nesvacumab) in patients with advanced solid malignancies.

#### **Late-Stage Antibody-based Clinical Programs**

##### ***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 SARIL-RA-MOBILITY Trial.* In the fourth quarter of 2013, we and Sanofi announced that in the SARIL-RA-MOBILITY Phase 3 clinical trial in adult patients with active RA who were inadequate responders to MTX therapy, sarilumab treatment in combination with MTX improved disease signs and symptoms as well as physical function, and inhibited progression of joint damage. The 52 week SARIL-RA-MOBILITY Phase 3 trial enrolled approximately 1,200 patients with active, moderate-to-severe rheumatoid arthritis, and who were inadequate responders to MTX therapy. Patients were randomized to one of three subcutaneous treatment groups, all in combination with MTX and dosed every other week: sarilumab 200 mg, sarilumab 150 mg, or placebo.

Both sarilumab groups showed clinically relevant and statistically significant improvements compared to the placebo group in all three co-primary endpoints ( $p < 0.0001$ ).

In the SARIL-RA-MOBILITY trial, infections were the most frequently reported adverse events and were reported with a higher incidence in the sarilumab groups compared to placebo, all in combination with MTX. Among patients treated with sarilumab, a dose dependent decrease in mean neutrophil counts was observed. Serious infections were not associated with grades 3 and 4 neutropenia in this study. Increases in mean LDL cholesterol and transaminases were observed.

The efficacy and safety data from the SARIL-RA-MOBILITY study will be presented at an upcoming medical conference.

**Additional Phase 3 Studies.** We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-TARGET, SARIL-RA-COMPARE, and SARIL-RA-ASCERTAIN. 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 (TNF-alpha) inhibitor therapy. SARIL-RA-TARGET is a randomized, double-blind, placebo-controlled study evaluating sarilumab in combination with non-biologic, disease-modifying anti-rheumatic drugs (DMARDs) in moderate-to-severe active RA patients with inadequate responses to, or who are intolerant of, one or more TNF-alpha inhibitors. The SARIL-RA-COMPARE study is evaluating the safety and efficacy of sarilumab plus MTX compared to etanercept (a TNF-alpha inhibitor) plus MTX in adult patients with moderate-to-severe RA who demonstrate an inadequate response to adalimumab as their first TNF-alpha inhibitor therapy. The SARIL-RA-ASCERTAIN study is a safety study evaluating the safety and tolerability of sarilumab versus a calibrator, tocilizumab, both in combination with MTX, in patients with RA who are inadequate responders to, or intolerant of, TNF-alpha inhibitors. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, or SARIL-RA-ASCERTAIN 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.** A Phase 2 study, SARIL-NIU-SATURN, was initiated in the fourth quarter of 2013 and is a placebo-controlled proof-of-concept study evaluating the safety and efficacy of sarilumab in non-infectious uveitis.

### **Alirocumab (REGN727; PCSK9 Antibody) 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 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. PCSK9 is a secreted protein that plays a key role in modulating LDL cholesterol (LDL-C) levels in the body. PCSK9 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. We used our *VelocImmune* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called alirocumab, that is intended to lower LDL cholesterol.

#### Clinical Programs

**Phase 2 Studies.** Alirocumab has been studied in three Phase 2 clinical studies, two in patients with primary hypercholesterolemia and one in patients with heterozygous familial hypercholesterolemia (heFH). In the Phase 2 studies, alirocumab significantly reduced LDL-C from baseline up to 72% on top of standard of care statin therapy. In the Phase 2 program, injection site reactions were the most common AEs with alirocumab, and were rare. Rare cases of hypersensitivity reaction were also reported. SAEs were reported in 1.8% of patients in the active treatment arms and 2.6% of patients in the placebo groups.

In the first quarter of 2014, the first Phase 2 study with alirocumab in Japanese patients met its primary endpoint. The results demonstrated that the mean LDL-C percentage reduction from baseline to week 12, the primary efficacy endpoint of the study, was significantly greater in patients randomized to receive one of three doses of alirocumab administered every other week (Q2W) - 150 mg, 75 mg, and 50 mg, in combination with statin therapy, compared to patients receiving placebo. At week 12, the mean percentage reduction in LDL-C from baseline in patients receiving alirocumab 50 mg Q2W was 55%, alirocumab 75 mg Q2W was 62% and alirocumab 150 mg Q2W was 72%, compared to 3 percent in the placebo group. TEAEs in this study were reported by 52% of patients in the alirocumab 50 mg group, 48% of patients in the 75 mg group, and 64% of patients in the 150 mg group, compared to 32% in the placebo group. The most frequently reported TEAEs were nasopharyngitis, injection site reaction, back pain, cystitis and ligament sprain.

**Phase 3 ODYSSEY Program.** We and Sanofi initiated the global Phase 3 ODYSSEY program for alirocumab in the second quarter of 2012. The ODYSSEY program is expected to enroll more than 23,000 patients. This includes eleven clinical trials evaluating the effect of alirocumab, dosed every two weeks, on lowering LDL cholesterol. In addition, the 18,000 patient ODYSSEY



OUTCOMES trial, assessing reduction in serious cardiovascular events, is currently enrolling patients, while the other trials exploring every two week dosing in the ODYSSEY program are fully enrolled. LDL cholesterol reduction is expected to be the primary efficacy endpoint for initial regulatory filings. Additionally, the ODYSSEY program includes two trials of alirocumab dosed every four weeks, ODYSSEY CHOICE I, which was initiated in the fourth quarter, and ODYSSEY CHOICE II, which was initiated in the first quarter of 2014; both of these trials are fully enrolled. Patients in the ODYSSEY CHOICE I trial receive alirocumab 300 mg in combination with statins each month and patients in the CHOICE II trial receive alirocumab 150 mg monotherapy and in combination with non-statin lipid lowering therapy each month. The ODYSSEY studies are being conducted in clinical centers around the world including North America, Western and Eastern Europe, South America, Australia, and Asia.

The first trial to report data from the Phase 3 ODYSSEY program was the ODYSSEY MONO trial (in the fourth quarter of 2013), which evaluated the efficacy and safety of alirocumab monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. The study achieved its primary efficacy endpoint and demonstrated that patients randomized to receive alirocumab monotherapy experienced a mean reduction in LDL-C levels of 47.2% from baseline to week 24, compared to 15.6% in patients receiving ezetimibe monotherapy ( $p < 0.0001$ ). The percentage of patients who reported TEAEs was 78.4% in the ezetimibe group and 69.2% in the alirocumab group. The most common class of AEs was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related AEs occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab.

### ***Dupilumab (REGN668; IL-4R Antibody) for allergic and immune 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 dermatitis and asthma. Dupilumab is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to bind to IL-4R.

#### Atopic Dermatitis

*Phase 2a Trial.* Data from a European Phase 2a study of dupilumab in atopic dermatitis were presented during the annual meeting of the American Academy of Allergy Asthma and Immunology in March 2014. In this study of 109 patients with moderate-to-severe atopic dermatitis, dupilumab 300 mg administered weekly was associated with rapid and marked sustained improvements in several endpoints such as Eczema Severe Score Index (EASI), Scoring of Atopic Dermatitis (SCORAD), Investigator's Global Assessment Score (IGA), baseline Body Surface Area (BSA), and pruritus. After 12 weeks of treatment, patients receiving dupilumab achieved statistically superior clinical outcomes compared to patients in the placebo group in all measures of disease activity and pruritus. There were notably fewer patients with skin infections associated with dupilumab treatment (5.5%), compared with placebo (24.1%). There were no infection related SAEs or eczema herpeticum in the dupilumab group. In the placebo group, three patients with skin infections and four patients with atopic dermatitis exacerbations required hospitalization. The most common TEAEs were nasopharyngitis, headache, and conjunctivitis.

*Phase 2b Trial.* In the second quarter of 2013, a Phase 2b trial in atopic dermatitis was initiated, and is currently fully enrolled.

#### Asthma

*Phase 2a Trial.* Data from a Phase 2a trial in asthma patients with elevated eosinophils were presented at the American Thoracic Society in May 2013, and were also published in the *New England Journal of Medicine* in June 2013. In this study, patients receiving dupilumab at 300 mg weekly for 12 weeks experienced an 87% reduction in the incidence of asthma exacerbations compared to patients receiving placebo ( $p < 0.0001$ ). Clinically meaningful and statistically significant improvements were observed for lung function and other asthma control parameters, such as forced expiratory volume over one second (FEV<sub>1</sub>). TEAEs were reported by a similar proportion of patients in both treatment groups (76.9% placebo; 80.8% dupilumab). AEs were generally non-specific and of mild-to-moderate intensity. The most common AEs for placebo and dupilumab were injection-site reaction, nasopharyngitis, upper respiratory tract infection, headache, and nausea.

*Phase 2b Trial.* In the second quarter of 2013, a Phase 2b trial in asthma was initiated and is currently enrolling patients.

#### Nasal Polyposis

*Phase 2 Study.* In the third quarter of 2013, a Phase 2 study in nasal polyposis was initiated and is currently enrolling patients.

### **Other Antibody-based Clinical Programs**

Each of the antibodies in the table below was generated using our *VelocImmune* technology.

Program	Overview	Clinical Status
<b>Enoticumab (REGN421; Dll4 Antibody) for advanced malignancies*</b>	In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. Enoticumab is a fully human monoclonal antibody to Dll4.	In Phase 1 clinical development.
<b>Nesvacumab (REGN910; Ang2 Antibody) for oncology*</b>	The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, Ang2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. Enhanced anti-tumor effects have been observed in preclinical models with combined blockade of both VEGF and Ang2. Nesvacumab is a fully human monoclonal antibody that is designed to block Ang2.	In Phase 1 clinical development in oncology.  In Phase 1b clinical development in combination with ZALTRAP in patients with advanced solid malignancies.
<b>REGN1033 (GDF8 Antibody)*</b>	REGN1033 is a fully human monoclonal antibody to GDF8. Myostatin has been validated as a target to increase muscle mass and strength through genetic mutations in both animals and humans that abrogate its bioactivity.	In Phase 2 clinical development.
<b>REGN2009*</b>	REGN2009 is a fully human monoclonal antibody against an undisclosed target.	In Phase 1 clinical development.
<b>REGN2222*</b>	REGN 2222 is a fully human monoclonal antibody against an undisclosed target.	In the second quarter of 2014, we initiated a Phase 1 clinical study.
<b>REGN1400 (ErbB3 Antibody) for oncology</b>	REGN1400 is a fully human monoclonal antibody against ErbB3.	In Phase 1 clinical development.
<b>REGN1154**</b>	REGN1154 is a fully human monoclonal antibody against an undisclosed target.	Our Phase 1 clinical study in Australia has been completed. We are currently evaluating next steps for this program.
<b>REGN1500**</b>	REGN1500 is a fully human monoclonal antibody against an undisclosed target.	In Phase 1 clinical development.
<b>REGN1193**</b>	REGN1193 is a fully human monoclonal antibody against an undisclosed target.	In Phase 1 clinical development.
<b>REGN1908-1909**</b>	REGN1908-1909 is a fully human monoclonal antibody combination against an undisclosed target.	In Phase 1 clinical development.
<b>REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA) for ophthalmology***</b>	REGN2176-3 is a combination product comprised of an antibody to PDGFR-beta, which was generated using our <i>VelocImmune</i> technology, co-formulated with EYLEA for use in ophthalmology.	In February 2014, we initiated a Phase 1 clinical study for the treatment of wet AMD.
<b>Fasinumab (REGN475; NGF Antibody) for pain (on clinical hold)</b>	Fasinumab is a fully human monoclonal antibody to NGF which is designed to block pain sensitization in neurons. Preclinical experiments indicate that fasinumab specifically binds to and blocks NGF activity and does not bind to or block cell signaling for the closely related neurotrophins NT-3 and BDNF.	In December 2012, the FDA placed fasinumab and other investigational agents targeting NGF on clinical hold based on preclinical findings with other anti-NGF agents in development. Prior to the FDA clinical hold action, we were planning to initiate late-stage clinical trials with fasinumab. There are currently no ongoing trials with fasinumab that are either enrolling or treating patients.

\* Being developed in collaboration with Sanofi.

\*\* Sanofi did not opt-in to, or elected not to continue co-development of, the program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of the product candidate.

\*\*\* Being developed in collaboration with Bayer HealthCare.



## Research Programs

Our preclinical research programs are in the areas of oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

## 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 our three approved products, 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*<sup>®</sup>, 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 we expect to advance into clinical development later in 2014, targets CD20 and CD3.

**Regeneron Genetics Center.** We recently launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC. RGC will leverage 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 intends to pursue both large population-based efforts as well as family-based approaches.

Central to the work of RGC will be 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.

## Collaboration Agreements

### Collaborations with Sanofi

**ZALTRAP.** Since September 2003, we and Sanofi have been parties to a global collaboration for the development and commercialization of ZALTRAP. Under the current terms of our collaboration agreement we and Sanofi share co-promotion rights and share profits and losses from commercialization of ZALTRAP outside of Japan. In Japan, we are entitled to receive a percentage of approximately 35% on sales of ZALTRAP, subject to certain potential adjustments.

Under the collaboration agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by Sanofi. If the collaboration becomes profitable, we will be obligated to reimburse Sanofi out of our share of ZALTRAP profits for 50% of the development expenses that they funded. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the ZALTRAP profits in the quarter unless we elect to reimburse Sanofi at a faster rate. As a result, we expect that, for the foreseeable future, our share of any ZALTRAP profits will be used to reimburse Sanofi for this repayment obligation.

**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 and a License and Collaboration Agreement (each as amended). Pursuant to the collaboration, Sanofi is funding up to \$160 million per year of our antibody discovery activities over the period from 2010-2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an 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 discovery agreement, Sanofi has the option to license rights to the candidate under the license 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.

Sanofi will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. 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 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.

### 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 May 2012, Bayer HealthCare's Japanese subsidiary, Bayer Yakuhin, Ltd., and Santen Pharmaceutical Co., Ltd. entered into an agreement to co-promote EYLEA in Japan. In conjunction with this agreement, we and Bayer HealthCare amended our existing global license and collaboration agreement for EYLEA to convert the 50/50 profit share for Japan into an agreement under which we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales in Japan. In certain specified circumstances, the Japan arrangement may revert to a profit share arrangement.

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 for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO will be shared equally, and profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared (for countries other than Japan). As described above, we are entitled to receive a tiered percentage of EYLEA net sales in Japan.

Since inception of the agreement, we have received \$110.0 million of development milestone payments and \$75.0 million of sales milestone payments from Bayer HealthCare. In addition, we may earn up to \$90.0 million in additional sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels.

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, initially, 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 first quarter of 2014. 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 \$15.0 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 European Union 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.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing a PDGFR-beta antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both us and Bayer HealthCare in writing.

#### **Collaboration with Avalanche Biotechnologies, Inc.**

In May 2014, we entered into a research collaboration and license agreement with Avalanche Biotechnologies, Inc., a privately held company, to discover, develop, and commercialize novel gene therapy products for the treatment of ophthalmologic diseases.

In connection with the agreement, we are required to make a \$2.0 million upfront payment and a \$6.0 million pre-payment of collaboration research costs, and are obligated to pay potential additional research costs, potential development and regulatory milestones (for products directed to as many as eight therapeutic targets), and royalties on any future sales of such products. We have also purchased an aggregate of \$5.0 million of Avalanche preferred stock. Under the agreement, we will collaborate with Avalanche to conduct research for the discovery of novel gene therapy vectors. Subsequent to the filing of an Investigational New Drug application ("IND") with the FDA for a product candidate, we may exercise our right to obtain exclusive worldwide rights to further research, develop, and commercialize such product candidates directed to the applicable therapeutic target. In addition, Avalanche has the option to share in development costs and profits for products directed toward up to two therapeutic targets of its choice.

## **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. 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 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 our 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 2014 to date were, and plans for the next twelve months are, as follows:

**Trap-based Clinical Programs:**

<b>2014 Events to Date</b>	<b>2014-2015 Plans (next 12 months)</b>
<b>EYLEA</b>	
• Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with wet AMD and continued to pursue regulatory applications for marketing approval in additional countries	• Bayer HealthCare to file for China regulatory approval for the treatment of wet AMD
• Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with macular edema secondary to CRVO and continued to pursue regulatory applications for marketing approval in additional countries	• Bayer HealthCare to file for additional ex-US regulatory approvals in DME and additional Asia regulatory approvals in myopic CNV
• Bayer HealthCare opted-in to the global development and commercialization outside the United States for the treatment of macular edema following BRVO	• Report one-year results from the Phase 3 VIBRANT BRVO study
• Reported positive two-year results from the Phase 3 VISTA-DME study	• Bayer HealthCare to file for regulatory approvals outside the United States for the treatment of macular edema following BRVO
• Bayer HealthCare reported positive results from the VIVID-Japan study and submitted an application for marketing authorization of EYLEA for the treatment of DME in Japan	• Regulatory agency decisions on applications in the United States and outside the United States for the treatment of DME and macular edema following BRVO
• Supplemental BLA accepted for regulatory approval in the United States for the treatment of macular edema following BRVO	• Report two year results from Phase 3 VIVID-DME study
<b>ZALTRAP</b>	
• Sanofi received regulatory approval in additional countries for ZALTRAP for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen	• Regulatory agency decisions outside the United States on additional applications for ZALTRAP in the treatment of previously treated mCRC patients

**Antibody-based Clinical Programs:**

	<b>2014 Events to Date</b>	<b>2014-2015 Plans (next 12 months)</b>
<b><i>Sarilumab (IL-6R Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Obtained positive results from Phase 1b RA trial in Japan</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue enrollment in Phase 3 SARIL-RA program</li> <li>ÿ Continue patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis</li> <li>ÿ Initiate additional clinical studies</li> </ul>
<b><i>Alirocumab (PCSK9 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Initiated Phase 3 ODYSSEY CHOICE II trial</li> <li>ÿ Completed patient enrollment in the ODYSSEY CHOICE I and CHOICE II trials</li> <li>ÿ Initiated Phase 3 program in Japan</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue enrollment of Phase 3 ODYSSEY OUTCOMES trial</li> <li>ÿ Report results from additional Phase 3 ODYSSEY trials</li> </ul>
<b><i>Dupilumab (IL-4R Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Reported positive Phase 2a data in atopic dermatitis</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Complete patient enrollment in Phase 2 asthma trials</li> <li>ÿ Report results from Phase 2b study in atopic dermatitis</li> <li>ÿ Initiate Phase 3 trial in atopic dermatitis</li> </ul>
<b><i>Enoticumab (DII4 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Completed patient enrollment in the Phase 1 expansion study</li> </ul>	
<b><i>Nesvacumab (Ang2 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 program</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Complete patient enrollment in the Phase 1b program in advanced malignancies</li> <li>ÿ Initiate clinical development in ophthalmology</li> </ul>
<b><i>REGN1033 (GDF8 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 and Phase 2a studies</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Complete patient enrollment in Phase 1 and Phase 2a programs</li> </ul>
<b><i>REGN2009 (target not disclosed)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 program</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 1 program</li> </ul>
<b><i>REGN2222 (target not disclosed)</i></b>	<ul style="list-style-type: none"> <li>ÿ Initiated Phase 1 program</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 1 program</li> </ul>
<b><i>REGN1400 (ErbB3 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 program</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 1 program</li> </ul>
<b><i>REGN1154 (target not disclosed)</i></b>		<ul style="list-style-type: none"> <li>ÿ Determine future development plan</li> </ul>
<b><i>REGN1500 (target not disclosed)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 program</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 1 program</li> </ul>
<b><i>REGN1193 (target not disclosed)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 program</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 1 program</li> </ul>
<b><i>REGN1908-1909 (target not disclosed)</i></b>	<ul style="list-style-type: none"> <li>ÿ Completed patient enrollment of First in Human study</li> </ul>	
<b><i>REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA)</i></b>	<ul style="list-style-type: none"> <li>ÿ Initiated Phase 1 program</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 1 program</li> </ul>
<b><i>Fasimumab (NGF Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ On clinical hold</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Determine future development plan</li> </ul>

**Results of Operations****Three Months Ended March 31, 2014 and 2013****Net Income**

Net income for the three months ended March 31, 2014 and 2013 consists of the following:

<i>(In millions)</i>	<b>2014</b>	<b>2013</b>
Revenues	\$ 625.7	\$ 439.7
Operating expenses	(439.8)	(286.6)
Other expenses	(10.7)	(11.2)
Income before income taxes	175.2	141.9
Income tax expense	(109.8)	(43.0)
Net income	<u>\$ 65.4</u>	<u>\$ 98.9</u>

**Revenues**

Revenues for the three months ended March 31, 2014 and 2013 consist of the following:

<i>(In millions)</i>	<b>2014</b>	<b>2013</b>
Net product sales	\$ 362.4	\$ 318.7
Collaboration revenue:		
Sanofi	130.5	99.3
Bayer HealthCare	125.3	14.9
Total collaboration revenue	255.8	114.2
Technology licensing and other revenue	7.5	6.8
Total revenues	<u>\$ 625.7</u>	<u>\$ 439.7</u>

**Net Product Sales**

Net product sales consist of U.S. sales of EYLEA and ARCALYST. In November 2011, we received marketing approval from the FDA for EYLEA for the treatment of wet AMD, at which time product sales commenced. In addition, in September 2012, we received marketing approval from the FDA for EYLEA for the treatment of macular edema following CRVO. For the three months ended March 31, 2014, EYLEA net product sales increased to \$359.0 million from \$313.9 million for the three months ended March 31, 2013 due to higher sales volume. For the three months ended March 31, 2014 and 2013, we also recognized ARCALYST net product sales of \$3.4 million and \$4.8 million, respectively.

For the three months ended March 31, 2014 and 2013, we recorded 79% and 77%, 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 (including Medicaid), distribution-related fees, prompt pay discounts, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions for the three months ended March 31, 2014 and 2013.

<i>(In millions)</i>	<b>Rebates &amp; Chargebacks</b>	<b>Distribution- Related Fees</b>	<b>Other Sales- Related Deductions</b>	<b>Total</b>
Balance as of December 31, 2013	\$ 4.4	\$ 19.7	\$ 0.5	\$ 24.6
Provision related to current period sales	6.9	16.9	0.4	24.2
Credits/payments	(6.7)	(16.3)	(0.4)	(23.4)
Balance as of March 31, 2014	<u>\$ 4.6</u>	<u>\$ 20.3</u>	<u>\$ 0.5</u>	<u>\$ 25.4</u>
Balance as of December 31, 2012	\$ 3.0	\$ 15.3	\$ 0.5	\$ 18.8
Provision related to current period sales	5.5	13.9	0.2	19.6
Credits/payments	(4.8)	(11.5)	(0.2)	(16.5)
Balance as of March 31, 2013	<u>\$ 3.7</u>	<u>\$ 17.7</u>	<u>\$ 0.5</u>	<u>\$ 21.9</u>

#### *Sanofi Collaboration Revenue*

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses that we incurred, our share of losses in connection with Sanofi's commercialization of ZALTRAP, and recognition of previously deferred revenue related to non-refundable up-front payments.

<b><u>Sanofi Collaboration Revenue</u></b>	<b><u>Three months ended March 31,</u></b>	
<i>(In millions)</i>	<b><u>2014</u></b>	<b><u>2013</u></b>
<b>ZALTRAP:</b>		
Regeneron's share of losses in connection with commercialization of ZALTRAP	\$ (3.2)	\$ (7.8)
Reimbursement of Regeneron research and development expenses	1.1	2.1
Other	2.2	1.9
Total ZALTRAP	<u>0.1</u>	<u>(3.8)</u>
<b>Antibody:</b>		
Reimbursement of Regeneron research and development expenses	126.8	99.6
Other	3.6	3.5
Total Antibody	<u>130.4</u>	<u>103.1</u>
Total Sanofi collaboration revenue	<u>\$ 130.5</u>	<u>\$ 99.3</u>

Sanofi commenced sales of ZALTRAP for treatment, in combination with FOLFIRI, of patients with 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. Regeneron's share of the loss in connection with commercialization of ZALTRAP, as shown in the table below, represents our 50% share of ZALTRAP net product sales less cost of goods sold and shared commercialization and other expenses.

<b><u>Regeneron's share of losses in connection with commercialization of ZALTRAP</u></b>	<b><u>Three months ended March 31,</u></b>	
<i>(In millions)</i>	<b><u>2014</u></b>	<b><u>2013</u></b>
Net product sales recorded by Sanofi	\$ 21.6	\$ 14.1
Regeneron's share of collaboration losses	(3.2)	(7.8)



Our share of the loss in the first quarter of 2014 and 2013 represents our share of the costs of launching and commercializing ZALTRAP, partly offset by net product sales. Sanofi provides us with an estimate of our share of the profit or loss from commercialization of ZALTRAP 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 quarter of 2014, Sanofi's reimbursement of our antibody research and development expenses consisted of \$40.2 million under our discovery agreement and \$86.6 million of development costs under our license agreement, compared to \$44.4 million and \$55.2 million, respectively, in the first quarter of 2013. The higher reimbursement of development costs in the first quarter of 2014, compared to the same period in 2013, was primarily due to increased development activities for dupilumab.

Other Sanofi antibody revenue relates primarily to recognition of deferred revenue from an \$85.0 million up-front payment and other payments. As of March 31, 2014, \$58.4 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

#### *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, recognition of sales milestones achieved, cost-sharing of Regeneron development expenses, and reimbursement of other Regeneron EYLEA expenses.

<b><u>Bayer HealthCare Collaboration Revenue</u></b> <b>(In millions)</b>	<b>Three months ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>EYLEA:</b>		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$ 61.2	\$ 6.4
Sales milestones	30.0	—
Cost-sharing of Regeneron EYLEA development expenses	20.3	5.9
Other	10.9	2.7
<b>Total EYLEA</b>	<b>122.4</b>	<b>15.0</b>
<b>PDGFR-beta antibody:</b>		
Cost-sharing of REGN2176-3 development expenses	0.5	—
Other	2.4	—
<b>Total PDGFR-beta antibody</b>	<b>2.9</b>	<b>—</b>
<b>Total Bayer HealthCare collaboration revenue</b>	<b>\$ 125.3</b>	<b>\$ 15.0</b>

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in the fourth quarter of 2012 and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below.

<b><u>Regeneron's Net Profit from EYLEA Sales Outside the United States</u></b> <b>(In millions)</b>	<b>Three months ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Net product sales outside the United States	\$ 218.1	\$ 62.0
Regeneron's share of collaboration profit from sales outside the United States	75.6	19.6
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(14.4)	(13.2)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$ 61.2	\$ 6.4

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 first quarter of 2014 and 2013, 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 quarter of 2014, we earned, and recorded as revenue, two \$15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding \$500 million and \$600 million, respectively, over a twelve-month period.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare increased in the first quarter of 2014 compared to the same period in 2013. 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 will be 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 will also be shared.

Other EYLEA revenue principally consists of (i) reimbursement of other Regeneron EYLEA expenses, primarily related to Bayer HealthCare's share of royalties payable to Genentech which commenced in May 2013 pursuant to the license and settlement agreement as described below under "Liquidity and Capital Resources - *License and Settlement Agreements with Genentech - EYLEA*", in connection with sales of EYLEA outside the United States, and (ii) recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of March 31, 2014, \$19.8 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 in connection with the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "*Collaboration 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 and non-substantive milestones received in the first quarter of 2014. In connection with the agreement, Bayer HealthCare made a \$25.5 million non-refundable upfront payment to us in January 2014, as well as two \$2.5 million development milestone payments to us in the first quarter of 2014 (which, for the purpose of revenue recognition, were not considered substantive). As of March 31, 2014, \$28.2 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 first quarter of both 2014 and 2013, we recognized \$5.9 million of technology licensing and other revenue related to this agreement. As of March 31, 2014, \$98.7 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

Under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' canakinumab. In the first quarter of 2014 and 2013, technology licensing and other revenue included \$1.6 million and \$0.8 million, respectively, of royalties from Novartis.

#### *Expenses*

Total operating expenses increased to \$439.8 million in the first quarter of 2014 from \$286.6 million in the first quarter of 2013. Our average headcount in the first quarter of 2014 increased to 2,389 from 1,996 in the same period in 2013, principally in connection with expanding our research and development, and commercialization activities.

Operating expenses in the first quarter of 2014 and 2013 included a total of \$81.4 million and \$53.0 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 first quarter of 2014 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 2013 compared to recent prior years.

## Research and Development Expenses

Research and development expenses increased to \$287.4 million in the first quarter of 2014 from \$180.3 million in the same period of 2013. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2014 and 2013:

<b>Research and Development Expenses</b> <i>(In millions)</i>	<b>Three months ended March 31,</b>		<b>Increase</b>
	<b>2014</b>	<b>2013</b>	<b>(Decrease)</b>
Payroll and benefits <sup>(1)</sup>	\$ 97.2	\$ 69.1	\$ 28.1
Clinical trial expenses	48.2	24.7	23.5
Clinical manufacturing costs <sup>(2)</sup>	54.4	48.6	5.8
Research and other development costs	27.8	14.1	13.7
Occupancy and other operating costs	30.0	21.4	8.6
Cost-sharing of Bayer HealthCare and Sanofi development expenses <sup>(3)</sup>	29.8	2.4	27.4
<b>Total research and development expenses</b>	<b>\$ 287.4</b>	<b>\$ 180.3</b>	<b>\$ 107.1</b>

<sup>(1)</sup> Includes Non-cash Compensation Expense of \$37.6 million for the three months ended March 31, 2014 and \$23.7 million for the three months ended March 31, 2013.

<sup>(2)</sup> 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. Includes Non-cash Compensation Expense of \$5.7 million for the three months ended March 31, 2014 and \$3.1 million for the three months ended March 31, 2013.

<sup>(3)</sup> Under our collaborations with Bayer HealthCare and Sanofi, in periods when Bayer HealthCare or Sanofi incur certain development expenses, we also recognize, as additional research and development expense, the portion of our collaboration partners' development expenses that we are obligated to reimburse. Our collaboration partners 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 collaboration partners' 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 higher costs for clinical studies of alirocumab and dupilumab. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing dupilumab, partly offset by lower costs related to manufacturing clinical supplies of alirocumab. Research and other development costs increased primarily due to two \$5.0 million development milestone payments we made to Sanofi in the first quarter of 2014 in connection with our acquisition from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors in May 2013. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and higher information technology and facility-related costs at our Tarrytown and Rensselaer, New York sites. Cost-sharing of Bayer HealthCare and Sanofi development expenses increased primarily due to our obligation to fund 20% of Sanofi's Phase 3 alirocumab and sarilumab development costs, which commenced during the fourth quarter of 2013.

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 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:

<b>Project Costs</b> <i>(In millions)</i>	<b>Three months ended March 31,</b>		<b>Increase</b>
	<b>2014</b>	<b>2013</b>	<b>(Decrease)</b>
EYLEA	\$ 33.4	\$ 30.4	\$ 3.0
Alirocumab	53.5	31.2	22.3
Sarilumab	19.4	5.5	13.9
Dupilumab	43.1	12.2	30.9
Other antibody candidates in clinical development	43.8	27.9	15.9
Other research programs and unallocated costs	94.2	73.1	21.1
<b>Total research and development expenses</b>	<b>\$ 287.4</b>	<b>\$ 180.3</b>	<b>\$ 107.1</b>

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 \$108.9 million in the first quarter of 2014 from \$77.3 million in the first quarter of 2013 primarily due to higher expenses in connection with contributions to a not-for-profit organization that assists patients with chronic disease conditions and higher Non-cash Compensation Expense principally for the reason described under "Expenses" above. Selling, general, and administrative expenses included \$37.6 million and \$25.8 million of Non-cash Compensation Expense in the first quarter of 2014 and 2013, respectively.

### *Cost of Goods Sold*

Cost of goods sold was \$27.5 million in the first quarter of 2014 and \$28.0 million in the first quarter of 2013. Cost of goods sold primarily consisted of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies. In addition, in the first quarter of 2014 and 2013, cost of goods sold included inventory write-downs and reserves totaling \$1.1 million and \$3.2 million, respectively. We record a charge to cost of goods sold to write down our inventory to its estimated realizable value if certain batches or units of product do not meet quality specifications or are expected to expire prior to sale.

### *Cost of Collaboration Manufacturing*

We manufacture commercial supplies of product for our collaborators. Cost of collaboration manufacturing increased to \$16.1 million in the first quarter of 2014 from \$1.0 million in the first quarter of 2013 primarily due to royalties payable to Genentech, which commenced in May 2013 pursuant to the license and settlement agreement as described below under "Liquidity and Capital Resources - *License and Settlement Agreements with Genentech - EYLEA*", in connection with sales of EYLEA outside the United States. Cost of collaboration manufacturing also includes costs in connection with producing commercial supplies for our collaborators. 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.

### *Other Income and Expense*

Total other expenses, net, decreased to \$10.7 million in the first quarter of 2014 from \$11.2 million in the first quarter of 2013, and consisted of investment income and interest expense. Interest expense in the first quarter of 2014 and 2013 primarily includes interest associated with our \$400.0 million aggregate principal amount of 1.875% convertible senior notes, including amortization of the note discount and debt issuance costs, and interest associated with our facility lease obligations.

### *Income Taxes*

In the first quarter of 2014 and 2013, we recorded income tax expense of \$109.8 million and \$43.0 million, respectively. The effective tax rate for the first quarter of 2014 was 62.7% and was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, and (iii) recently enacted New York State tax legislation. 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 10.4% for the first quarter of 2014.

The effective tax rate for the first quarter of 2013 was 30.3%, which included, as a discrete item, the impact of enacting The American Taxpayer Relief Act in January 2013. The American Taxpayer Relief Act included a provision to extend the income tax credit for increased research activities retroactively for the tax year ended December 31, 2012. As a result, our 2012 research tax credit reduced our effective tax rate for the first quarter of 2013 by 12.3%.

### *Liquidity and Capital Resources*

#### *Sources and Uses of Cash for the Three Months Ended March 31, 2014 and 2013*

At March 31, 2014, we had \$1,182.8 million in cash, cash equivalents, and marketable securities compared with \$1,083.9 million at December 31, 2013. In connection with our U.S. product launch of EYLEA in the fourth quarter of 2011, we offered extended payment terms to our EYLEA customers. EYLEA net trade accounts receivable were \$800.2 million at March 31, 2014 and \$785.8 million at December 31, 2013. During the three months ended March 31, 2014, we collected \$368.1 million of EYLEA trade receivables. Effective January 2014, we have shortened the payments terms to certain of our EYLEA customers, which will reduce our cash collection cycle.

#### *Cash Provided by Operating Activities*

Net cash provided by operating activities was \$53.5 million in the first quarter of 2014. Our net income of \$65.4 million in the first quarter of 2014 included the following non-cash expenses: (i) Non-cash Compensation Expense of \$81.4 million, (ii) depreciation and amortization of \$11.5 million, and (iii) non-cash interest expense of \$5.9 million, primarily resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes, which were issued in October 2011. In addition, deferred tax assets at March 31, 2014 increased by \$8.5 million, compared to end-of-year 2013, primarily due to an increase in Non-cash Compensation Expense and deferred revenue, partly offset by the reduction of our deferred tax assets related to the recently enacted New York State tax legislation, which reduced our New York State income tax rate to zero percent effective in 2014.

At March 31, 2014, Sanofi, Bayer HealthCare, and trade accounts receivable increased by \$92.5 million, compared to end-of-year 2013, primarily due to higher trade accounts receivable in connection with U.S. EYLEA product sales, higher amounts receivable from Sanofi in connection with reimbursement of our antibody development costs, and higher amounts receivable from Bayer HealthCare in connection with the commercialization of EYLEA outside the United States. Inventories increased by \$15.6 million, compared to end-of-year 2013, primarily in connection with increased production of EYLEA commercial supplies. Prepaid expenses and other assets increased by \$20.9 million, compared to end-of-year 2013, primarily due to higher prepaid sales-related fees. Our deferred revenue at March 31, 2014 increased by \$37.1 million, compared to end-of-year 2013, primarily due to (i) the receipt of a \$25.5 million upfront payment as well as two \$2.5 million non-substantive development milestone payments in connection with our PDGFR-beta antibody collaboration agreement with Bayer HealthCare, and (ii) higher deferred revenue in connection with manufacturing commercial supplies of EYLEA for Bayer HealthCare. This revenue is deferred until the product is sold by Bayer HealthCare to third-party customers. These increases were partly offset by amortization of a previously received and deferred \$165.0 million payment under our license agreement with Astellas and amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities decreased by \$14.1 million at March 31, 2014, compared to end-of-year 2013, primarily due to lower payroll-related liabilities as our year-end 2013 employee cash bonuses were paid in the first quarter of 2014 and lower liabilities for vendor invoices received but not yet paid, partly offset by higher accruals for sales-related charges.

Net cash provided by operating activities was \$86.2 million in the first quarter of 2013. Our net income of \$98.9 million in the first quarter of 2013 included (i) Non-cash Compensation Expense of \$53.0 million, (ii) depreciation and amortization of \$9.4 million, (iii) non-cash interest expense of \$5.8 million, resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes, which were issued in October 2011, and (iv) other non-cash charges, including inventory write-downs and reserves of \$3.2 million. In addition, deferred tax assets at March 31, 2013 decreased by \$39.5 million, compared to end-of-year 2012, due to utilization of these assets to offset income taxes payable for the first quarter of 2013.

At March 31, 2013, Sanofi, Bayer HealthCare, and trade accounts receivable increased by \$117.8 million, compared to end-of-year 2012, primarily due to higher trade accounts receivable in connection with EYLEA product sales. Inventories increased by \$17.6 million, compared to end-of-year 2012, primarily in connection with production of EYLEA commercial supplies. Prepaid expenses and other current assets increased by \$17.8 million, compared to end-of-year 2012, primarily due to higher prepaid sales-related fees. Accounts payable, accrued expenses, and other liabilities increased by \$32.1 million at March 31, 2013, compared to end-of-year 2012, primarily due to higher sales-related charges, deductions, and royalties related to EYLEA and higher payroll-related liabilities.

#### *Cash Used in Investing Activities*

Net cash used in investing activities was \$236.2 million and \$147.7 million in the first quarter of 2014 and 2013, respectively. In the first quarter of 2014 and 2013, purchases of marketable securities exceeded sales or maturities by \$171.4 million and \$126.5 million, respectively. Capital expenditures of \$64.8 million and \$21.2 million, in the first quarter of 2014 and 2013, respectively, included costs in connection with purchasing manufacturing equipment, expanding our Rensselaer, New York manufacturing facilities, and tenant improvement and associated costs related to our leased facilities in Tarrytown, New York.

#### *Cash Provided by Financing Activities*

Net cash provided by financing activities was \$109.0 million and \$11.5 million in the first quarter of 2014 and 2013, respectively. Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were \$55.0 million in the first quarter of 2014 compared to \$13.0 million in the first quarter of 2013. In addition, payments for employee tax obligations in connection with stock option exercises were \$63.1 million in the first quarter of 2014 compared to \$3.1 million in the first quarter of 2013. Cash flows from financing activities also increased by \$117.3 million and \$2.3 million in the first quarter of 2014 and 2013, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations.

**Fair Value of Marketable Securities**

At March 31, 2014 and December 31, 2013, we held \$720.9 million and \$548.3 million, respectively, of marketable securities which consisted of debt securities issued by investment grade institutions as well as equity securities. The composition of our portfolio of marketable securities on these dates was as follows:

<b>Investment type</b>	<b>March 31, 2014</b>		<b>December 31, 2013</b>	
	<b>Fair Value</b>	<b>Percent</b>	<b>Fair Value</b>	<b>Percent</b>
U.S. government and government agency obligations	\$ 78.3	11%	\$ 107.5	20%
Corporate bonds	579.6	81%	369.2	68%
Commercial paper	—	—	24.0	4%
Municipal bonds	43.4	6%	36.9	7%
International government agency obligations	8.2	1%	2.0	—
Certificates of deposit	7.9	1%	7.5	1%
Equity securities	3.5	—	1.2	—
Total marketable securities	<u>\$ 720.9</u>	<u>100%</u>	<u>\$ 548.3</u>	<u>100%</u>

In addition, at March 31, 2014 and December 31, 2013, we had \$461.9 million and \$535.6 million, respectively, of cash and cash equivalents, primarily held in bank deposits and money market funds.

**License and Settlement Agreements with Genentech - EYLEA**

In December 2011, we entered into a Non-Exclusive License and Partial Settlement Agreement with Genentech (the Original Genentech Agreement) that covered making, using, and selling EYLEA in the United States for the prevention and treatment of human eye diseases and disorders in the United States, and ended the litigation relating to those matters. The Original Genentech Agreement provided for us to make payments to Genentech based on U.S. sales of EYLEA through May 7, 2016, the date the Davis-Smyth patents expire. Under the Original Genentech Agreement, we made a \$60.0 million milestone payment when cumulative U.S. sales reached \$400 million and are obligated to pay royalties of 4.75% on cumulative relevant sales of EYLEA between \$400 million and \$3 billion and 5.5% on any cumulative relevant sales of EYLEA over \$3 billion.

In May 2013, we entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech (the Amended Genentech Agreement), which amended the Original Genentech Agreement to include all sales of EYLEA worldwide and ended the litigation relating to those matters. Under the Amended Genentech Agreement, we received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of human eye diseases and eye disorders through administration of EYLEA to the eye. Under the Amended Genentech Agreement, we are obligated to make payments to Genentech based on sales of EYLEA in the United States and EYLEA manufactured in the United States and sold outside the United States through May 7, 2016 using the same milestone and royalty rates as in the Original Genentech Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare under our license and collaboration agreement. All payments to Genentech under the Original Genentech Agreement and the Amended Genentech Agreement have been or will be made by Regeneron. Bayer HealthCare will share in all such payments based on the proportion of EYLEA sales outside the United States to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.



### **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 are expected to be completed in the second half of 2015, at our current Tarrytown, New York location. The term of the lease, which is expected to commence in 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 are expected to commence in 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 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. We will allocate a portion of our future lease payments to the Buildings and the land on which the Buildings are being constructed. The land element of the lease is treated for accounting purposes as an operating lease.

### **Capital Expenditures**

Our cash expenditures for property, plant, and equipment totaled \$64.8 million in the first quarter of 2014 and \$21.2 million in the first quarter of 2013.

In July 2013, we reached preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, subject to entering into definitive agreements as well as securing permits from the local government in Limerick. We intend to renovate this facility to accommodate and support our growth, primarily in connection with expanding our manufacturing capacity to support our global supply chain.

We expect to incur capital expenditures of approximately \$280 to \$350 million during the remainder of 2014 primarily in connection with expanding our manufacturing facilities at our Rensselaer facility, tenant improvements primarily related to the two new buildings under construction at our leased Tarrytown facilities, purchasing and commencing renovations on the new Limerick facility described above (predicated on finalizing its purchase), and purchases of equipment.

### **Funding Requirements**

We expect continued growth in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), capital expenditures, and commercialization of EYLEA. We believe that our existing capital resources, funds generated by anticipated EYLEA product sales, and funding for reimbursement of development costs that we are entitled to receive under our collaboration agreements will enable us to meet our projected operating needs for the foreseeable future. As described above, research and development expenses that we incur in connection with our antibodies collaboration are generally funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed antibody drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. In addition, as described above, we and Bayer HealthCare share (i) agreed-upon development expenses that both companies incur in connection with our EYLEA collaboration, and (ii) development costs under the initial development plan in connection with our PDGFR-beta antibody collaboration.

Under our collaboration agreements with Sanofi and Bayer HealthCare, we and our collaborator will 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 becomes profitable, we have contingent contractual obligations to reimburse Sanofi and, in connection with EYLEA outside the United States, Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by Sanofi and Bayer HealthCare, respectively. These reimbursements would be deducted each quarter, in accordance with a formula, from our share of the collaboration profits (and, for our ZALTRAP collaboration with Sanofi and 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, 2013, our contingent reimbursement obligation to Sanofi for ZALTRAP was approximately \$443 million, while our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately \$272 million. Therefore, we expect that, for the foreseeable future, our share of profits from sales of ZALTRAP, and a portion of our share of profits from sales of EYLEA outside the United States, will be used to reimburse our collaborators for these obligations.

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. With respect to PDGF antibodies, we made two \$5.0 million development milestone payments in the first quarter of 2014, and are obligated to pay up to \$30.0 million in potential additional development milestones as well as royalties on any future sales.



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 new indications for our marketed products, 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 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.

Our commercialization costs over the next few years will depend on, among other things, whether or not new indications for our marketed products or our antibody product candidates in later stage clinical development receive regulatory approval, the market potential for such new indications or 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 commercial products. In the future, if we are able to successfully develop, market, and sell EYLEA for other indications, or 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 Patient Protection and Affordable Care Act 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. This fee is allocated to companies, including Regeneron, based on their prior year market share of total branded prescription drug sales into these government programs.

As described above, in the first quarter of 2014 and 2013, we made cash payments of \$63.1 million and \$3.1 million, respectively, for employee tax obligations in connection with stock option exercises. 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 April 2014, we received notification that \$61.1 million principal amount of our 1.875% convertible senior notes were surrendered for conversion, and settlement is anticipated during the second quarter of 2014. In accordance with the terms of the notes, we elected to settle these conversion obligations through a combination of cash, in an amount up to the principal amount of the converted notes, and shares in respect of any excess thereof (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 convertible note hedges, for which we expect to receive shares of Common Stock equivalent to the number of shares we will be required to issue to settle the non-cash portion of the related note conversions.

We may also from time to time seek to repurchase or retire our outstanding convertible senior notes, or other outstanding securities, through cash purchases or exchanges for other securities, in open market purchases, privately negotiated transactions, or otherwise; amounts involved may be material.

Due to the amounts of our net operating loss and tax credit carry-forwards available for tax purposes, which totaled \$450.4 million and \$120.1 million, respectively, at December 31, 2013, we do not anticipate making significant payments for cash income taxes for at least the next twelve months, although we do expect to make payments of alternative minimum tax in 2014 for which we will receive a credit against income taxes in future years.

In connection with our EYLEA collaboration with Bayer HealthCare, we are entitled to receive up to \$60.0 million in additional sales milestones based on total twelve-month sales of EYLEA outside the United States achieving certain specified levels up to \$1 billion. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of our EYLEA clinical data for a regulatory filing, we became eligible to receive up to \$30.0 million in additional sales milestone payments if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels up to \$200 million.

In connection with our PDGFR-beta antibody agreement with Bayer HealthCare, we are eligible to receive up to \$15.0 million in future development milestone payments from Bayer HealthCare (representing 50% of the development milestone payments potentially due to Sanofi as described above), although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration. Furthermore, if Bayer HealthCare exercises their right to opt-in to the collaboration, they will be obligated to pay a \$20.0 million opt-in payment to us, and pay a \$20.0 million development milestone to us upon receipt of the first marketing approval in the European Union or Japan.

### **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 2013 Form 10-K. There have been no material changes to our market risks or to our management of such risks during the three months ended March 31, 2014.

### **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 March 31, 2014 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. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

#### ***Proceedings Relating to '287 Patent and '018 Patent***

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. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (referred to below as "'287 Patent Infringement Litigation" and "'018 Patent Infringement Litigation," respectively), we claim infringement of several claims of the '287 Patent and the '018 Patent (as applicable), and seek, 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).

On January 3, 2014, we commenced '287 Patent Infringement Litigation against Novo Nordisk A/S, a company based in Denmark, in the English High Court of Justice, Chancery Division, Patents Court, in London. On March 27, 2014, Novo Nordisk served a defense to our lawsuit and counterclaimed alleging invalidity of the '287 Patent. Novo Nordisk also intervened in the opposition to the '287 Patent in the European Patent Office on April 3, 2014.

On March 11, 2014, we commenced '287 Patent Infringement Litigation and '018 Patent Infringement Litigation against Merus B.V., a company based in Utrecht, The Netherlands, in the District Court of The Hague and the United States District Court for the Southern District of New York, respectively. Merus previously filed an opposition to the '287 Patent in the European Patent Office in June 2013.

Also on March 11, 2014, we commenced '018 Patent Infringement Litigation against Ablexis, LLC, a Delaware corporation with a principal place of business in San Francisco, California, in the United States District Court for the Southern District of New York.

## 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 are unable to continue to commercialize EYLEA or if we are unable to obtain additional marketing approvals, 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 three months ended March 31, 2014 and 2013, EYLEA net sales in the United States represented 57% and 71% 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. In addition, if we are unable to obtain approval of EYLEA in the United States for the treatment of DME, or if Bayer HealthCare is unable to obtain approval of EYLEA in additional countries or in additional indications, our prospects would be materially harmed.

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

EYLEA is currently available in the United States, EU, Japan, and certain other countries outside of the United States for treatment of wet AMD and macular edema following CRVO. We are subject to significant ongoing regulatory obligations with respect to EYLEA for the treatment of wet AMD and macular edema following CRVO in the United States and the EU, and, in other countries, the commercialization of EYLEA is subject to additional significant ongoing regulatory obligations and oversight in those countries where the product is approved. If we fail to maintain regulatory compliance for EYLEA for the treatment of wet AMD and macular edema following CRVO, we may lose marketing approval, 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.***

There are risks inherent in intravitreal injections, including intravitreal injections with EYLEA, such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, retinal tear, and other side effects, all of which are reported from time to time to the FDA. 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.

***Our regulatory approval for sales of EYLEA is limited to the treatment of wet AMD and macular edema following CRVO and is limited geographically. If we don't receive approval for EYLEA for other indications, or if approvals are not obtained for sales in other countries, sales and profits will be limited.***

We and Bayer HealthCare have received regulatory approvals for sale of EYLEA for the treatment of wet AMD and macular edema following CRVO in certain countries throughout the world. If we do not receive approval for EYLEA for other uses, or if approvals for sales in other countries are not obtained, sales will be limited and our potential for profits will be limited. As a result, our business, prospects, operating results, and financial condition would be materially impacted.

***Our 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 part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in 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 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 agree to 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 are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis<sup>®</sup>, for the treatment of wet AMD, macular edema following CRVO, DME, visual impairment due to mCNV, and other eye indications. Lucentis<sup>®</sup> 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), and in August 2012 for the treatment of DME. Lucentis<sup>®</sup> was also approved by the European Medicines Agency 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.

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, in January 2012, Genentech submitted an IND for such an extended delivery device. Novartis is developing ESBA1008 (RTH258), a humanized monoclonal single-chain Fv (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated Phase 2 trials comparing ESBA1008 and EYLEA in 2013. Allergan is developing an anti-VEGF-A DARPIn<sup>®</sup> for wet AMD and related conditions and a Phase 2 trial is ongoing. 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<sup>™</sup>, 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<sup>™</sup>, including Lucentis<sup>®</sup> + Fovista<sup>™</sup>, Avastin<sup>®</sup> + Fovista<sup>™</sup>, and EYLEA + Fovista<sup>™</sup>. Genentech initiated a Phase 1 trial of a bi-specific antibody targeting both VEGF and Ang2 for wet AMD.

In addition, ophthalmologists are using with success off-label, third-party repackaged versions of Genentech's approved VEGF antagonist, Avastin<sup>®</sup>, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with Avastin<sup>®</sup> in patients with wet AMD presents a significant competitive challenge in this indication. Long-term, controlled clinical trials comparing Lucentis<sup>®</sup> to Avastin<sup>®</sup> 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<sup>®</sup> dosed monthly was non-inferior to Lucentis<sup>®</sup> 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<sup>®</sup> was non-inferior to monthly Lucentis<sup>®</sup> in mean visual acuity gain; as-needed dosing was *not* non-inferior to monthly dosing. Avastin<sup>®</sup> 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<sup>®</sup> and off-label use of Avastin<sup>®</sup> 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 Avastin<sup>®</sup> 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 wet AMD, macular edema following CRVO, or other eye 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.

***Our product sales could be reduced by imports from countries where our products are available at lower prices.***

Our sales of products in the United States may be reduced if our products are imported into the United States from lower priced markets, whether legally or illegally. 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 will be 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 is marketed in those nations and imported into the United States. 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 could be reduced.

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

***If we do not obtain and maintain regulatory approval for our products and 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, including EYLEA for the treatment of ophthalmologic diseases other than wet AMD and macular edema following CRVO, the value of our company and our business, prospects, operating results, and financial condition will be materially harmed. Our product candidates, including EYLEA for DME and macular edema following BRVO, may not receive regulatory approval. If we are unable to obtain regulatory approval for EYLEA in DME and macular edema following BRVO, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition will be materially harmed. In addition, if we fail to maintain regulatory approval for EYLEA for the treatment of wet AMD and macular edema following CRVO, we may lose marketing approval and the ability to generate EYLEA product sales revenue, which would materially and negatively impact our business, prospects, operating results, and financial condition.

***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. Foreign governments also regulate drugs distributed in their country and approval in any country is similarly likely to be a lengthy and expensive process, and approval is highly uncertain.

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. 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 and requirements include all of the risks associated with FDA approval as well as country specific regulations, and 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. 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 wet AMD and macular edema following CRVO. 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 and ZALTRAP. 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. In addition, patients given infusions of any protein, including ZALTRAP delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. 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, 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 the development and/or commercialization of EYLEA or ZALTRAP.

We and Sanofi are conducting a global development program, currently in Phase 3, studying alirocumab, our PCSK9 antibody for the reduction of LDL cholesterol, as discussed above in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Late-Stage Antibody-based Clinical Programs." As part of this development program, we and Sanofi collect adverse events and report them to the FDA and foreign regulatory authorities. In the Phase 2 program, injection site reactions were the most common adverse events with alirocumab, and were rare. Rare cases of hypersensitivity reaction were also reported. In a recent Phase 3 trial comparing alirocumab with ezetimibe, the most common class of adverse events was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related adverse events occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab. We and Sanofi have been advised by the FDA that it has become aware of neurocognitive adverse events in the PCSK9 inhibitor class. Neurocognitive adverse events have also been associated with the use of statins for lowering LDL cholesterol. We do not know the circumstances under which the FDA became aware of these adverse events or whether these adverse events were observed with a drug candidate tested as monotherapy or in combination with a statin or other cholesterol-lowering agent. The FDA has requested that we and Sanofi make an assessment of potential neurocognitive adverse events across the global development program for alirocumab, especially in the longer-term studies. Additionally, the FDA requested that we address the feasibility of incorporating neurocognitive testing into at least a subset of patients in our ODYSSEY OUTCOMES trial or other long-term Phase 3 trial(s). While we are not aware of any neurocognitive adverse event signal relating to alirocumab, if this or another adverse event signal is detected, the further development of alirocumab may be delayed or fail, or its commercial value diminished, which could severely harm our future prospects.

We have studied fasinumab in a variety of pain indications, including osteoarthritis of the knee. In December 2010, the FDA placed fasinumab and other investigational agents targeting NGF on clinical hold after a case of rapidly progressive osteoarthritis leading to joint replacement was seen in another company's anti-NGF program due to the FDA's concern that this case was suggestive of a class effect. In December 2012, the FDA removed the clinical hold on fasinumab after reviewing our proposed Phase 3 program in osteoarthritis. However, shortly thereafter, the entire class was again placed on clinical hold as a result of preclinical data from other investigational agents targeting NGF in development. There are currently no trials with fasinumab that are either enrolling or treating patients. Discussions with the FDA about fasinumab are ongoing.

***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.

### **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 own 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 an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. 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 patent applications from challenges by others from time to time in the future. Certain patent applications filed in the United States 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, and could be subject to damage awards if we are found to have infringed, patents or other proprietary rights of others.***

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. For example, we are currently parties to patent infringement proceedings 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 II, Item 1. "Legal Proceedings." We are aware of patents and pending applications owned by others that respectively claim antibodies to IL-6R, IL-4R, and PCSK9 and methods of treating rheumatoid arthritis, atopic dermatitis and asthma, and hypercholesterolemia with such antibodies. We are developing sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis; dupilumab, an antibody to IL-4R, for the treatment of atopic dermatitis, asthma, and nasal polyposis; and alirocumab, a PCSK9 antibody, for LDL cholesterol reduction. Although we do not believe that sarilumab, dupilumab, or alirocumab 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 sarilumab, dupilumab, or alirocumab, as applicable. We are also aware of a U.S. patent jointly



owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. None of ARCALYST, ZALTRAP, or EYLEA is a recombinant antibody. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates 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 drug 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 drug candidates, or our other late-stage 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 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 now a new, 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 new 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 our other product candidates or other indications for our marketed products if they receive regulatory approval, and to advance our clinical pipeline.***

Our manufacturing facility would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA, 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 may 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 reached preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, subject to entering into definitive agreements as well as securing permits from the local government in Limerick, 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, our contemplated acquisition of the Limerick, Ireland facility remains subject to entering into definitive agreements as well as securing permits from the local government, and there is no guarantee that a final agreement will be reached on terms favorable to us or that we will be able to obtain the 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, ZALTRAP, 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 our 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, 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, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products to which those intellectual property rights apply, which could materially harm our business, prospects, operating results, and financial condition.

***If sales of EYLEA and ZALTRAP do not meet the levels currently expected, or if the launch of new indications for EYLEA or 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 facilities to produce bulk product of EYLEA for the treatment of wet AMD and macular edema following CRVO, bulk product of ZALTRAP for the treatment of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, bulk product of ARCALYST for the treatment of CAPS, 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 natural 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 at the facilities.

Also, certain raw materials or other products necessary for the manufacture and formulation of EYLEA, ZALTRAP, ARCALYST, and our 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 EYLEA, ZALTRAP, ARCALYST, and our 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. This, in turn, could materially and adversely affect our ability to manufacture or supply EYLEA, ZALTRAP, ARCALYST, and our 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, 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.

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.

Currently, we have three marketed products, EYLEA, ZALTRAP, and ARCALYST. While we have established our own sales and marketing organization for EYLEA in the United States for the treatment of wet AMD and macular edema following CRVO, we have limited commercialization experience and we have no sales, marketing, commercial, or distribution capabilities outside the United States. In addition, EYLEA faces intense competition from Lucentis<sup>®</sup> and from off-label use of repackaged Avastin<sup>®</sup>, both of which have been on the market for a number of years and, potentially, from new competitive products currently in clinical development. 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<sup>®</sup>, and the willingness of retinal specialists and patients to switch from Lucentis<sup>®</sup> or off-label use of Avastin<sup>®</sup> 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 new health care legislation currently being implemented in the United States.

Under the terms of our license and collaboration agreement with Bayer HealthCare, 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. In addition, if we or our collaborators are unable to successfully commercialize new product candidates or new indications for our marketed product, our future prospects would be materially impaired.

***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.

As previously noted, Genentech has an approved VEGF antagonist, Avastin<sup>®</sup>, on the market for treating certain cancers, and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen Inc., Imclone LLC/Eli Lilly, Pfizer Inc., AstraZeneca, and GlaxoSmithKline. Some of these molecules may offer competitive advantages over our molecule. Each of Pfizer, Onyx Pharmaceuticals (a subsidiary of Amgen), together with its partner Bayer HealthCare, and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. In January 2012, Roche announced that a Phase 3 trial of Avastin<sup>®</sup> (bevacizumab) had met the primary endpoint of overall survival in mCRC in patients who had previously received Avastin<sup>®</sup> with standard chemotherapy. The positive results of this trial in a similar patient population could impact the potential commercial opportunity for ZALTRAP in mCRC. It will be difficult for ZALTRAP to compete against Avastin<sup>®</sup> and the FDA-approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

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."

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 (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Johnson & Johnson (in partnership with GlaxoSmithKline), Bristol-Myers Squibb (in partnership with Alder Biopharmaceuticals), Ablynx (in partnership with AbbVie), and Pfizer have antibodies against IL-6 or IL-6R in clinical development. Several companies, including Amgen, Pfizer, Genentech, Bristol-Myers Squibb, and Eli Lilly, have development programs for antibodies against PCSK9. Amgen's PCSK9 program appears to be the most advanced of the competitors, having already announced positive results from multiple Phase 3 trials, and may obtain marketing approval in one or more countries before our PCSK9 antibody is approved. 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. 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-6), Teva (an antibody against IL-5), AstraZeneca (antibodies against IL-5R and IL-13), and Novartis (a bi-specific antibody against IL-4 and IL-13). Further, Amgen, Genentech, and AstraZeneca have development programs underway for antibodies against Ang2 for indications in oncology. Celgene (in partnership with OncoMed Pharmaceuticals, Inc.) and AstraZeneca have antibodies that target DLL4 in clinical development. For muscle-wasting conditions, both Pfizer and Eli Lilly have anti-GDF8 monoclonal antibodies in development, and Novartis has a competing antibody targeting ActRIIB.

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 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 agree to 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, and other third-party payers, including Medicare and Medicaid, do not 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, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

Government and other third-party payers 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 Avastin<sup>®</sup> rather than Lucentis<sup>®</sup> 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 for the treatment of wet AMD, macular edema following CRVO, and other eye diseases, and ZALTRAP for the treatment of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, will likely continue to be too expensive for most patients to afford without health insurance coverage, if these products are unable to obtain adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, our ability to successfully commercialize these products would be materially adversely impacted. Third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse for these 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 vary widely from country to country. 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 three distributors and several 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 three months ended March 31, 2014 and 2013, we recorded 79% and 77%, 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. Our product liability 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.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, 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. In addition, as part of the PPACA, the federal government recently enacted provisions imposing reporting and disclosure requirements on pharmaceutical manufacturers for any "transfers of value" made or distributed to prescribers and other healthcare providers. These statutory provisions and related regulations (commonly known as the "Sunshine Act") require pharmaceutical manufacturers to report annually to the Secretary of the U.S. Department of Health and Human Services payments or other transfers of value made to physicians or teaching hospitals. In February 2013, regulations were released that contain detailed guidance regarding the information that must be collected and reported. We started to be required to collect information regarding such payments in August 2013 and submitted our 2013 Reporting Entity and Payment Aggregate Data in March 2014, as required by the Sunshine Act. Over the next several years, we will need to dedicate significant resources to enhance our systems and processes in order to comply with these regulations. The PPACA also includes various provisions designed to strengthen significantly 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. Many of these requirements and standards are new and 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 the 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 and the cost of currency exchange;
- our ability to deploy overseas funds in an efficient manner;
- adverse tax consequences, including those that might result from the failure to operate in conformity with the requirements for certain tax treatment, tax incentives, or grants;
- 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 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 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. Our clinical research efforts are not directly regulated by HIPAA. However, conduct by a person that may not be prosecuted directly under HIPAA's criminal provisions could potentially be prosecuted under aiding-and-abetting or conspiracy laws. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider or research institution that has not satisfied HIPAA's disclosure standards. In addition, international data protection laws, including the EU Data Protection Directive and member state implementing legislation, may apply to some or all of the clinical data obtained outside of the U.S. Furthermore, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our 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 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.

### **Risks Related to Our Reliance on Third Parties**

***If our antibody collaboration 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. Sanofi has committed to pay up to \$160 million per year, or a total of \$1.28 billion, between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. Sanofi also initially funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that Sanofi elects to co-develop with us. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us, such as sarilumab, alirocumab, dupilumab, enoticumab, nesvacumab, REGN1033, and REGN2009, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on Sanofi to lead the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us if they receive regulatory approval. If Sanofi does not elect to co-develop the antibodies that we discover or opts out of their development, unless we enter into a partnership 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, and decided not to opt in to the REGN1154, REGN 1193, REGN1500, and other programs. If Sanofi terminates the antibody collaboration 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. Even though none of the antibodies from this collaboration may ever be successfully developed and commercialized, if Sanofi does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

***If our collaboration with Sanofi for ZALTRAP is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop and commercialize ZALTRAP, would be materially harmed.***

We rely heavily on Sanofi to lead much of the development of ZALTRAP and the commercialization of ZALTRAP. If Sanofi fails to perform its obligations in a timely manner, or at all, our ability to develop and commercialize ZALTRAP in previously-treated mCRC will be significantly adversely affected. Sanofi has the right to terminate its collaboration agreement with us at any time upon twelve months' advance notice. If Sanofi were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our collaborator, which we would have to develop or outsource at substantial additional costs to us. In particular, we have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Termination of the Sanofi collaboration agreement for ZALTRAP would create substantial new and additional risks to the successful development and commercialization of ZALTRAP.

***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 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. EYLEA is currently available in the United States, EU, Japan, and certain other countries outside of the United States for treatment of wet AMD and macular edema following CRVO. We cannot assure you that additional regulatory approvals will be received for EYLEA outside the United States or that EYLEA will be successfully commercialized. 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 partner, 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 EYLEA for the treatment of wet AMD and macular edema following CRVO, ZALTRAP for the treatment of patients with mCRC, ARCALYST for the treatment of CAPS, 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 rely on third-party service providers to support the distribution of EYLEA in the United States and for many other related activities in connection with the commercialization of this marketed product. Despite our arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, our sales of EYLEA 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 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 Senior Vice President, Research and Development Sciences. As we continue to commercialize EYLEA, 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 them potentially vulnerable to breakdown, malicious intrusion, and computer viruses, which may result in the impairment of production and key business processes.

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 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**

***We have a history of operating losses and have only recently achieved profitability. 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, 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 ongoing marketing of EYLEA and the potential 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, and British pound sterling. 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 March 31, 2014, we had \$461.9 million in cash and cash equivalents and \$721.0 million in marketable securities. Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds, direct obligations of the U.S. government and its agencies, and other debt securities guaranteed by the U.S. government. These 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. If 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 and, to a lesser degree, sales of ZALTRAP;
- 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;
- 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 or decisions by government authorities or insurers affecting the coverage or reimbursement 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 collaborative partners 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; and
- general market conditions.

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. 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 April 17, 2014, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 50.4% 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 April 17, 2014. As of April 17, 2014, Sanofi beneficially owned 20,018,090 shares of our Common Stock, representing approximately 20.2% of the shares of Common Stock then outstanding. Under our 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 discovery and preclinical development 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. 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 April 17, 2014, holders of Class A Stock held 16.8% 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 April 17, 2014:

- our current executive officers and directors beneficially owned 10.1% 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 April 17, 2014, and 22.0% 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 April 17, 2014; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 50.4% 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 April 17, 2014. In addition, these five shareholders plus our Chief Executive Officer held approximately 55.7% 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 April 17, 2014.

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.

***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 ("convertible senior notes" or "notes"), 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.

In connection with hedging these transactions, the hedge counterparties and/or their affiliates may enter 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 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 restated 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’s 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; (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 provide for severance benefits in the event of termination as a result of a change in control of our company. Also, many of our stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan, as amended and restated, may become fully vested in connection with a “change in control” of our company, as defined in the plan. 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, as described above under “*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.*” These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.



**ITEM 6. EXHIBITS**

(a) Exhibits

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
10.1	(a) Amended and Restated Investor Agreement, dated as of January 11, 2014, by and among Sanofi, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
10.2*	License and Collaboration Agreement, dated as of January 10, 2014, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
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

(a) Incorporated by reference to Exhibit 10.1 to the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 13, 2014.

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

**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: May 8, 2014

By: /s/ Robert E. Landry

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

**REDACTED**

LICENSE AND COLLABORATION AGREEMENT

By and Between

BAYER HEALTHCARE LLC

and

REGENERON PHARMACEUTICALS, INC.

Dated as of January 10, 2014

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## LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT ("Agreement"), dated as of January 10, 2014 (the "Effective Date"), is by and between BAYER HEALTHCARE LLC, a Delaware limited liability company having a principal place of business at 100 Bayer Boulevard, Whippany, New Jersey 07981-0915 ("Company"), and REGENERON PHARMACEUTICALS, INC., a New York corporation having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Company and Regeneron referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, Regeneron owns and has licensed certain Patents, Know-How and other rights related to PDGF Products in the Territory;

WHEREAS, Company and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory;

WHEREAS, Regeneron and Company have previously entered into a certain License and Collaboration Agreement, dated October 18, 2006 and amended on May 6, 2012 (the "EYLEA Agreement"), for the development, manufacture and commercialization of EYLEA;

WHEREAS, Regeneron has conducted certain research and development activities with respect to PDGF Products and intends to conduct additional development of PDGF Products;

WHEREAS, Bayer has conducted certain research and development activities with respect to Non-Collaboration PDGF Products and intends to conduct additional development of such products; and

WHEREAS, Company wishes to obtain, and Regeneron wishes to grant, an option, exercisable upon completion of the first proof of concept study for a Licensed Product under the Initial Development Plan, under the terms and conditions set forth herein (the "Option") to enter into a collaboration with Regeneron to Develop and Manufacture Licensed Products in the Field and Commercialize Licensed Products in the Field in the Territory, including for use in combination with EYLEA, under the terms and conditions set forth herein (the "Collaboration").

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 “Additional Development Costs” shall mean, with respect to a Discretionary Amendment under which Company elects not to fund any Development Costs in excess of the Budget Threshold pursuant to Section 2.2(c)(iii), Company’s applicable share of the Development Costs incurred by or on behalf of Regeneron under such Discretionary Amendment in excess of the Budget Threshold not to exceed [\*\*\*\*\*], from the Effective Date through completion of the Initial Development Plan.

1.2 “Additional Major Market Country” shall mean any country in the Territory, other than the Major Market Countries referred to in the definition thereof, in which Net Sales in a Contract Year are [\*\*\*\*\*] or more of aggregate Net Sales in the Territory in such Contract Year. Once designated as an Additional Major Market Country, a country shall continue to be an Additional Major Market Country from and after January 1 of the next Contract Year, and each Contract Year thereafter as long as Net Sales in such country in the immediately preceding Contract Year(s) are [\*\*\*\*\*] or more of aggregate Net Sales in the Territory in such Contract Year(s). Notwithstanding the foregoing, the Parties shall have the right to mutually agree that a country that 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 exceed such [\*\*\*\*\*] Net Sales threshold on an ongoing basis.

1.3 “Affiliate” shall mean, with respect to any Person, another Person that controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such 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.

1.4 “Aflibercept” shall mean VEGF Trap as defined in the EYLEA Agreement.

1.5 “Agreement” shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

1.6 “Antibody(ies)” shall mean a [\*\*\*\*\*].

1.7 “Anticipated First Commercial Sale” shall mean, with respect to a Licensed Product in the Field, on a country-by-country basis in the Territory, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in such country in the Territory.

1.8 “Approval” shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the development, Manufacture or commercialization of such Licensed Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

1.9 “Aventis” shall mean sanofi-aventis US LLC (successor in interest to Aventis Pharmaceuticals, Inc.).

1.10 “Aventis Agreement” shall mean the Collaboration Agreement, dated as of September 3, 2003, by and between Aventis and Regeneron Pharmaceuticals, Inc., as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, and the Fourth Amendment, dated as of January 31, 2006, as the same may be further amended from time to time.

1.11 “Aventis Development Milestone Payments” shall have the meaning set forth in Section II of Schedule 3.

1.12 “Aventis Letter Agreement” shall mean that certain letter agreement, dated as of May 1, 2013, by and between Aventis and Regeneron Pharmaceuticals, Inc., as the same may be further amended from time to time.

1.13 “Aventis Royalties” shall have the meaning set forth in Section III of Schedule 3.

1.14 “Budget Threshold” shall mean (a) [\*\*\*\*\*], as applicable.

1.15 “Business Day” shall mean a day on which commercial banking institutions in New York, New York are open for business.

1.16 “Change of Control” shall mean, with respect to Regeneron, any of the following events: (a) any Person is or becomes the “beneficial owner” (as such term

is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder, except that a Person shall be deemed to have “beneficial ownership” of all shares that any such Person has the right to acquire, whether such right may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all classes of capital stock then outstanding of Regeneron normally entitled to vote in elections of directors; (b) Regeneron consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into Regeneron, other than (i) a merger or consolidation that would result in the voting securities of Regeneron outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of Regeneron or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (ii) a merger or consolidation effected to implement a recapitalization of Regeneron (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of voting securities of Regeneron representing a majority of the combined voting power of Regeneron’s then outstanding securities; or (c) Regeneron conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly-owned Affiliate of Regeneron.

1.17 “Class A Stock” shall mean the Class A Stock of Regeneron, par value \$0.001 per share.

1.18 “Clinical Supply Cost” shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the Development Plans, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture comparator agent or placebo requirements for activities contemplated under the Development Plans, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging and labeling Clinical Supply Requirements, comparator agent and/or placebo, as the case may be, for activities contemplated under the Development Plans and (d) any VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements.

1.19 “Clinical Supply Requirements” shall mean, with respect to a Licensed Product, the quantities of Finished Product, comparator agent and/or placebo as are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, pre-clinical studies and clinical trials in connection with a Development Plan, and quantities of such 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.

1.20 “COGS” for a Quarter shall mean cost (calculated in accordance with GAAP or IAS/IFRS) of Manufacturing the Licensed Products sold in the Field in the Territory in the Quarter.

1.21 “Combination PDGF Product” shall mean a form or dosage of pharmaceutical composition or preparation that is comprised of or contains as active ingredients a PDGF Receptor Antibody together with Aflibercept [\*\*\*\*\*].

1.22 “Commercialize” or “Commercialization” shall mean any and all activities directed to marketing, promoting, detailing, distributing, importing, offering for sale, having sold and/or selling a Licensed Product in the Field in the Territory, including, without limitation, market research, pre-launch marketing and educational activities, sampling and Non-Approval Trials in the Territory.

1.23 “Commercial Overhead Charge” shall mean, on a country-by-country basis in the Territory, beginning on the First Commercial Sale in the applicable country, an amount (agreed upon by the JFC at least eighteen (18) months prior to the Anticipated First Commercial Sale in the country) to [\*\*\*\*\*], such amount to be determined by the JFC as of January 1 of each following Contract Year. For the avoidance of doubt, “Commercial Overhead Charge” shall not include any amounts included in Company HQ Costs, Medical Affairs Cost, Sales Force Cost, or Other Shared Expenses or any other amounts included in Shared Promotion Expenses (other than Commercial Overhead Charge). Unless otherwise agreed by the JFC and JCC, the Commercial Overhead Charge shall be a fixed amount for each Contract Year. Notwithstanding the foregoing, the Parties shall have the right to mutually agree to adjust the Commercial Overhead Charge once in a given Contract Year for a given country to reflect unforeseen circumstances.

1.24 “Commercially Reasonable Efforts” shall mean, 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 such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that such efforts shall be consistent with the Collaboration Purpose and substantially equivalent to those efforts and resources commonly used by a 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). 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 regulatory authority approved labeling, competitiveness of the product or alternative products that are in the marketplace (including EYLEA) 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 Territory Profit Split nor other

payments made or required to be made from one Party to the other under this Agreement shall be considered in determining market potential (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must pay the Territory Profit Split or make milestone or any other payments hereunder to the other Party). By way of example, for purposes of determining whether Company uses Commercially Reasonable Efforts to Commercialize a Licensed Product in a Major Market Country, a basis for comparison shall be the efforts used by Company to commercialize in such Major Market Country another Company product that is wholly owned by Company, is at a similar stage of commercialization to the Licensed Product and has both anticipated total sales and overall profitability to Company in such Major Market Country substantially similar to that of the Licensed Product, taking into account total sales and total profitability of the Licensed Product in such Major Market Country, but without consideration of any of the payments required to be made from one Party to the other under this Agreement.

1.25 “Commercial Supply Cost” shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Commercial Supply Requirements, (b) the Out-of-Pocket Costs and/or the Manufacturing Costs for filling, packaging and labeling Commercial Supply Requirements, and (c) any VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.

1.26 “Commercial Supply Requirements” shall mean, with respect to each Licensed Product, quantities of Finished Product as are required by Company to fulfill its (or its Affiliate’s or Sublicensee’s) requirements for commercial sales, Non-Approval Trials and Licensed Product sampling with respect to such Licensed Product in the Field in the Territory.

1.27 “Committee” shall mean any of the JSC, JDC, JCC or JFC, each as described in Article IV (together with the Working Groups or other committees contemplated herein or established in accordance with this Agreement).

1.28 “Common Stock” shall mean the common stock of Regeneron, par value \$0.001 per share.

1.29 “Company Collaboration Intellectual Property” shall mean the Company Collaboration Patent Rights and Company Collaboration Know-How.

1.30 “Company Collaboration Know-How” shall mean all Know-How that is conceived, developed, created or otherwise made by or on behalf of Company (or its Affiliates or its or their Sublicensees) under or in connection with the Development, Manufacture or Commercialization of Licensed Products under the Collaboration during the Term of this Agreement (or any wind-down period as provided in Article II or transition period as provided in Schedules 7, 8 or 9), excluding any Joint Inventions. Company Collaboration Know-How shall include New Information of Company. For clarity, any Know-How conceived, developed, created or otherwise made by or on behalf



of Company (or its Affiliates or its or their Sublicensees (other than Regeneron and its Affiliates)) in the exercise of Company's (or its Affiliates' or its or their Sublicensees') rights under the license grants and other grant of rights that come into effect pursuant to Section 20.8(d) and Schedule 10 shall not constitute Company Collaboration Know-How. For clarity, all Know-How that is conceived, developed, created or otherwise made by or on behalf of Company (or its Affiliates or its or their sublicensees) in connection with the development, manufacture or commercialization of products that are not Licensed Products or Additional PDGF Receptor Antibodies outside of this Agreement and without use of any (a) then existing Company Collaboration Intellectual Property, (b) Joint Intellectual Property, or (c) any Regeneron Collaboration Intellectual Property or Regeneron Licensed Intellectual Property shall not constitute Company Collaboration Know-How.

1.31 "Company Collaboration Patent Rights" shall mean those Patents that (a) claim or cover the Company Collaboration Know-How and (b) are Controlled by Company or any of its Affiliates (other than by operation of the license and other grants in Article V).

1.32 "Company EYLEA Intellectual Property" shall mean (a) the Company Intellectual Property as defined in the EYLEA Agreement and (b) Company's interest in any Joint Inventions (as defined in the EYLEA Agreement) and Joint Patent Rights (as defined in the EYLEA Agreement).

1.33 "Company Future Non-Collaboration Patent Rights" shall mean those Patents Controlled by Company or any of its Affiliates (other than by operation of the license and other grants in Article V) that (a)(i) are necessary or useful for the Exploitation of Licensed Products in the Field and (ii) are not Company Collaboration Patent Rights or Joint Patent Rights and (b) (i) do not claim Know-How existing as of the effective date of the termination of this Agreement or the Regeneron Opt-Out Exercise, as applicable, or (ii) do not claim priority to any Patents that claim Know-How existing as of the effective date of the termination of this Agreement or the Regeneron Opt-Out Exercise, as applicable.

1.34 "Company Global HQ Costs" shall have the meaning set forth in Section 1.35.

1.35 "Company HQ Costs" shall mean the sum of (a) beginning on the First Commercial Sale of a Licensed Product in any Major Market Country, the product of (i) the number of Company HQ Unit FTEs performing activities directly related to the Commercialization of Licensed Products in the Field across the Territory (and to the extent agreed by Regeneron, globally) and (ii) the applicable HQ FTE Rate and (b) the Out-of-Pocket Costs of the type identified in clauses (f) through (h) of the definition of Shared Promotion Expenses that are incurred by the Company HQ Unit in connection with performing activities directly related to the Commercialization of Licensed Products in the Field across the Territory (and to the extent agreed by Regeneron, globally), in each case ((a) and (b)), in accordance with the approved HQ Plan and HQ Budget. The

Company HQ Costs (x) allocated to the Territory pursuant to the HQ Budget (such costs, "Company Territory HQ Costs") shall be considered Shared Promotion Expenses and (y) allocated globally pursuant to the HQ Budget (such costs, "Company Global HQ Costs") shall be considered Global HQ Costs. For clarity, the cost and expense of activities of the type set forth in the definition of Commercial Overhead Charge that are performed by the Company HQ Unit shall be Company HQ Costs and not Commercial Overhead Charges.

1.36 "Company HQ Unit" shall mean those employees of Company who are performing activities directly related to the Commercialization of Licensed Products in the Field across the Territory (and to the extent agreed by Regeneron, globally) and not for specific country(ies) or Region(s).

1.37 "Company Non-Collaboration Patent Rights" shall mean all Patents Controlled by Company or any of its Affiliates (other than by operation of the license and other grants in Article V) that (a) are necessary or useful for the Exploitation of Licensed Products in the Field and (b) are not Company Collaboration Patent Rights, Joint Patent Rights or Company Future Non-Collaboration Patent Rights.

1.38 "Company Territory HQ Costs" shall have the meaning set forth in Section 1.35.

1.39 "Competing PDGF Product" shall mean any form or dosage of pharmaceutical composition or preparation that [\*\*\*\*\*]. Notwithstanding the foregoing, [\*\*\*\*\*].

1.40 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by Company (based on information reported under Sections 6.5 and 10.3) setting forth in reasonable detail, for each Reporting Country in the Territory, for each Region in the Territory, in the aggregate for all countries in the Territory, and with respect to the Company HQ Unit and the Regeneron HQ Unit, as applicable, (a) Net Sales, COGS and Shared Promotion Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter under the Global PDGF Development Plan and the Territory PDGF Development Plan, (c) Other Shared Expenses incurred by each Party for such Quarter, including the allocation of global costs pursuant to Section 4.4(b)(xii), (d) Commercial Supply Costs incurred by each Party for such Quarter, (e) Company HQ Costs and Regeneron HQ Costs incurred by Company and Regeneron, as applicable, for such Quarter under the HQ Plan and HQ Budget, and (f) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.

1.41 "Contract Year" shall mean the period beginning on January 1, 2014 and ending on December 31, 2014, and each succeeding consecutive twelve (12)-month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of this Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.

1.42 “Control” shall mean, with respect to any item of New Information or Party Information, material, regulatory documentation, Patent or other intellectual property right, or PDGF Receptor Antibody, 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, Patent or other intellectual property right, or PDGF Receptor Antibody as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.43 “Controlling Party” shall mean Regeneron with respect to the filing, prosecution and maintenance of a Joint Patent Right that claims or covers a PDGF Product (or the Manufacture or use thereof, including, without limitation, any devices for the administration of such Licensed Product or any component thereof) and/or EYLEA (or the Manufacture or use thereof, including, without limitation, any devices for the administration of EYLEA or any component thereof), and Company in the case of all other Joint Patent Rights.

1.44 “Country PDGF Commercialization Report” shall mean, for each Reporting Country in the Territory, a written report summarizing the Commercialization activities undertaken by Company (or its Affiliate) during the previous Quarter in connection with the applicable Country/Region PDGF Commercialization Plan for such Reporting Country, including the number of details for the Licensed Product in the Field in the applicable country, together with a detailed project-level statement of Shared Promotion Expenses (calculated in U.S. dollars and local currency) incurred by Company (or its Affiliate) during such Quarter in the applicable country.

1.45 “Country/Region PDGF Commercialization Budget” shall mean the three (3)-year rolling budget(s) (with full detailed budgets for the first year and sales and expense data that are available for the following two years) approved by the JCC for a particular Country/Region PDGF Commercialization Plan.

1.46 “Country/Region PDGF Commercialization Plan” shall mean, for each Reporting Country and each Region in the Territory, the three (3)-year rolling plan for Commercializing Licensed Products in the Field in such Reporting Country or such Region, including the applicable Country/Region PDGF Commercialization Budget, developed and approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country/Region PDGF Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 7.3.

1.47 “CPI” for the Excluded Territory shall mean the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index). For countries and Regions in the Territory (other than Japan), “CPI” shall mean the “Euro area (changing composition) - HICP - Overall index, Monthly Index, Eurostat, neither seasonally nor working day adjusted, as

published by the European Central Bank” (or its successor equivalent index). In Japan, “CPI” shall mean Consumer Prices (MEI) – All Items, 2010=100 for Japan, as published by Organization for Economic Co-Operation and Development.

1.48 “Develop” or “Development” shall mean (a) activities directly and specifically relating to research, pre-clinical and clinical drug development of a Licensed Product in the Field, including, without limitation, 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, submission and maintenance of Registration Filings and Approvals (including post-marketing clinical trials imposed by applicable Law or as required by a Regulatory Authority (other than Non-Approval Trials)) and activities necessary or useful to obtain a Pricing Approval, reimbursement and/or listing on health care providers’ and payers’ formularies, and (b) any other development activities with respect to a Licensed Product in the Field, including, without limitation, activities to support new product formulations, delivery technologies and/or new indications in the Field either before or after the First Commercial Sale. For clarity, (x) the Development of Aflibercept for use in a Combination PDGF Product that is a Licensed Product shall be governed by this Agreement and not the EYLEA Agreement and all related costs of Developing Aflibercept for use in a Combination PDGF Product that is a Licensed Product shall be Development Costs hereunder, but (y) the Development (as such term is defined in the EYLEA Agreement) of EYLEA (other than for use in a Combination PDGF Product that is a Licensed Product) shall not constitute Development under this Agreement and the costs relating to the Development (as such term is defined in the EYLEA Agreement) of EYLEA (other than for use in a Combination PDGF Product that is a Licensed Product) shall not constitute Development Costs under this Agreement.

1.49 “Development Costs” shall mean costs incurred by a Party in connection with the Development of Licensed Products in the Field in accordance with this Agreement and, except as provided in Sections 6.3(b) and 6.3(c), the Development Plan(s) (or prior to the first Development Plan, the Initial Development Plan) (including Development Costs for EYLEA as part of a Combination PDGF Product that is a Licensed Product), including, without limitation:

- (a) all Out-of-Pocket Costs incurred in connection with such Development, including, without limitation, fees and expenses associated with obtaining and maintaining Registration Filings and Approvals (including Pricing Approvals, reimbursement and formulary listings) necessary for the Development and Commercialization of the 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) activities relating to the Manufacturing process, formulation, cleaning, and shipping development and validation, (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 Out-of-Pocket Costs 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, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up, 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 Existing Licenses or New Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory (which, for the avoidance of doubt, include activities in the Excluded Territory performed under the Global PDGF Development Plan, but exclude the Aventis Development Milestone Payments and Aventis Royalties); and

(f) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.

Notwithstanding the foregoing, Medical Affairs Costs shall be excluded from Development Costs. For clarity, it is the intent of the Parties that any costs or expenses incurred under this Agreement (including any costs included in the foregoing definition of Development Costs) will not be unfairly allocated to the Licensed Products in the Field (to the extent that any such costs or expenses are attributable, in part, to products or activities outside the scope of this Agreement). For further clarity, the costs of Developing Aflibercept for use in a Combination PDGF Product that is a Licensed Product shall be Development Costs hereunder, but the costs relating to the Development (as such term is defined in the EYLEA Agreement) of EYLEA (other than for use in a Combination PDGF Product that is a Licensed Product) shall not constitute Development Costs under this Agreement.

1.50 "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 activity as set forth in the approved Development Plan and (b) the applicable Development FTE Rate.

1.51 "Development FTE Rate" for [\*\*\*\*\*], such amounts to be adjusted as of January 1, 2015 and annually thereafter, with each annual adjustment effective as of January 1 of each Contract Year, by the percentage increase or decrease, if any, in the applicable CPI (determined based on the location of the Development

personnel) for the twelve (12) months ending June 30 of the prior Contract Year. The Development FTE Rate shall be inclusive of the FTE Costs and Expenses.

1.52 “Development Plan(s)” shall mean the Global PDGF Development Plan and the Territory PDGF Development Plan, as applicable.

1.53 “Dollars” and/or “\$” shall mean United States Dollars.

1.54 “Effective Date” shall have the meaning set forth in the introductory paragraph.

1.55 “EMA” shall mean the European Medicines Agency or any successor agency thereto.

1.56 “Excluded Territory” shall mean the United States.

1.57 “Executive Officers” shall mean the Chief Executive Officer of Regeneron and the senior-most executive officer of Bayer HealthCare’s global healthcare business.

1.58 “Existing Licenses” shall mean the agreements listed in Schedule 4.

1.59 “Exploit” or “Exploitation” shall mean to make, have made, import, export, use, sell, have sold or offer for sale or otherwise dispose of.

1.60 “EYLEA” shall mean a pharmaceutical product containing Aflibercept as its sole active ingredient and commercialized by the parties pursuant to the EYLEA Agreement.

1.61 “EYLEA Agreement” shall have the meaning set forth in the recitals.

1.62 “EYLEA Commercial Supply Agreement” shall mean that certain Commercial Formulated Bulk Supply Agreement by and between Company and Regeneron, dated September 18, 2012 and amended on August 1, 2013, as the same may be further amended from time to time.

1.63 “EYLEA Regulatory Documentation” shall mean any and all Registration Filings (as defined in the EYLEA Agreement), Approvals (as defined in the EYLEA Agreement) and other regulatory documentation related to EYLEA, in each case, Controlled by Company or any of its Affiliates.

1.64 “EYLEA Trademark” shall mean the Product Trademark as defined in the EYLEA Agreement.

1.65 “FDA” shall mean the United States Food and Drug Administration and any successor agency thereto.

1.66 “FFDCA” shall mean the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations, guidelines, guidance and other requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.67 “Field” shall mean the treatment of any ocular disease or disorder through the local administration of any product to the eye, including, without limitation, by topical, intravitreal, periorbital, implants or other means of local administration to the eye.

1.68 “Finished Product” shall mean a 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.

1.69 “First Commercial Sale” shall mean, with respect to a Licensed Product in a country in the Territory, the first 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.

1.70 “Formulated Bulk Product” shall mean (a) with respect to a Monotherapy PDGF Product, the PDGF Receptor Antibody included therein; (b) with respect to a Combination PDGF Product combined in a single formulation, Aflibercept, the PDGF Receptor Antibody and any other active ingredients included therein; or (c) with respect to any other Licensed Product, including, without limitation, any other Combination PDGF Product, each of the PDGF Receptor Antibody and, if applicable, Aflibercept and any other active ingredients included therein, in each case ((a), (b) and (c)), formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the Finished Product.

1.71 “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 hereof shall be [\*\*\*\*\*] per year.

1.72 “FTE Costs and Expenses” shall mean the sum of (a) all Out-of-Pocket Costs and other expenses for the employee providing the applicable services, including, without limitation, salaries, wages, bonuses, benefits, profit sharing, stock option grants, and FICA costs and other similar ex-U.S. costs, travel, meals and entertainment, training, recruiting, relocation, operating supplies, and equipment and other disposable goods to the extent required for the performance of the applicable services and (b) a *pro rata* allocation of equipment maintenance costs, utilities, general,

administrative and facilities expenses, including allocated building operating costs and depreciation and repairs and maintenance. For clarity, FTE Costs and Expenses shall not include any Commercial Overhead Charges.

1.73 “GAAP” shall mean generally accepted accounting principles in the United States.

1.74 “Genentech Agreement” shall mean that certain Amended and Restated Non-Exclusive License and Settlement Agreement by and between Regeneron and Genentech, Inc. (“Genentech”), dated May 17, 2013, pursuant to which Genentech granted Regeneron rights to certain Genentech Patents and Regeneron agreed to make certain payments to Genentech relating to certain of Regeneron’s or Company’s sales of EYLEA in the Territory.

1.75 “Genentech Covenant Not to Sue” shall mean that certain agreement by and between Regeneron, Regeneron UK Ltd, Bayer Pharma AG, Bayer Australia Limited, and Genentech Inc, dated May 17, 2013.

1.76 “Global HQ Costs” shall mean the Company Global HQ Costs and the Regeneron Global HQ Costs.

1.77 “Global PDGF Development Budget” shall mean the three (3)-year rolling budget(s) approved by the JSC in the Global PDGF Development Plan.

1.78 “Global PDGF Development Plan” shall mean the three (3)-year rolling plan approved by the JSC for Developing Licensed Products in the Field as part of an integrated worldwide Development program, including the related Global PDGF Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Global PDGF Development Plan activities may be undertaken entirely or partially in the Excluded Territory if approved by the JSC. For clarity, the Global PDGF Development Plan will not include (a) any Development activities that are conducted or sponsored by a Party that are only required for an Approval specific to the Territory (including activities under the Territory PDGF Development Plan) or the Excluded Territory, (b) Non-Approval Trials or (c) any studies conducted for Pricing Approval or formulary approval.

1.79 “Good Practices” shall mean compliance with the applicable standards contained in then-current “Good Laboratory Practices,” “Good Manufacturing Practices” and/or “Good Clinical Practices,” as promulgated by the FDA and any analogous guidelines promulgated by the EMA, ICH or other country regulatory agencies, as applicable.

1.80 “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.

1.81 “HQ Budget” shall have the meaning set forth in Section 7.4.

1.82 “HQ FTE Rate” shall mean (a) for Company HQ Unit personnel and Regeneron HQ Unit personnel based in the Excluded Territory, the Development FTE Rate for the Excluded Territory and (b) for Company HQ Unit personnel and Regeneron HQ Unit personnel based in the Territory, the applicable Development FTE Rate for the Territory. The HQ FTE Rate shall be inclusive of the FTE Costs and Expenses.

1.83 “HQ Plan” shall mean the three (3)-year rolling plan for Commercializing the Licensed Products in the Field in the Territory (and, if and to the extent agreed by Regeneron, the Excluded Territory) approved by the JSC, including the HQ Budget (with full detailed budgets for the first year and expense data that are available for the following two years), as the same may be amended from time-to-time in accordance with the terms of this Agreement. The HQ Plan shall set forth the activities to be performed by the Company HQ Unit and Regeneron HQ Unit.

1.84 “HQ Report” shall mean a written report summarizing the Commercialization activities undertaken by the Company HQ Unit during the previous Quarter in connection with the applicable HQ Plan, including the number of Company HQ Unit FTEs and the activities performed thereby, together with a detailed project-level statement of Out-of-Pocket Costs included in Company HQ Costs (calculated in United States Dollars and, if applicable and to the extent available and generated by Company’s and its Affiliates’ internal reporting systems, local currency) during such Quarter.

1.85 “IAS/IFRS” shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.86 “ICH” shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.87 “IND” shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with the FDA with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.

1.88 “Initial Development Budget” shall mean the budget(s) included as part of the Initial Development Plan.

1.89 “Initial Development Plan” shall mean the initial plan for the Development of Licensed Products in the Field under this Agreement (together with the

Initial Development Budget), as set forth on Schedule 5, which irrespective of the Effective Date shall include [\*\*\*\*\*].

1.90 “Initiation” shall mean, with respect to a clinical study, the first dosing of the first human subject in such clinical trial.

1.91 “Joint Intellectual Property” shall mean Joint Patent Rights and Joint Inventions.

1.92 “Joint Patent Rights” shall mean Patents that cover a Joint Invention.

1.93 “Know-How” shall mean 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 (whether or not patentable or otherwise protected by trade secret Law).

1.94 “Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

1.95 “Lead Regulatory Party” shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field and for related regulatory duties, in each case, as set forth in this Agreement.

1.96 “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.

1.97 “Licensed Products” shall mean PDGF Products that contain as an active ingredient (a) any PDGF Receptor Antibodies that are Controlled and being developed by Regeneron or any of its Affiliates as of the Effective Date as set forth on Schedule 1.97, and (b) any Additional PDGF Receptor Antibodies to which Company or any of its Affiliates obtains rights pursuant to Section 2.6.

1.98 “Major Market Country” shall mean [\*\*\*\*\*].

1.99 “Manufacture” or “Manufacturing” shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of a product, including, without limitation, Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.

1.100 “Marketing Approval” shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.

1.101 “Medical Affairs Cost” shall mean, for each country in the Territory, the product of (a) the number of FTEs supporting Medical Education Activities related to the Licensed Products in the Field as agreed upon in the Country/Region PDGF Commercialization Plan or Territory PDGF Commercialization Plan and (b) the applicable Medical Affairs FTE Rate.

1.102 “Medical Affairs 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 prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, 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 Contract Year. The Medical Affairs FTE Rate shall be inclusive of the FTE Costs and Expenses.

1.103 “Medical Education Activities” shall mean activities conducted in accordance with a Plan that are designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, Licensed Products sold in the Territory, including by way of example: (a) activities of medical scientific liaisons who, among their other functions may (i) conduct service based medical activities including providing input and assistance with consultancy meetings, recommend investigators for clinical trials and provide input in the design of such trials and other research related activities, and (ii) deliver non-promotional communications and conduct non-promotional activities including presenting new clinical trial and other scientific information; (b) grants to support continuing medical education, symposia, or research related to a Licensed Product (excluding Development activities); (c) development, publication and dissemination of publications relating to Licensed Products, as well as medical information services provided in response to inquiries communicated via the sales representatives or otherwise received by a Party or its Affiliates; (d) the support of Non-Approval Trials; and (e) establishment and implementation of risk, evaluation and mitigation and strategies (REMS).

1.104 “Monotherapy PDGF Product” shall mean any form or dosage of pharmaceutical composition or preparation that contains a PDGF Receptor Antibody as the sole active ingredient; *provided, however*, that if the foregoing is combined in a single package with Aflibercept or is formulated or packaged separately from Aflibercept but sold together for a single price, such product shall constitute a Combination PDGF Product, not a Monotherapy PDGF Product.

1.105 “Net Sales” shall mean the gross amount invoiced for bona fide arms’ length sales of Licensed Products in the Field in the Territory by or on behalf of Company or its Affiliates or Sublicensees to Third Parties (other than Sublicensees), less the following deductions determined in accordance with Company’s standard methods as generally and consistently applied by Company:

- Product sales;
- (a) normal and customary trade, cash and/or quantity discounts allowed and taken with respect to Licensed
  - (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates and allowances;
  - (c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;
  - (d) Third Party cash rebates and chargebacks related to sales of the Licensed Product, to the extent allowed;
  - (e) retroactive price reductions that are actually allowed or granted;
  - (f) compulsory payments and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;
  - (g) freight, insurance and other transportation charges, to the extent included in the invoice price;
  - (h) tariffs, duties, excise, value-added, consumption or other taxes (other than taxes based on income), to the extent included in the invoice price; and
  - (i) any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within categories substantially equivalent to those listed above.

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 a 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. In the event that a Licensed Product is sold in any country in the form of a combination product (other than a Combination PDGF Product that contains a PDGF Receptor Antibody and Aflibercept as its sole active ingredients), Net Sales of such combination product for the purpose of determining the Territory Profit Split pursuant to this Agreement shall be calculated by multiplying actual Net Sales of the combination product in such country by the fraction  $A/(A+B)$ , where A is the fair market value of the portion of the combination product that contains the PDGF Receptor Antibody(s) and, if applicable, Aflibercept, and B is the fair market value of the portion of the combination product containing the other active ingredient(s) included in such combination product, as such fair market values are determined by mutual agreement of

the Parties through the JFC. For clarity, sales of a Combination PDGF Product that is a Licensed Product and that contains PDGF Receptor Antibody(ies) and Aflibercept as its sole active ingredients shall not be subject to the adjustment described in the immediately preceding sentence.

Sales of a Combination PDGF Product that is a Licensed Product by or on behalf of Company or its Affiliates or Sublicensees to Third Parties (other than Sublicensees) shall constitute Net Sales hereunder and shall not be considered “Net Sales” (as such term is defined in the EYLEA Agreement) under the terms of the EYLEA Agreement.

1.106 “New Information” shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials (whether or not patentable or protectable as a trade secret) or other proprietary information not generally known to the public that arise or are conceived or developed by (a) either Party, (b) any Affiliate of Company that is engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement, (c) any of Regeneron’s Affiliates that are engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement or (d) the Parties or their Affiliates jointly, in each case ((a) - (d)), after the Opt-In Effective Date under or in connection with this Agreement but only in each case ((a) - (d)) to the extent specifically related to any PDGF Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement. For clarity, all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials (whether or not patentable or protectable as a trade secret) or other proprietary information not generally known to the public that arise or are conceived or developed by either Party in connection with the development, manufacture or commercialization of products that are not Licensed Products or, with respect to Company, Additional PDGF Receptor Antibodies, outside of this Agreement and without use of any Company Collaboration Intellectual Property or Joint Intellectual Property or, with respect to Company, any Regeneron Collaboration Intellectual Property or Regeneron Licensed Intellectual Property shall not constitute New Information.

1.107 “New License” shall mean any license approved by the JSC, other than Existing Licenses, required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.108 “Non-Collaboration PDGF Product” shall mean [\*\*\*\*\*].

1.109 “Option Period” shall mean the period during the Term from the Effective Date until (a) the date that Company exercises its Opt-In Right; or (b) the end of the Opt-Out Notice Period following a Company Opt-Out Exercise, whichever is earlier.

1.110 “Other Shared Expenses” shall mean those costs and expenses specifically referred to in Sections 4.4(b)(xii), 8.7, 12.4, 13.2(e), 13.3(b), 14.1(e), 14.3(b),

14.3(d), 14.4(c) and 18.2(a) that, except as set forth in Section 4.4(b)(xii) or elsewhere in this Agreement, shall be shared equally between the Parties. For clarity, [\*\*\*\*\*] shall constitute Other Shared Expenses. Notwithstanding anything to the contrary in this Agreement, [\*\*\*\*\*] shall not constitute Other Shared Expenses.

1.111 “Out-of-Pocket Costs” shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with the applicable Plan.

1.112 “Party Information” shall mean, with respect to a Party, any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials (whether or not patentable or protectable as a trade secret) or other proprietary information not generally known to the public regarding such Party’s or its Affiliates’ technology, products (other than Licensed Products), business or objectives (in each case, other than New Information) that are disclosed or made available by or on behalf of such Party or such Party’s Affiliates to the other Party or the other Party’s Affiliates in connection with this Agreement. Notwithstanding anything in this Agreement to the contrary, (a) all confidential information disclosed by Regeneron under the terms of the confidentiality agreement between the Parties dated December 20, 2012, as subsequently amended, is hereby deemed Party Information of Regeneron and (b) all Party Information (as defined in the EYLEA Agreement) of a Party under the EYLEA Agreement shall be Party Information of such Party under this Agreement.

1.113 “Patents” shall mean (a) all national, regional and international patents and patent applications, including, without limitation, 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, without limitation, 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, without limitation, 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, without limitation, 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, without limitation, 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.

1.114 “PDGF Beta Receptor” [\*\*\*\*\*].

1.115 “PDGF Products” shall mean any form or dosage of pharmaceutical composition or preparation that contains a PDGF Receptor Antibody, whether as the sole active ingredient or combined with one or more other active ingredients (either combined in a single formulation or package, as applicable, or

formulated or packaged separately but sold together for a single price by or on behalf of a Party or its Affiliates or Sublicensees).

1.116 “PDGF Receptor Antibody” shall mean any Antibody that, [\*\*\*\*\*].

1.117 “PDGF Royalty Term” shall have the meaning ascribed to it in the Aventis Letter Agreement.

1.118 “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.

1.119 “Phase 1 Trial” shall mean a clinical trial of a Licensed Product that generally provides for the first introduction into humans of such product candidate, with the principal purpose of obtaining, either alone or in combination with one more other Phase 1 Trials, data regarding the safety, metabolic and pharmacokinetic properties and clinical pharmacology of such Licensed Product.

1.120 “Phase 2 Trial” shall mean a controlled dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.

1.121 “Phase 3 Trial” shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one Phase 2 Trial.

1.122 “Plan” shall mean any Country/Region PDGF Commercialization Plan, Territory PDGF Commercialization Plan, Global PDGF Development Plan, Territory PDGF Development Plan, HQ Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of Licensed Products in the Field under this Agreement.

1.123 “Pricing Approval” shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and/or will be reimbursed by Governmental Authorities in countries where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.124 “Product Trademark” shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or

accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.

1.125 “Promotional Materials” shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.

1.126 “Quarter” or “Quarterly” shall refer to a calendar quarter, except that the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of this Agreement. For clarity, the first Quarter shall commence on January 1, 2014, irrespective of the Effective Date.

1.127 “Regeneron Collaboration Intellectual Property” shall mean the Regeneron Collaboration Patent Rights and Regeneron Collaboration Know-How.

1.128 “Regeneron Collaboration Know-How” shall mean all Know-How that is conceived, developed, created or otherwise made by or on behalf of Regeneron (or its Affiliates or its or their Sublicensees) under or in connection with the Development, Manufacture or Commercialization of Licensed Products under the Collaboration, during the Term of this Agreement (or any wind-down period as provided in Article II or transition period as provided in Schedules 7, 8 or 9), excluding any Joint Inventions. Regeneron Collaboration Know-How shall include New Information of Regeneron. For clarity, any Know-How conceived, developed, created or otherwise made by or on behalf of Regeneron (or its Affiliates or its or their Sublicensees (other than Company and its Affiliates)) in the exercise of Regeneron’s (or its Affiliates’ or its or their Sublicensees’) rights under the license grants and other grant of rights that come into effect pursuant to Section 20.8(d) and Schedule 10 shall not constitute Regeneron Collaboration Know-How. For clarity, all Know-How that is conceived, developed, created or otherwise made by or on behalf of Regeneron (or its Affiliates or its or their sublicensees) in connection with the development, manufacture or commercialization of products that are not Licensed Products outside of this Agreement and without use of any Company Collaboration Intellectual Property or Joint Intellectual Property shall not constitute Regeneron Collaboration Know-How.

1.129 “Regeneron Collaboration Patent Rights” shall mean those Patents that (a) claim or cover the Regeneron Collaboration Know-How and (b) are Controlled by Regeneron or any of its Affiliates (other than by operation of the license and other grants in Article II or Article V).

1.130 “Regeneron EYLEA Intellectual Property” shall mean (a) the Regeneron Intellectual Property as defined in the EYLEA Agreement and (b) Regeneron’s interest in any Joint Inventions (as defined in the EYLEA Agreement) and Joint Patent Rights (as defined in the EYLEA Agreement).



1.131 “Regeneron Future Non-Collaboration Patent Rights” shall mean all Patents Controlled by Regeneron or any of its Affiliates (other than by operation of the license and other grants in Article II or Article V) that (a)(i) are necessary or useful for the Exploitation of Licensed Products in the Field and (ii) are not Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights or Joint Patent Rights and (b)(i) do not claim Know-How existing as of the effective date of the Regeneron Opt-Out Exercise or (ii) do not claim priority to any Patents that claim Know-How existing as of the effective date of the Regeneron Opt-Out Exercise.

1.132 “Regeneron Global HQ Costs” shall have the meaning set forth in Section 1.133.

1.133 “Regeneron HQ Costs” shall mean the sum of (a) beginning on the First Commercial Sale of a Licensed Product in any Major Market Country, the product of (i) the number Regeneron HQ Unit FTEs performing activities directly related to the Commercialization of Licensed Products in the Field across the Territory (or globally) and (ii) the applicable HQ FTE Rate and (b) the Out-of-Pocket Costs of the type identified in clauses (f) through (h) of the definition of Shared Promotion Expenses that are incurred by the Regeneron HQ Unit in connection with performing activities directly related to the Commercialization of Licensed Products in the Field across the Territory (or globally), in each case ((a) and (b)), in accordance with the approved HQ Plan and HQ Budget. The Regeneron HQ Costs (x) allocated to the Territory pursuant to the HQ Budget (such costs, “Regeneron Territory HQ Costs”) shall be considered Shared Promotion Expenses and (y) allocated globally pursuant to the HQ Budget (such costs, “Regeneron Global HQ Costs”) shall be considered Global HQ Costs.

1.134 “Regeneron HQ Unit” shall mean those employees of Regeneron who are performing activities directly related to the Commercialization of Licensed Products in the Field across the Territory (or globally) and not for specific country(ies) or Region(s).

1.135 “Regeneron Licensed Intellectual Property” shall mean the Regeneron Licensed Patent Rights and Regeneron Licensed Know-How.

1.136 “Regeneron Licensed Know-How” shall mean all Know-How that (a)(i) is Controlled as of the Effective Date by Regeneron or any of its Affiliates (other than by operation of the license and other grants in Article II or Article V) and (ii) relates to a PDGF Product in the Field and is necessary or useful for the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory and (b) is not included in the Regeneron EYLEA Intellectual Property.

1.137 “Regeneron Licensed Patent Rights” shall mean those Patents that (a) claim or cover the Regeneron Licensed Know-How and (b) are Controlled by Regeneron or any of its Affiliates (other than by operation of the license and other grants in Article II or Article V).

1.138 “Regeneron Non-Collaboration Patent Rights” shall mean all Patents Controlled by Regeneron or any of its Affiliates (other than by operation of the license and other grants in Article II or Article V) that (a) are necessary or useful for the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory and (b) are not Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Joint Patent Rights or Regeneron Future Non-Collaboration Patent Rights.

1.139 “Regeneron Territory HQ Costs” shall have the meaning set forth in Section 1.133.

1.140 “Regeneron VEGF Product” shall mean Product as defined in the EYLEA Agreement.

1.141 “Region” shall mean [\*\*\*\*\*].

1.142 “Registration Filing” shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.

1.143 “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 Licensed Product in the Field. The term “Regulatory Authority” includes, without limitation, the FDA, the EMA and the Japanese Ministry of Health, Labour and Welfare.

1.144 “Reporting Country” shall mean any [\*\*\*\*\*].

1.145 “Sales Force Cost” shall mean, for a country in the Territory, the product of (a) the number of FTEs detailing the Licensed Products in the Field in the country in accordance with the approved Country/Region PDGF Commercialization Plan and (b) the applicable Sales Force FTE Rate. Notwithstanding the foregoing, neither “Sales Force Cost” nor, for clarity, “Shared Promotion Expenses,” shall include the costs related to [\*\*\*\*\*].

1.146 “Sales 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 FTE), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale of the first Licensed Product in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives, reimbursement representatives and account managers of pharmaceutical companies in the Field in the applicable country, 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 Contract Year. The Sales Force FTE Rate shall be inclusive of the FTE Costs and Expenses.

1.147 “Shared Promotion Expenses” shall mean the sum of the following items, in each case to the extent attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country/Region PDGF Commercialization Plan, Territory PDGF Commercialization Plan or HQ Plan:

- (a) [\*\*\*\*\*] to cover the cost of distribution, freight, insurance and warehousing, related to the sale of Licensed Products in the Field in the Territory;
- (b) bad debt attributable to Licensed Products in the Field sold in the Territory;
- (c) Sales Force Cost;
- (d) Medical Affairs Cost;
- (e) Company Territory HQ Costs and Regeneron Territory HQ Costs;
- (f) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;
- (g) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion (i) relate to both Licensed Products and other Company products or (ii) relate to Licensed Products in the Field in both the Territory and the Excluded Territory, in each case, as agreed upon in an approved Territory PDGF Commercialization Plan or Country/Region PDGF Commercialization Plan;
- (h) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, and 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; and
- (i) Commercial Overhead Charge.

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 not be unfairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Promotion Expense is attributable, in part, to products or activities other than the 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.

1.148 “Shares of Then Outstanding Capital Stock” shall mean, at any time, the issued and outstanding shares of Common Stock and Class A Stock of Regeneron at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend or reclassification of Common Stock or Class A Stock distributable, on a pro rata basis, to all holders of Common Stock and Class A Stock.

1.149 “Sublicensee” shall mean (a) with respect to Company, a Third Party to whom Company will have granted a license or sublicense under Company’s rights pursuant to Section 5.3 or (b) with respect to Regeneron, a Third Party to whom Regeneron will have granted a license or sublicense under Regeneron’s rights pursuant to Section 5.3. For the avoidance of doubt, a “Sublicensee” will include a Third Party to whom Company will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Company a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.

1.150 “Technical Development Matter” shall mean any matter involving the Development of a Licensed Product in the Field, including, without limitation, the determination of clinical trial design and any Development or regulatory dispute referred to the Executive Officers pursuant to Section 4.10(b).

1.151 “Territory” shall mean all the countries of the world, except the Excluded Territory.

1.152 “Territory HQ Costs” shall mean the Company Territory HQ Costs and the Regeneron Territory HQ Costs.

1.153 “Territory PDGF Commercialization Budget” shall mean the three (3)-year rolling budget(s) included in the Territory PDGF Commercialization Plan.

1.154 “Territory PDGF Commercialization Plan” shall mean the three (3)-year rolling plan for Commercializing the Licensed Products in the Field in the Territory approved by the JSC, including the Territory PDGF Commercialization Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. The Territory PDGF Commercialization Plan shall set forth for each Licensed Product, the information, plans and forecasts set forth in Section 7.2.

1.155 “Territory PDGF Development Budget” shall mean the three (3)-year rolling budget(s) approved by the JSC in the Territory PDGF Development Plan.

1.156 “Territory PDGF Development Plan” shall mean the three (3)-year rolling plan approved by the JSC for Developing the Licensed Products in the Field for a specific country (or countries) in the Territory, including the related Territory PDGF Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, the Territory PDGF Development Plan will not include (a) any Development activities that are conducted as part of the Global PDGF Development Plan or (b) Non-Approval Trials, but will include any other clinical trials of the Licensed Products in the Field in the Territory, including any studies or other activities conducted for Pricing Approval.

1.157 “Third Party” shall mean any Person other than Company or Regeneron or any Affiliate of either Party.

1.158 “Trap” shall mean any [\*\*\*\*\*].

1.159 “United States,” “US” or “U.S.” shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.160 “Valid Claim” shall mean a claim (a) of any issued and unexpired Patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) of any Patent application that has not been cancelled, withdrawn or abandoned or pending for more than seven (7) years.

1.161 “Additional Definitions.” Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE
Acquisition Proposal	21.16(c)
Additional Antibody Payment	2.6
Additional Antibody Summary	2.6
Additional Information	2.5
Additional PDGF Receptor Antibody	2.6
Affected Party	7.17(c)
Alliance Manager	4.2(a)
Audit Dispute	15.2(b)
Aventis Development Milestone	Schedule 3
Aventis Royalty Report	10.1(e)
Collaboration	Preamble
Collaboration Purpose	4.1(b)
Commercialization Overrun	10.13(d)
Company Indemnitees	18.1(b)

DEFINITION	SECTION/SCHEDULE
Company Non-Compete Period	7.17(b)(i)
Company Opt-Out Exercise	2.9
Company Sole Inventions	13.1(a)
Confidential Property and Information	Section 3.7
Cost of Finishing	Schedule 1
Damages	18.1(a)
Default Interest Rate	10.8
Development Budget(s)	6.4
Development Overrun	10.12
Discretionary Amendment	2.2(c)(iii)
Expert Panel	11.4
Force Majeure	Article XIX
Fully Burdened Manufacturing Cost	Schedule 1
Genentech	1.74
Global Brand	4.4(b)(i)
Global True-Up	Schedule 2
Governance Dispute	11.2
Indemnified Party	18.4
Indemnifying Party	18.4
Infringement	14.1(a)
Initial Global PDGF Development Plan	2.7(a)
Initial Territory PDGF Development Plan	2.7(a)
Investor	21.16
JCC	4.1(a)
JDC	4.1(a)
JFC	4.1(a)
Joint Invention	13.1(b)
JSC	4.1(a)
Key Results Memo	2.4(b)
Manufacturing Cost	Schedule 1
Manufacturing Plan	9.4
Marketing Guidelines	4.4(b)(v)
Modified Clause	21.7
Non-Approval Trials	7.2(j)
Non-Incurred Amount	6.4
Offering Party	5.5
Offeror	21.16(c)
Option	Preamble
Opt-In Effective Date	2.7(d)
Opt-In Package	2.5
Opt-In Payment	10.1(d)

DEFINITION	SECTION/SCHEDULE
Opt-In Right	2.7(d)
Opt-Out Notice Period	2.9(i)
Project Manager	4.9
Proposing Party	6.3
Quarterly True-Up	Schedule 2
Regeneron Development Milestone	Schedule 3
Regeneron Development Milestone Payment	10.1(b)
Regeneron Indemnities	18.1(a)
Regeneron Non-Compete Period	7.17(b)(ii)
Regeneron Reimbursement Amount	Schedule 2
Regeneron Sole Inventions	13.1(a)
Regulatory Amendment	2.2(c)(ii)
Sole Inventions	13.1(a)
Supplemental Option Payment	2.2(c)(iii)
Term	20.1(a)
Territory Profit Split	Schedule 2
Third Party Claim	18.1(a)
Working Group	4.1(a)

## **ARTICLE II OPTION DEVELOPMENT ACTIVITIES**

2.1 General. Regeneron shall and does hereby grant Company the Option, as more fully set forth in this Article II, to enter into the Collaboration. As partial consideration for the grant of the Option, Company shall pay to Regeneron the upfront payment pursuant to Section 10.1(a), Company shall reimburse Regeneron for Development Costs incurred by it or its Affiliates as provided in Section 10.2(a) and, irrespective of whether Company elects to exercise the Option, Company shall pay to Regeneron pursuant to Section 10.1(c) fifty percent (50%) of each Aventis Development Milestone Payment for which the corresponding Aventis Development Milestone is achieved on or prior to the date of the Company Opt-Out Exercise and twenty-five percent (25%) of each Aventis Development Milestone Payment for which the corresponding Aventis Development Milestone is achieved after the date of the Company Opt-Out Exercise. During the Option Period, only the following provisions of this Agreement shall be effective: Sections 3.2, 3.3, 3.4, 3.5 (*provided, however*, that all references to Committee approved Plans shall be deemed to refer to the Initial Development Plan), 3.6 (only the first sentence), 3.7, 7.17, 8.1(d), 8.2(b) (solely to the extent related to EYLEA), 8.3 (solely to the extent related to EYLEA), 8.5 to the extent applicable, 10.1, 10.2(a), 10.7, 10.8, 10.9, 10.10, 11.4, 11.5, 12.5 and Article I, Article II, Article XV, Article XVI, Article XVII, Article XVIII, Article XIX, Article XX, and Article XXI. Upon exercise of the Option by Company pursuant to Section 2.7(a) or

Section 2.7(c), subject to Section 20.8(d)(v), this Agreement shall be effective in its entirety.

## 2.2 Development Activities.

(a) Development of Licensed Products. Unless and until Company exercises the Option, Regeneron shall have the sole right to Develop Licensed Products in the Field in the Territory and shall use Commercially Reasonable Efforts to undertake all Development activities with respect to Licensed Products in the Field pursuant to the Initial Development Plan, including the Initial Development Budget. For clarity, Regeneron shall be the Lead Regulatory Party with respect to Licensed Products in the Field in the Territory prior to the Opt-In Effective Date, and Regeneron shall own all Approvals and Registration Filings with respect to the Development of Licensed Products in the Field in the Territory under the Initial Development Plan.

(b) Development Costs Under Initial Development Plan. The Parties' obligations with respect to the Development Costs incurred under the Initial Development Plan (and the associated Initial Development Budget) are set forth in Section 10.2(a).

### (c) Amendment of Initial Development Plan.

(i) Except as provided in Sections 2.5(b) and 2.7(b), in the event that Regeneron desires to amend the Initial Development Plan (including, without limitation, by increasing the Initial Development Budget), Regeneron shall provide the terms of such proposed amendment to Company, and the Parties shall discuss such proposed amendment. In the event that the Parties agree on an amendment to the Initial Development Plan, the Initial Development Plan and Initial Development Budget shall be amended as agreed by the Parties. In the event that the Parties cannot agree on an amendment to the Initial Development Plan, either Party may, in a written notice to the other Party, formally request that the dispute be resolved pursuant to Section 2.2(e). In the event that the Executive Officers agree on an amendment to the Initial Development Plan, the Initial Development Plan and Initial Development Budget shall be amended as agreed by the Parties. In the event that the Executive Officers are unable to resolve such dispute within the period specified in Section 2.2(e), Regeneron shall have the final decision-making authority regarding amending the Initial Development Plan, which it shall exercise by delivering to Company the revised Initial Development Plan and Initial Development Budget, in which case the terms of Section 2.2(c)(ii) or 2.2(c)(iii) shall apply, as applicable.

(ii) In the event that Regeneron unilaterally amends the Initial Development Plan after escalation to the Executive Officers pursuant to Section 2.2(c)(i) and such amendment occurs as a result of



activities or actions required or recommended by any Regulatory Authority (any such amendment, a “Regulatory Amendment”), then Company shall, within ten (10) Business Days following receipt of the revised Initial Development Plan and Initial Development Budget, either (A) provide to Regeneron written notice of its exercise of the Company Opt-Out Exercise, whereupon this Agreement will terminate pursuant to the terms of Section 2.9 or (B) be deemed to have agreed to such Regulatory Amendment (including, for clarity, any increase to the Initial Development Budget).

(iii) In the event that Regeneron unilaterally amends the Initial Development Plan after escalation to the Executive Officers pursuant to Section 2.2(c)(i) and such amendment occurs for any reason other than as a result of activities or actions required or recommended by any Regulatory Authority as provided in Section 2.2(c)(ii) (any such amendment, a “Discretionary Amendment”), then Company shall, within ten (10) Business Days following receipt of the revised Initial Development Plan and Initial Development Budget, either (A) provide to Regeneron written notice of its exercise of the Company Opt-Out Exercise, whereupon this Agreement will terminate pursuant to the terms of Section 2.9, (B) provide to Regeneron written notice of its election not to fund any additional Development Costs under the Initial Development Budget, as amended, in excess of the Budget Threshold, in which case Regeneron shall be responsible for all such Development Costs in excess of the Budget Threshold, or (C) in the absence of providing written notice under clause (A) or (B) above, be deemed to have agreed to such Discretionary Amendment (including, for clarity, any increase to the Initial Development Budget). In the event that Company elects not to fund any such Development Costs above the Budget Threshold pursuant to clause (B) of the immediately preceding sentence and later either (X) agrees to amend the Initial Development Plan to include a new Phase 2 Trial pursuant to Section 2.7(b) or (Y) exercises its Opt-In Right, whichever comes first, Company shall pay to Regeneron an amount equal to [\*\*\*\*\*] (such amount, the “Supplemental Option Payment”), which amount, if not previously paid in connection with an amendment to the Initial Development Plan pursuant to Section 2.7(b), shall become due in accordance with Section 10.1(d) when and if Company exercises its Opt-In Right.

(d) Development Overruns and Shortfalls. In the event that, during any Contract Year, any Development activity expressly provided for in the Initial Development Budget to be completed during such Contract Year is not completed during such Contract Year and the full expense budgeted for such activity for such Contract Year is not incurred, then such incomplete activity shall be completed during Contract Years following such first Contract Year and the budgeted amounts not yet incurred shall be

automatically included in the Initial Development Budget for such succeeding Contract Year(s). In the event that, during any Contract Year, any Development activity expressly provided for in the Initial Development Budget to be completed over subsequent Contract Year(s) is accelerated such that expenses budgeted for such activity in such subsequent Contract Year(s) are incurred in such first Contract Year, then, to the extent that such expenses are not reimbursed to Regeneron pursuant to Section 10.2(a) in such first Contract Year, they shall be reimbursed in such subsequent Contract Year(s) in an amount not to exceed the amount included in the Initial Development Budget for such activity for such Contract Year(s). Without limiting the foregoing, Company shall not be required to pay any Development Costs under the Initial Development Plan for a Contract Year that are in excess [\*\*\*\*\*] (as such budget may be (i) amended pursuant to Section 2.2(c) or (ii) adjusted to include any budgeted amounts not yet incurred from prior Contract Years pursuant to the first sentence of this Section 2.2(d)), unless such budget overrun has been approved by both Parties or, for clarity, included in an amended Initial Development Budget pursuant to Section 2.2(c). For clarity, the Parties shall share, to the extent provided in Section 10.2(a), Development Costs that are over the budgeted amounts in the Initial Development Plan in its entirety, as amended, up to [\*\*\*\*\*] of such budgeted amounts.

(e) Dispute Resolution. In the event of a dispute between the Parties as to an amendment to the Initial Development Plan pursuant to Section 2.2(c), 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 of receiving such written notification or such longer period as the Parties may agree in writing. In the event that the Executive Officers are unable to resolve such dispute within such period, Regeneron shall have the final decision-making authority with respect to such disputed issue.

2.3 Development Updates. Prior to the Opt-In Effective Date, Regeneron shall provide to Company at least once each three (3) months during the Option Period a written high-level summary of all Development activities performed and any results achieved and progress against timelines and budgets under the Initial Development Plan; *provided* that any proposed amendment of the Initial Development Plan shall be accompanied by an updated Development summary covering the period from the delivery of the prior Development summary until ten (10) Business Days prior to Regeneron's written notice of such proposed amendment.

2.4 License Grants. During the Option Period and for so long as Regeneron is conducting any wind-down activities associated with the early termination of any activity in the Initial Development Plan, Company hereby grants to Regeneron and its Affiliates:

(a) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free

(i) co-exclusive sublicensable right and license under the Company Collaboration Intellectual Property to make, have made, use, develop, import and export PDGF Products for use in the Field in the Territory and the Excluded Territory for the sole purpose of performing all Development activities under the Initial Development Plan;

(ii) (A) co-exclusive sublicensable right and license under the Company EYLEA Intellectual Property to make, have made, use, develop, import and export PDGF Products for use in the Field in the Excluded Territory for the sole purpose of performing all Development activities under the Initial Development Plan and (B) non-exclusive sublicensable right and license under the Company EYLEA Intellectual Property to make, have made, use, develop, import and export PDGF Products for use in the Field in the Territory for the sole purpose of performing all Development activities under the Initial Development Plan; and

(iii) non-exclusive sublicensable right and license under the Company Non-Collaboration Patent Rights and Party Information of Company to make, have made, use, develop, import and export PDGF Products for use in the Field in the Territory and the Excluded Territory for the sole purpose of performing all Development activities under the Initial Development Plan; and

(b) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free, co-exclusive right of reference and use, with the right to grant further rights of reference and use, under the EYLEA Regulatory Documentation to Develop or Manufacture PDGF Products in the Field in the Territory and the Excluded Territory in connection with performing all Development activities under the Initial Development Plan.

2.5 Key Results and Opt-In Package. Regeneron shall provide to Company a copy of the key results memo that Regeneron delivers to its senior management for the primary endpoints for the first Phase 2 Trial (or “new” Phase 2 Trial, if amended pursuant to Section 2.7(b)) of the first Licensed Product (such memo, the “Key Results Memo”) and the data and information listed on Exhibit A hereto (such data and information, the “Additional Information” and together with the Key Results Memo, the “Opt-In Package”) within fifteen (15) days after the later of the date that Regeneron delivers the Key Results Memo to its senior management and the date that Regeneron has received and compiled the Additional Information. Regeneron shall endeavor to provide Bayer with at least thirty (30) days’ notice of delivery of the Opt-In Package in order to facilitate Bayer’s ensuring that it has sufficient resources to undertake a prompt and efficient review of the Opt-In Package when received. Following Regeneron’s delivery

of the Opt-In Package, Company may request in writing that Regeneron provide specific additional background information and data (although not including raw data) to further clarify the contents of the Opt-In Package, which information and data, Regeneron shall promptly make available to Company to the extent that such request(s) are commercially reasonable and to the extent and in such form as such information and data are in Regeneron's possession and Control. Regeneron shall not have any obligation to conduct any additional studies or undertake any further analysis of any data or information in accordance with the preceding sentence. In addition, if reasonably requested by Company, appropriate functional Regeneron representatives shall meet with Company functional representatives in person or by phone, at times mutually agreed to by the Parties, to discuss the contents of the Opt-In Package and Company's request(s) for additional information and data. For purposes of clarity, any notice of estimated timeline for the delivery of the Opt-In Package or exchange of information described in the prior four sentences of this Section 2.5 will not impact or modify any of the other provisions, including timelines, of this Article II. Within [\*\*\*\*\*] to Company, Regeneron shall provide Company with a written estimate of the Supplemental Option Payment and Additional Antibody Payment, if applicable, and written notice of Regeneron's election to:

- (a) proceed with the continued Development of Licensed Products in the Field, subject to the provisions of Section 2.7(a);
- (b) amend the Initial Development Plan to include an additional Phase 2 Trial, subject to the provisions of Section 2.7(b); or
- (c) elect not to participate in or fund the further Exploitation of Licensed Products for use in the Field in the Territory pursuant to this Agreement (such right, the "Regeneron Opt-Out Exercise"), subject to the provisions of Section 2.7(c).

2.6 Additional Antibodies. At the same time that Regeneron provides to Company the Opt-In Package pursuant to Section 2.5, Regeneron shall also provide to Company (a) a high-level summary (including with respect to all development activities performed and any results achieved) (such summary, the "Additional Antibody Summary") of [\*\*\*\*\*] (any such antibody, an "Additional PDGF Receptor Antibody") and (b) a [\*\*\*\*\*]. Regeneron shall also provide to Company such other information related to the Additional PDGF Receptor Antibodies as Company may reasonably request. Company shall have the right to include PDGF Products containing Additional PDGF Receptor Antibodies in the Collaboration as Licensed Products by (y) exercising its Opt-In Right to the Licensed Products that are subject to the Initial Development Plan pursuant to Section 2.7 (and providing written notice to Regeneron in connection therewith of its election to include PDGF Products containing Additional PDGF Receptor Antibodies in the Collaboration) and (z) reimbursing Regeneron for [\*\*\*\*\*] (such payment, the "Additional Antibody Payment"), which payment shall become due in accordance with Section 10.1(d). For clarity, Company shall have no right to acquire rights to PDGF Products containing Additional PDGF Receptor

Antibodies unless and until Company exercises its Opt-In Right with respect to all Licensed Products pursuant to Section 2.7.

2.7 Option Right; Continuation of Development; and Opt-Out Exercise.

(a) Continuation of Development. Together with Regeneron's written notice of its election to proceed with the continued Development of Licensed Products in the Field pursuant to Section 2.5(a), Regeneron shall provide to Company either (i) a proposed plan and budget for the continued Development of Licensed Products in the Field on a global basis (including, without limitation, Phase 3 Trial(s)) (such plan and budget, "Initial Global PDGF Development Plan") or (ii) in the event that Regeneron elects to cease development of Licensed Products in the Field in the Excluded Territory but proceed with the Development of Licensed Products in the Field in the Territory pursuant to this Agreement and provides written notice to Company thereof, a proposed plan and budget for the continued Development of Licensed Products in the Field in the Territory (including, without limitation, Phase 3 Trial(s)) (such plan and budget, "Initial Territory PDGF Development Plan"). In each case ((i) and (ii)), such plan shall incorporate any ongoing Development under the Initial Development Plan, including, without limitation, the completion of any ongoing Phase 2 Trial(s). By the later of (i) [\*\*\*\*\*], as applicable and (ii) [\*\*\*\*\*], if any, Company shall either (i) exercise its Opt-In Right or (ii) exercise (or be deemed to have exercised) the Company Opt-Out Exercise, whereupon this Agreement will terminate pursuant to Section 2.9.

(b) Amendment of Initial Development Plan. Together with Regeneron's written notice of its election to amend the Initial Development Plan to include an additional Phase 2 Trial pursuant to Section 2.5(b), Regeneron shall provide such proposed amendment to Company. By the later of (i) [\*\*\*\*\*] and (ii) [\*\*\*\*\*], Company shall either (i) exercise the Company Opt-Out Exercise by providing written notice thereof to Regeneron, whereupon this Agreement will terminate pursuant to the terms of Section 2.9 or (ii) be deemed to have agreed to the revised Initial Development Plan and Initial Development Budget. For clarity, in the event that the Parties agree to amend the Initial Development Plan and Initial Development Budget to include an additional Phase 2 Trial pursuant to this Section 2.7(b), (x) Company shall be obligated to share any costs incurred under such amended Initial Development Plan and amended Initial Development Budget pursuant to Section 10.2(a) and shall pay the Supplemental Option Payment to Regeneron pursuant to Section 10.1(d), and (y) Company shall not be required to exercise its Opt-In Right at the time the Parties agree to such amendment, but rather the provisions of this Article II shall apply to such "new" Phase 2 Trial (as such Phase 2 Trial may be modified or changed by any subsequent amendment to the revised Initial Development Plan pursuant to Section 2.2(c)) and the Parties shall have the same rights and obligations under this Article II with respect to such new Phase 2 Trial and such amended Initial Development Plan.

(c) Regeneron Opt-Out Exercise. By the later of (1) [\*\*\*\*\*] and (2) [\*\*\*\*\*], Company shall either (i) exercise its Opt-In Right or (ii) exercise (or be deemed to have exercised) the Company Opt-Out Exercise, whereupon this Agreement will terminate pursuant to Section 2.10.

(d) Opt-In Right. As set forth in this Section 2.7, Company shall have the right to elect to exercise the Option to participate in and fund the further Development, Manufacture and Commercialization of Licensed Products in the Field pursuant to this Agreement (such right, the “Opt-In Right”) by providing written notice of such election to Regeneron (including with respect to whether Company is including PDGF Products containing Additional PDGF Receptor Antibodies in the Collaboration pursuant to Section 2.6) within the applicable timeframe set forth in this Section 2.7 and paying the Opt-In Payment and, if applicable, the Additional Antibody Payment to Regeneron pursuant to Section 10.1(d). Subject to Company having paid its applicable share of all Aventis Development Milestone Payments otherwise due pursuant to Section 10.1(c), Company’s exercise of its Opt-In Right shall be effective on the date that Regeneron receives written notice confirming Company’s exercise of its Opt-In Right together with the Opt-In Payment and, if applicable, the Additional Antibody Payment and/or the Supplemental Option Payment (such date, the “Opt-In Effective Date”).

## 2.8 Effect of Company Opt-In Right.

(a) Collaboration Under Agreement. In the event that Company exercises its Opt-In Right pursuant Section 2.7(a), (i) this Agreement shall be effective in its entirety as of the Opt-In Effective Date and (ii) the Parties shall Develop, Manufacture and Commercialize Licensed Products in the Field pursuant to the terms of this Agreement. Company shall have no right to Develop, Manufacture, Commercialize or otherwise Exploit Licensed Products (or Additional PDGF Receptor Antibodies) in the Field during the Term unless and until it exercises its Opt-In Right (and, if applicable, pays the Additional Antibody Payment) pursuant to Section 2.7 (unless otherwise agreed by the Parties in writing).

(b) Company Opt In; Regeneron Opt-Out Exercise. In the event that Company exercises the Company Opt-In Right pursuant Section 2.7(c), (i) this Agreement shall be effective in its entirety (except as otherwise set forth in Section 20.8(d)) as of the Opt-In Effective Date; (ii) as between the Parties, Company shall have the right, exclusive during the Regeneron Non-Compete Period, to Develop, Manufacture and Commercialize PDGF Products (other than Combination PDGF Products) in the Field in the Territory (including for use with EYLEA (but not as a Combination PDGF Product)) at its sole cost and expense; (iii) Regeneron shall not be responsible for bearing any remaining ongoing Development Costs under the Initial Development Plan other than (A)(1) seventy-five percent (75%) of any Development Costs incurred under the Initial Development Plan and the Initial Development Budget (each as in effect at the termination of this Agreement) after the effective date of the termination of this Agreement that are not specific to the Territory activities and (2) fifty percent (50%) of

all Development Costs incurred under the Initial Development Plan and the Initial Development Budget (each as in effect at the termination of this Agreement) after the effective date of the termination of this Agreement that are specific to the Territory, in each case ((1) and (2)) for a period of sixty (60) days following Regeneron's exercise of the Regeneron Opt-Out Exercise, and (B) any wind-down costs associated with the early termination of any activity in the Initial Development Plan (irrespective of whether such wind-down costs are included in the Initial Development Budget) during the six (6)-month period following Regeneron's exercise of the Regeneron Opt-Out Exercise pursuant to Section 2.5(c), with such costs being shared by the Parties in the same way that Development Costs related to such activity would be shared, in each case, as provided in Section 10.2(a); (iv) Company shall be responsible for paying [\*\*\*\*\*] of all amounts owed to Third Parties and all reasonable Out-of-Pocket Costs and FTE costs incurred by Regeneron in meeting its obligations under any Existing Licenses or New Licenses, in each case, as a result of Company's (or its Affiliate's or Sublicensee's) Development, Manufacture or Commercialization of PDGF Products in the Field in the Territory (including, without limitation, the Aventis Development Milestone Payments and Aventis Royalties (and providing all Aventis Royalty Reports) directly to Aventis within the same timeframes as provided in Section 10.1(c) and 10.1(e)); and (v) the provisions of Sections 7.17(b) and 20.8(d) shall apply. Notwithstanding the occurrence of a Regeneron Opt-Out Exercise, each Party shall be obligated to pay its applicable share of all amounts otherwise due under this Agreement prior to the date of the Regeneron Opt-Out Exercise (including, without limitation, such Party's applicable share of the Development Costs incurred under the Initial Development Plan and Initial Development Budget and all Aventis Development Milestone Payments).

2.9 Effect of Company Opt-Out Exercise. In the event that Company (a) elects to opt-out of this Agreement as a result of an amendment to the Initial Development Plan pursuant to Section 2.2(c), (b) fails to provide Regeneron with written notice of its exercise of its Opt-In Right (or otherwise elects not to exercise its Opt-In Right by providing written notice thereof to Regeneron) pursuant to Section 2.7(a) or 2.7(c) (including within the applicable required time periods) and Regeneron has not exercised the Regeneron Opt-Out Exercise pursuant to Section 2.5(c), or (c) elects to opt-out of this Agreement as a result of an amendment to the Initial Development Plan pursuant to Section 2.7(b) (each of (a), (b) and (c), a "Company Opt-Out Exercise"):

(i) this Agreement (A) shall continue in full force and effect for a period of sixty (60) days after Company provides notice of its exercise of the Company Opt-Out Exercise or is deemed to have exercised the Company Opt-Out Exercise pursuant to Section 2.9(b) (such sixty (60)-day period, the "Opt-Out Notice Period") and (B) shall terminate pursuant to Section 20.4 (except as otherwise set forth in Section 20.8(c)) at the end of the Opt-Out Notice Period;

(ii) as between the Parties, Regeneron shall have the right, exclusive during the Company Non-Compete Period, to develop,

manufacture or commercialize PDGF Products (other than Combination PDGF Products) in the Field in the Territory (including for use with EYLEA (but not as a Combination PDGF Product)) at its sole cost and expense;

(iii) Company shall be responsible for paying its applicable share of (A) any remaining ongoing Development Costs incurred by Regeneron under and in accordance with the Initial Development Plan and Initial Development Budget for activities performed during the Opt-Out Notice Period and (B) any wind-down costs associated with the early termination of any activity in the Initial Development Plan (irrespective of whether such wind-down costs are included in the Initial Development Budget) during the six (6)-month period after the end of the Opt-Out Notice Period, with such costs being shared by the Parties in the same way that Development Costs related to such activity would be shared, in each case, as provided in Section 10.2(a);

(iv) Company shall be responsible for paying (A) all amounts otherwise due under this Agreement prior to the end of the Opt-Out Notice Period (including, without limitation, Company's applicable share of the Development Costs incurred under the Initial Development Plan and Initial Development Budget) and (B) its applicable share of each Aventis Development Milestone Payment as set forth in Section 2.1; and

(v) the provisions of Sections 7.17(b) and 20.8(c) shall apply.

Notwithstanding the foregoing, in the event that Company exercises the Company Opt-Out Exercise, Regeneron shall have no obligation to continue performing the Development activities set forth in the Initial Development Plan or provide any Development updates to Company under Section 2.3 and Company shall have no rights with respect to the Option. For clarity, Company may opt out of this Agreement only by (x) electing to opt-out of this Agreement as a result of an amendment to the Initial Development Plan pursuant to Section 2.2(c), (y) failing to provide Regeneron with written notice of its exercise of its Opt-In Right (or otherwise electing not to exercise its Opt-In Right by providing written notice thereof to Regeneron) pursuant to Section 2.7(a) or 2.7(c), or (z) electing to opt-out of this Agreement as a result of an amendment to the Initial Development Plan pursuant to Section 2.7(b).

2.10 Termination Upon Mutual Written Agreement or Mutual Opt-Out Exercise. The Parties may elect to cease further Development, Manufacture and Commercialization of Licensed Products in the Field hereunder and terminate this Agreement in its entirety (a) by mutual written agreement at any time during the Option Period or (b) by mutually exercising their respective opt-out rights pursuant to Section 2.7(c). In the event that the Parties terminate this Agreement pursuant to Section 2.7(c)



or this Section 2.10, (x) this Agreement shall terminate (except as otherwise set forth in Section 20.9), (y) the Parties shall be obligated to pay (i) wind-down costs associated with the early termination of any activity in the Initial Development Plan, as provided in Section 10.2(a) and (ii) all amounts otherwise due under this Agreement prior to the date of such termination (including, without limitation, each Party's applicable share of the Development Costs incurred under the Initial Development Plan and Initial Development Budget and all Aventis Development Milestone Payments), and (z) for clarity, the provisions of Sections 7.17(b) shall not apply and the licenses granted in Section 2.4 shall terminate and be of no further force and effect upon completion of any wind-down activities under the Initial Development Plan.

### **ARTICLE III COLLABORATION**

3.1 Scope of Collaboration. From and after the Opt-In Effective Date, the Parties will cooperate in good faith under this Agreement and each Party will use Commercially Reasonable Efforts to Develop Licensed Products in the Field for the purpose of Commercializing Licensed Products in the Field in the Territory. Company will use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory. The Parties shall establish various Committees as set forth in Article IV of this Agreement to oversee and/or coordinate the Development of Licensed Products in the Field and oversee the Commercialization of Licensed Products in the Field in the Territory, and each Party shall, subject to the terms and conditions set forth in Article XVII, provide (or cause its Affiliates to provide) to any relevant Committee (and with respect to the Excluded Territory, Regeneron) any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to effectively and efficiently Develop and Manufacture Licensed Products in the Field in the Territory and the Excluded Territory and for Company (and, if agreed to by Company or set forth in the Plans, Regeneron) to effectively and efficiently Commercialize the Licensed Products in the Field in the Territory under this Agreement. The Parties acknowledge and agree that all Development, Manufacture and Commercialization and other activities specifically related to EYLEA as part of a Combination PDGF Product that is a Licensed Product shall be governed by the provisions of this Agreement and not by the EYLEA Agreement.

3.2 Compliance with Law. Both Company and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in the Territory 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 that it believes, in good faith, may violate, any applicable Law.

3.3 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 by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party 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 by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish to the other Party all information in its possession or under its control 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.

3.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Existing Licenses and the New Licenses to which it is a party and to notify the other Party of any terms or conditions in any such Existing License or New 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 to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Moreover, each Party shall take all actions reasonably necessary to ensure the other Party's ability to comply with (y) any such Existing License or New License (including any such terms and conditions with which such Party is required to comply as a sublicensee), and (z) any such material agreement entered into pursuant to a Plan. Neither Party may terminate or amend any Existing License, New License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory or with respect to the Development, Manufacture or commercialization of Licensed Products in the Field in the Excluded Territory.

3.5 Plans. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require in accordance with the terms of this Agreement.

3.6 Excluded Territory Activities. Regeneron shall have the exclusive right and authority, in its discretion, to Exploit PDGF Products in the Field in the Excluded Territory, in each case, subject only to the terms of this Agreement that expressly apply to Licensed Products in the Field in the Excluded Territory. Each Party agrees to reasonably communicate and consult with the other Party (through the JDC or the other Party's representatives on the JDC, with respect to Development activities, and

through the JCC or the other Party's representatives on the JCC, with respect to commercialization activities) on material Development and commercialization activities relating to Licensed Products in the Field in the Excluded Territory. Notwithstanding the foregoing or any other provision in this Agreement, neither Company nor any Committee shall have the right or authority to manage or control the internal operations of Regeneron or to approve, modify, impede or delay any of Regeneron's commercialization or Development plans or activities for its PDGF Products in the Excluded Territory (other than as contemplated under or in connection with the Global PDGF Development Plan). Regeneron shall reasonably inform the JDC or the JCC or Company's representatives on the JDC or JCC, as applicable, of (a) all material clinical and regulatory matters directly relating to its Licensed Products in the Excluded Territory, whether or not addressed in the Global PDGF Development Plan, and (b) any other Development or commercialization activities directly relating to its Licensed Products in the Excluded Territory to the extent such matters or activities would be reasonably expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Territory. To the extent any of the foregoing matters or activities in the Excluded Territory are undertaken pursuant to the Global PDGF Development Plan, each Party shall comply with the Global PDGF Development Plan; otherwise, Regeneron shall consider in good faith all comments of the JDC and the JCC (or Company's representatives on the JDC or JCC) with respect to its Licensed Product(s) in the Excluded Territory. Without limiting the foregoing, in the event that Regeneron elects to cease all development, manufacturing and commercialization of a Licensed Product in the Field in the Excluded Territory (including pursuant to Section 2.7(a)), Regeneron shall provide written notice to Company thereof, in which case the provisions of Section 6.2(c) and Section 10.2(c) shall apply with respect to such Licensed Product.

3.7 Information Protections. Company shall establish processes and procedures to ensure that confidential and proprietary information of Regeneron, including, without limitation, any New Information of either Party (together or individually, "Confidential Property and Information") are used solely for the purposes of the Collaboration. Such processes and procedures will ensure that the Confidential Property and Information are not used to benefit or advance any Company project outside the Collaboration, or to adversely affect the development, manufacture or commercialization of the Licensed Product in the Territory or the Excluded Territory. Company shall ensure that any Company employee (or any other individual performing activities by or on behalf of Company or its Affiliates under or in connection with this Agreement) that has access to any Confidential Property and Information is aware of the limitations on use of such Confidential Property and Information (including by means of appropriate training), and Company shall take all reasonable actions to prevent any provision or disclosure of the Confidential Property and Information within the Company to functions and individuals that do not need access to it for the purposes of the Collaboration. In the event that Regeneron reasonably believes that Company is in non-compliance with the provisions of this Section 3.7, Regeneron may require that the matter be submitted to the Executive Officers for resolution, and the Executive Officers shall

diligently and in good faith attempt to resolve the matter as soon as reasonably practicable (although no later than fifteen (15) Business Days) after such matter is referred to the Executive Officers. For clarity, the preceding sentence shall not limit either Party's rights under Section 20.2.

## **ARTICLE IV MANAGEMENT**

### 4.1 Committees/Management.

(a) Following Company's exercise of its Opt-In Right, the Parties will 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 Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future) and may be further designated by the JSC. 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 that establishes the Working Group determines.

(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 Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts (the definition of which, for purposes of this Section 4.1(b), shall not include the reference to the Collaboration Purpose) 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 (other than EYLEA) (the "Collaboration Purpose"). The Parties acknowledge and agree that, unless otherwise expressly agreed by the Parties in writing, the Parties shall seek to optimize the commercial potential of and financial returns from both the Licensed Products in the Field in the Territory under this Agreement and EYLEA under the EYLEA Agreement, and that, notwithstanding Section 3.1(b) of the EYLEA Agreement, the Parties shall have the right to consider Licensed Products in seeking to optimize the commercial potential of and financial returns from EYLEA under the EYLEA Agreement. 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 21.5.

(c) Notwithstanding anything to the contrary in this Agreement or the EYLEA Agreement, the Parties may (i) direct any such Committee to meet simultaneously or concurrently with, or as part of, the meeting of the comparable committee under the EYLEA Agreement or (ii) combine any Committee with the

comparable committee under the EYLEA Agreement, in each case ((i) and (ii)), for some or all purposes or for a limited period of time.

#### 4.2 Joint Steering Committee.

(a) Formation; Composition and Purpose. Within ten (10) days after the Opt-In Effective Date, the Parties will establish the JSC, which shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for (A) an integrated worldwide Development program for the Licensed Products, (B) the Manufacture of Licensed Products in the Field for use in activities under the Plans and (C) the Commercialization of 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 4.10 below on which such Committees are unable to reach consensus. The JSC 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). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager (“Alliance Manager”) to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually review and approve the Development Plan(s), Manufacturing Plan(s) and Territory PDGF Commercialization Plan(s); (ii) identify which Party or Third Party that will perform the filling, packaging, labeling and testing of the Formulated Bulk Product to supply Finished Product for Clinical Supply Requirements and Commercial Supply Requirements for use in the Field in the Territory under this Agreement; (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) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point communication for seeking consensus regarding key global strategy and Plan issues; (v) establish sub-committees of the JSC as the JSC deems appropriate and (vi) consider and act upon such other matters as are specified in this Agreement or otherwise agreed to by the Parties.

#### 4.3 Joint Development Committee.

(a) Formation; Composition and Purpose. Within ten (10) days after the Opt-In Effective Date, the Parties will establish the JDC. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the Development of Licensed Products in the Field as part of an integrated worldwide Development program; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Development Plan(s) (and related Development Budget(s)) and (iii) to oversee the implementation of the Development Plan(s) and the Development

operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; *provided* that each Party must appoint, as one of its representatives on the JDC, its Project Manager and *provided further*, 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) Specific Responsibilities. In particular, subject to Section 3.6, the JDC shall be responsible for:
- (i) advising the JSC on the overall global Development strategy for the Licensed Products in the Field;
  - (ii) facilitating an exchange of Development data between the Parties and developing and updating the Development Plans (and related Development Budgets), as described in Sections 6.2 and 6.4, for final approval by the JSC;
  - (iii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of, and compliance with, the Development Plans (including the Development Budgets);
  - (iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plans;
  - (v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans; advising on material clinical and regulatory matters and other Development activities in the Excluded Territory that are reasonably expected to materially adversely affect, or have a material impact on, the Development of Licensed Products in the Territory; and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under the Development Plans and for Non-Approval Trials;
  - (vi) reviewing and approving proposed target Licensed Product labeling and reviewing, and to the extent set forth herein approving, proposed changes to Licensed Product labeling in the Field in accordance with Section 8.2(e);
  - (vii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;

(viii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;

(ix) 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 Licensed Products in the Field;

(x) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global PDGF Development Plan; and

(xi) considering and acting upon such other matters as are specified in this Agreement or by the JSC.

#### 4.4 Joint Commercialization Committee.

(a) Formation; Composition and Purpose. Within twenty (20) days after the Opt-In Effective Date, the Parties will establish the JCC. The purpose of the JCC shall be (i) to develop and propose to the JDC and JSC the strategy for the Commercialization of Licensed Products in the Field in the Territory; (ii) to discuss and advise on certain commercialization activities for the Licensed Products in the Excluded Territory to the extent contemplated in Section 3.6; (iii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Territory PDGF Commercialization Plan (and related Territory PDGF Commercialization Budget); (iv) to develop (or oversee the development of), review and annually update and approve the Country/Region PDGF Commercialization Plans (and related Country/Region PDGF Commercialization Budgets); (v) to develop (or oversee the development of), review and annually update and approve the HQ Plan (and related HQ Budget) and (vi) to oversee the implementation of the Territory PDGF Commercialization Plan and the Commercialization operational aspects of the Collaboration. The JCC shall be composed of at least two (2) senior executives of each Party.

(b) JCC Responsibilities. In particular, subject to Section 3.6, the JCC shall be responsible for:

(i) recommending to the JSC whether a single brand will be used for commercialization of Licensed Products for one or more indications throughout the Excluded Territory and the Territory, including using the global brand under the EYLEA Agreement, in part, for Commercialization of Licensed Products hereunder (“Global Brand”). If the JCC agrees that a Global Brand(s) for the Licensed Products is desirable, [\*\*\*\*\*];

(ii) developing and proposing to the JSC the strategy for the Commercialization of the Licensed Products in the Field in the Territory;

(iii) commencing no later than three (3) years prior to the Anticipated First Commercial Sale of the first Licensed Product in the Territory, (A) developing, and updating at least annually, the Territory PDGF Commercialization Plans (and related Territory PDGF Commercialization Budgets) and HQ Plan (and related HQ Budget) for final approval by the JSC and (B) approving the Country/Region PDGF Commercialization Plan(s) (and related Country/Region PDGF Commercialization Budget(s));

(iv) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plans for review by the JSC;

(v) developing and updating, as necessary, [\*\*\*\*\*] (collectively, the items referred to in this paragraph (v) shall be referred to as the “Marketing Guidelines”) as part of the Territory PDGF Commercialization Plan;

(vi) developing target profiles for the Licensed Products in the Field;

(vii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of and compliance with the Territory PDGF Commercialization Plans (including the Territory PDGF Commercialization Budgets), HQ Plan (including the HQ Budget) and Country/Region PDGF Commercialization Plans (including the Country/Region PDGF Commercialization Budgets), including ensuring that country specific launch plans in the Territory are consistent with the Marketing Guidelines;

(viii) establishing, as necessary, sub-committees of the JCC;

(ix) selecting a Product Trademark for Licensed Products in the Field in accordance with Section 12.2 and giving guidance on trade dress in the Field [\*\*\*\*\*];

(x) if the Parties agree to use a Global Brand, [\*\*\*\*\*];



(xi) developing and implementing plans and policies regarding journal and other publications with respect to Licensed Products in the Field in concert with the JDC;

(xii) allocating the appropriate cost for Commercialization activities that support the Licensed Products in the Field in the Territory and the Excluded Territory as Other Shared Expenses and/or Shared Promotion Expenses, if applicable, in accordance with this Agreement and assigning responsibilities and approving budgets for such activities;

(xiii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;

(xiv) consulting on all commercialization activities for Licensed Products in the Field in the Excluded Territory that are reasonably expected to materially adversely affect, or have a material impact on, the Commercialization of Licensed Products in the Territory in accordance with, and subject to, Section 3.6 and Section 7.6;

(xv) consulting and coordinating with the JCC under the EYLEA Agreement with respect to the commercialization of Licensed Products under this Agreement and EYLEA under the EYLEA Agreement; and

(xvi) considering and acting upon such other matters as are specified in this Agreement or by the JSC or JDC.

4.5 Other Committees. Within ten (10) days after the Opt-In Effective Date, the Parties will establish the JFC, which shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article X and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC and the JCC, as needed. At least eighteen (18) months prior to the Anticipated First Commercial Sale, the Company's members of the JFC shall also include representatives who can address issues relating to the Commercialization of Licensed Products in the Field in the Major Market Countries and the Regions.

4.6 Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Company. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Company. 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 draft minutes of each meeting within seven (7) days thereafter and final minutes within thirty (30) days thereafter.

4.7 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than every Quarter during the Term. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties) 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 (or, with respect to Regeneron, commercialization) of the Licensed Products (under obligations of confidentiality and non-use substantially equivalent in scope to those included in Article XVII) 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 Day's prior written notice, except that emergency meetings may be called with at least one (1) Business Day's prior written notice.

4.8 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.

4.9 Project Manager. Each of Company and Regeneron shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Project Manager ("Project Manager"). Each Project Manager will be responsible for:

(a) coordinating the various functional activities of Company and Regeneron, as appropriate, in developing and executing strategies and Plans for the Licensed Products in the Field in an effort to ensure consistency and efficiency;

(b) providing single-point communication for seeking consensus both within the respective Party's organization and with the other Party's organization regarding key strategy and Plan issues, as appropriate, including facilitating review of external corporate communications; and

(c) identifying and raising cross-country, cross-Party and/or cross-functional disputes to the appropriate Committee in a timely manner.

4.10 Resolution of Governance Matters. As provided in Section 11.2, this Section 4.10 shall apply to matters constituting, or that if not resolved would constitute, a Governance Dispute.

(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:

(i) in the case of any matter that cannot be resolved by the JDC, JCC, JFC or any other committee established by the JSC, at the request of either Party, such matter shall promptly, and in any event within five (5) Business Days (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;

(ii) in the event a unanimous vote on any matter cannot be obtained at the JSC within five (5) Business Days after referral to it pursuant to (i) above, except as set forth in (iii) below, Company shall have the deciding vote with respect to those matters described in [\*\*\*\*\*], and Regeneron shall have the deciding vote with respect to those matters described in [\*\*\*\*\*]. Neither Party shall have the deciding vote with respect to matters described in [\*\*\*\*\*]. For the avoidance of doubt [\*\*\*\*\*].

(iii) notwithstanding the above, and subject to Section 8.2(e), if either Party (the “First Party”) [\*\*\*\*\*], then such dispute shall be resolved in accordance with the dispute resolution procedures set forth in Section 4.10(b); *provided, however*, that the dispute resolution procedures set forth in Section 4.10(b) shall not apply and the terms of Section 4.10(a)(ii) above shall apply (and thus, the final decision of the Party authorized to cast the deciding vote under Section 4.10(a)(ii) shall be final and binding on the First Party) [\*\*\*\*\*].

(b) Referral to Executive Officers. In the event that the JSC is, after a period of five (5) Business Days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, and one Party is not expressly allocated decision-making authority over the matter as set forth in this Agreement (or such dispute is not otherwise governed by the terms of Section 4.10(a)(iii)), 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 of receiving such written notification. In the event that the Executive Officers are unable to resolve such dispute within such ten (10)-Business Day period, (i) to the extent such dispute relates to a Technical Development Matter (except for Legal Disputes) (unless as jointly agreed by the Parties), either Party may by written notice to the other Party require the specific issue in dispute to be submitted for resolution by an Expert Panel pursuant to Section 11.4 and

(ii) to the extent such dispute relates to a Legal Dispute (unless as jointly agreed by the Parties), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise pursuant to the terms of Section 11.3.

(c) Interim Budgets. Pending resolution by the Executive Officers of any referred dispute under Section 4.10(b), 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 Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committee approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 4.10(c).

(d) 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.

## **ARTICLE V LICENSE GRANTS**

5.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 5.5) and any Existing License or New License to which Regeneron is a party, Regeneron hereby grants to Company:

(a) (i) the nontransferable (except as permitted by Section 21.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, Regeneron EYLEA Intellectual Property and Regeneron's interest in Joint Intellectual Property to make, have made, use, develop, import and export Licensed Products for use in the Field in the Territory, and (ii) the nontransferable (except as permitted by Section 21.9), exclusive right and license under the Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, Regeneron EYLEA Intellectual Property and Regeneron's interest in Joint Intellectual Property to sell, have sold and offer to sell Licensed Products in the Field in the Territory, subject to Regeneron's right to supply Licensed Products to Company, as contemplated by this Agreement. Company will have the right to grant sublicenses under the foregoing license only as set forth in Section 5.3; and

(b) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Regeneron Non-Collaboration Patent Rights and Party Information of Regeneron to make, have made, use, develop, sell, offer to sell, have sold, import and export Licensed Products for use in the Field in the Territory.

5.2 Company License Grants. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Company or any of its Affiliates is a party, Company hereby grants to Regeneron:

(a) the nontransferable (except as permitted by Section 21.9), royalty-free, (1) co-exclusive (with Company and its Affiliates) right and license under the Company Collaboration Intellectual Property and Company's interest in Joint Intellectual Property to make, have made, use, develop, import and export Licensed Products for use in the Field in the Territory, (2) non-exclusive right and license under the Company EYLEA Intellectual Property to make, have made, use, develop, import and export Licensed Products for use in the Field in the Territory and (3) non-exclusive right and license under the Company Collaboration Intellectual Property, Company EYLEA Intellectual Property and Company's interest in Joint Intellectual Property to make, have made, use, develop, import and export Licensed Products in the Field in the Territory for purposes of developing and commercializing Licensed Products in the Field in the Excluded Territory. Regeneron will have the right to grant sublicenses under the foregoing licenses (and under the license grant to the Product Trademark(s) and EYLEA Trademark in Section 12.5) only as set forth in Section 5.3;

(b) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Company Non-Collaboration Patent Rights and Party Information of Company to (i) make, have made, develop, use, import and export Licensed Products for use in the Field in the Territory (ii) make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products for use in the Excluded Territory and (iii) make, have made, use, develop, import and export Licensed Products in the Field in the Territory for the sole purpose of developing and commercializing PDGF Products in the Field in the Excluded Territory;

(c) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free, (1) exclusive, sublicensable right and license under Company Collaboration Intellectual Property, Company EYLEA Intellectual Property and Company's interest in Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products for use in the Field in the Excluded Territory and (2) non-exclusive, sublicensable right and license under Company Collaboration Intellectual Property, Company EYLEA Intellectual Property and Company's interest in Joint Intellectual Property to make, have made, develop, use, import and export PDGF Products in the Territory for the sole purpose of developing and commercializing PDGF Products in the Excluded Territory; and

(d) (i) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free, exclusive, sublicensable right and license under Company Collaboration Intellectual Property and Company's interest in Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products for use outside the Field worldwide, (ii) the nontransferable

(except as permitted by Section 21.9), fully paid-up, royalty-free, co-exclusive (with Company and its Affiliates), sublicensable right and license under Company Collaboration Intellectual Property and Company's interest in Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products that are not Licensed Products for use outside the Field in the Territory, (iii) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free, exclusive, sublicensable right and license under Company Collaboration Intellectual Property, Company EYLEA Intellectual Property and Company's interest in Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products for use outside the Field in the Excluded Territory, and (iv) the nontransferable (except as permitted by Section 21.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Company EYLEA Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export (1) Licensed Products for use outside the Field in the Territory and (2) PDGF Products that are not Licensed Products for use outside the Field in the Territory.

5.3 Sublicensing. Unless otherwise restricted by any Existing License or New License, Company will have the right to sublicense any of its rights under Section 5.1(a) only with the prior written consent of Regeneron, such consent not to be unreasonably withheld 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 Company may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. For clarity, pursuant to the terms of the Genentech Agreement, Company shall, during the term of the Genentech Agreement, provide Regeneron with notice of any sublicense granted by Company to any Third Party under any Patents licensed by Genentech to Regeneron under the Genentech Agreement and included in the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Regeneron Non-Collaboration Patent Rights or Regeneron EYLEA Intellectual Property. Unless otherwise restricted by any Existing License or New License, Regeneron will have the right to sublicense any of its rights under Section 5.2(a) (or under the license grant to the Product Trademark(s) in Section 12.5) only with the prior written consent of Company, such consent not to be unreasonably withheld 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 Company'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 by a Party to a Sublicensee (or an Affiliate) shall be pursuant to a written agreement and shall require the Sublicensee (or Affiliate) of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article XVII, and will include, with respect to a Sublicensee (or an Affiliate) of Company, an obligation of the Sublicensee (or Affiliate) to account for and report its sales of Licensed Products to Company on the same basis as if such sales were Net Sales by Company. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the Territory Profit Split based on Net

Sales of Licensed Products sold by Sublicensees (or Affiliates) of Company under this Agreement. In the event of a breach by a Sublicensee (or an Affiliate) of Company of any sublicense agreement that has or is reasonably likely to have a materially adverse effect on Regeneron or any of its Affiliates or any Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property or Regeneron EYLEA Intellectual Property, then Regeneron may cause Company or its Affiliate to exercise, and the Company or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee (or Affiliate). Any sublicense agreement entered into by Company and any of its Sublicensees (or Affiliates) will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee (or Affiliate) and Regeneron, at the option of Regeneron, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Company will forward to Regeneron a complete copy of each fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.

5.4 No Implied License. Except as expressly provided in this Article V 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 Patents, Know-How, Party Information or the other Party's interest in the Joint Intellectual Property either expressly or by implication, estoppel or otherwise. Except to the extent licensed or otherwise expressly provided in this Agreement, each Party retains all rights to develop, manufacture and commercialize any rights not licensed hereunder and retained by such Party in its Patents, Know-How, Party Information or interest in the Joint Intellectual Property.

5.5 Retained Regeneron Rights. With respect to the licenses granted under Section 5.1(a), Regeneron reserves for itself and its Affiliates and Third Party licensees under the Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, and Regeneron's interest in the Joint Intellectual Property, (a) the co-exclusive right to make, have made, import, export and use Licensed Products in the Field in the Territory solely for Development purposes, and (b) the co-exclusive right to Manufacture Licensed Products in the Territory. For the avoidance of doubt, Regeneron retains all rights in Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, Regeneron's interest in the Joint Intellectual Property and PDGF Products not expressly licensed hereunder, including, without limitation the right (i) to exploit Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, and Regeneron's interest in the Joint Intellectual Property to make, have made, use, sell, offer to sell, have sold, import and export PDGF Products for use outside the Field and (ii) to exploit Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, and Regeneron's interest in the Joint Intellectual Property to make, have made, use, sell, offer to sell, have sold, and import and export PDGF Products for use in the Field in the Excluded Territory.

5.6 Retained Bayer Rights. With respect to the licenses granted under Section 5.2, Company reserves for itself and its Affiliates and Third Party licensees under the Company Collaboration Intellectual Property and Company's interest in the Joint Intellectual Property, (a) the co-exclusive right to make, have made, import, export and use Licensed Products in the Field in the Territory for Development purposes, (b) the exclusive right to sell, offer to sell and have sold Licensed Products for use in the Field in the Territory, (c) the co-exclusive right to Manufacture Licensed Products in the Territory solely for use in the Field in the Territory and (d) the co-exclusive right to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products that are not Licensed Products for use outside the Field in the Territory.

5.7 Right of Negotiation for Excluded Territory. In the event that (a) Regeneron desires to enter into a license or co-promotion arrangement with a Third Party (other than with an Affiliate, distributor or contract sales force) with respect to commercialization of a Licensed Product in the Excluded Territory or (b) Company desires to enter into a license or co-promotion arrangement with a Third Party (other than with an Affiliate, distributor or contract sales force) with respect to commercialization of a Non-Collaboration PDGF Product in the Excluded Territory (the applicable Party in clause (a) or (b), the "Offering Party"), the Offering Party shall grant the other Party a first right of exclusive negotiation for such commercialization rights. If the Offering Party desires to enter into such a commercialization arrangement, the Offering Party shall give the other Party written notice thereof. The other Party shall [\*\*\*\*\*] to determine and to notify the Offering Party in writing whether the other Party desires to negotiate such a commercialization arrangement. Failure to provide written notice to the Offering Party within such [\*\*\*\*\*] shall be deemed to be a rejection of the Offering Party's offer to negotiate for such commercialization rights. If the other Party rejects the Offering Party's offer to negotiate for such commercialization rights, or if the other Party accepts the Offering Party's offer to negotiate for such commercialization rights but the Parties are unable to reach an agreement on such commercialization arrangement after negotiating in good faith, within [\*\*\*\*\*] of the date the Offering Party notified the other Party of its desire to enter into such commercialization arrangement, then the Offering Party shall have no further obligation to the other Party with respect to the Licensed Products (where Regeneron is the Offering Party) or the Non-Collaboration PDGF Products (where Company is the Offering Party), as applicable, in the Excluded Territory.

## **ARTICLE VI DEVELOPMENT ACTIVITIES**

6.1 Development of Licensed Products. Subject to the terms of this Agreement, following Company's exercise of its Opt-In Right, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Development Plans under the general direction and oversight of the JDC. Each Party shall (a) use Commercially Reasonable Efforts to Develop Licensed Products in the Field



pursuant to the terms of this Agreement and carry out the Development activities assigned to it in Development Plans in a timely manner and (b) conduct all such Development activities hereunder in compliance with applicable Laws, including, without limitation, Good Practices. Regeneron may conduct separate Development activities to support Licensed Products in the Excluded Territory, subject to the conditions and requirements set forth herein.

## 6.2 Development Plans.

(a) The JDC shall prepare and update Development Plans for Licensed Products in the Field under this Agreement for approval by the JSC. Except for the first Global PDGF Development Plan incorporating the Initial Development Plan, an updated Global PDGF Development Plan (and, if applicable, Territory PDGF Development Plan) will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Development Plan will set forth the plan for Development of each Licensed Product in the Field over at least three (3) Contract Years and will include (i) strategies and timelines for Developing and obtaining Approvals for the Licensed Products in the Field in the Territory and, subject to Section 3.6, the Excluded Territory, and (ii) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers to the extent provided by the applicable Development Plan.

(b) Each Development Plan will be reviewed and informally updated by the JDC not less frequently than every six (6) months for the ensuing three (3) year period. No later than sixty (60) days after the Opt-In Effective Date, the JDC will meet to finalize the first Global PDGF Development Plan (which, as provided above, shall incorporate, or be substantially consistent with, the Initial Global PDGF Development Plan) (and, if applicable, the first Territory PDGF Development Plan). Until the first Global PDGF Development Plan is approved by the JSC, the Parties will Develop the Licensed Products in the Field under this Agreement in accordance with the Initial Global PDGF Development Plan, unless otherwise agreed to by the JSC. Unless otherwise agreed to by the JDC, each update to the Development Plan(s) shall include the activities and timelines described in or referred to in the Initial Development Plan until the activities described therein are completed in a timely manner.

(c) Notwithstanding the foregoing, in the event that Regeneron elects to cease development, manufacturing and commercialization of a Licensed Product in the Field in the Excluded Territory pursuant to Section 2.7(a) or Section 3.6, the Parties shall Develop such Licensed Product in the Field in the Territory under this Agreement pursuant to a Territory PDGF Development Plan (and the first Territory PDGF Development Plan shall incorporate, or be substantially consistent with, the Initial Territory PDGF Development Plan).

## 6.3 Clinical Trials Outside of a Development Plan.

(a) If a Party (the “Proposing Party”) wishes to undertake additional clinical trials not contemplated in a Development Plan to support a Licensed Product in the Field, the Proposing Party shall present the proposed protocols and clinical trial designs to the JDC for approval and, for other than Non-Approval Trials or trials conducted solely for purposes of obtaining Approvals in the Excluded Territory, shall also present to the JDC the related budgets. If the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 6.6, then (i) Regeneron as the Proposing Party shall be free to undertake, at its sole expense, additional clinical trials and other Development in the Territory and the Excluded Territory outside the Development Plan for use in the Excluded Territory and (ii) Company as the Proposing Party shall be free to undertake, at its sole expense, additional clinical trials and other Development in the Territory outside the Development Plan that are necessary to obtain Marketing Approval in the Territory; *provided, however*, that the Proposing Party must first present the proposed protocols and clinical trial designs to the other Party for approval, such approval not to be unreasonably withheld or delayed. If the other Party does not approve any such protocols or clinical trial designs for material safety reasons, the Proposing Party may not proceed with the proposed clinical trials unless and until the dispute has been resolved as provided in Section 4.10(b) and, if necessary, Section 11.4.

(b) In the event that Regeneron conducts a clinical trial for a Licensed Product in the Field in the Excluded Territory outside the scope of a Development Plan pursuant to this Section 6.3 and Company desires to use any data from such clinical trial to support an application for Marketing Approval (including a new label claim) for a Licensed Product in the Field in the Territory, then Company shall pay to Regeneron an amount equal to [\*\*\*\*\*].

(c) In the event that Company conducts a clinical trial for a Licensed Product in the Field in the Territory outside the scope of a Development Plan pursuant to this Section 6.3 and uses data from such clinical trial to obtain Marketing Approval for a Licensed Product in the Field in the Territory, then (A) if Regeneron does not use any data from such clinical trial to support an application for Marketing Approval (including a new label claim) for a Licensed Product in the Field in the Excluded Territory, Regeneron shall pay to Company an amount equal to [\*\*\*\*\*] and (B) if Regeneron desires to use any data from such clinical trial to support an application for Marketing Approval (including a new label claim) for a Licensed Product in the Field in the Excluded Territory, Regeneron shall pay to Company an amount equal to [\*\*\*\*\*].

(d) The payment of any Development Costs and other amounts by a Party to a Proposing Party pursuant to this Section 6.3 shall not be subject to the Quarterly True-Up mechanism set forth in Article X and Schedule 2. Notwithstanding anything to the contrary in this Section 6.3, a Party shall not be required to reimburse the other Party for any Development Costs incurred by such other Party in conducting a clinical trial outside the scope of a Development Plan pursuant to this Section 6.3 if the

applicable data is used solely as part of an annual report, a safety report, or regular filing required by a Regulatory Authority or applicable Laws to maintain an Approval.

(e) For clarity, except as otherwise provided in this Section 6.3, neither Party shall have the right to use any data, results or other Know-How resulting from a clinical trial conducted by the other Party outside the scope of a Development Plan pursuant to this Section 6.3 to support the Development or Commercialization of Licensed Products in the Field in the Territory or the Development or commercialization of Licensed Products in the Field in the Excluded Territory, as applicable, under this Agreement.

6.4 Development Budgets. The Territory PDGF Development Plan shall include the Territory PDGF Development Budget, and the Global PDGF Development Plan shall include the Global PDGF Development Budget (each individually, a "Development Budget" and both collectively, the "Development Budgets"), and the Development Budgets shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Development Plans in accordance with this Agreement. Amendments and updates to any Development Budgets shall not be effective without the approval of the JSC. In the event that, during any Contract Year (the "First Year"), any Development activity expressly provided for in the approved Development Budget to be completed during such First Year is not completed during such First Year (to the extent incomplete, an "Incomplete Activity") and the full expense budgeted for such activity for such First Year is not incurred (to the extent not incurred, a "Non-Incurred Amount"), then such Incomplete Activity shall be completed during Contract Years following such First Year (the "Succeeding Year(s)") and the Non-Incurred Amount shall be included in the Development Budget for such Succeeding Year(s) as set forth in the following sentence. If the Development Budget for such Succeeding Year(s) has not yet been approved by the JSC, then the Non-Incurred Amount shall be included in the proposed Development Budget for such Succeeding Year(s) without otherwise limiting any other Development activities or any amounts related thereto, unrelated to the Incomplete Activity, which, pursuant to the Development Plan, would have been performed during such Succeeding Year, and if the Development Budget for the Succeeding Year(s) has been approved by the JSC, then the Development Budget for such Succeeding Year(s) shall be revised automatically to include the Non-Incurred Amount.

6.5 Development Reports. Within forty-five (45) days after the end of each Quarter after the Opt-In Effective Date, Regeneron and Company 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 each 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. Within forty-five (45) days after the end of a Contract

Year, the JFC will present the final Development Costs for such preceding Contract Year to the JSC for approval.

6.6 Review of Clinical Trial Protocols. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by either Party pursuant to Section 6.3, including, without limitation, pre-approval authorizations for Non-Approval Trials meeting established criteria. In no event will such procedures require more than ten (10) Business Days for the JDC to accept or reject a proposed protocol and/or clinical trial design for a clinical study to be conducted solely for purposes of obtaining an Approval in the Excluded Territory.

## **ARTICLE VII COMMERCIALIZATION**

7.1 Commercialization of Licensed Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC and in accordance with the Territory PDGF Commercialization Plan, the Country/Region PDGF Commercialization Plans and the HQ Plan. Except as set forth in this Agreement, Company shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory.

7.2 Territory PDGF Commercialization Plan. The Territory PDGF Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. The initial Territory PDGF Commercialization Plan will be prepared by Company, with Regeneron's participation and input with respect to the portions of such Plan directly applicable to the Major Market Countries, and submitted to the JCC for review and approval. Once approved by the JCC, the Territory PDGF Commercialization Plan will be presented to the JSC for review and approval [\*\*\*\*\*] before the Anticipated First Commercial Sale of the first Licensed Product in the Territory. The Territory PDGF Commercialization Plan for each subsequent Contract Year shall be updated by the JCC and approved by the JSC at least two (2) months prior to the end of the then current Contract Year. Each Territory PDGF Commercialization Plan shall include (with sufficient detail, relative to time remaining to the Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

- (a) the overall strategy for Commercializing Licensed Products in the Field in the Territory, including Licensed Product target product profiles, branding, positioning, promotional materials and core messages;
- (b) subject to applicable Law, Licensed Product pricing guidelines in the Field in the Territory;

(c) the Territory PDGF Commercialization Budget;

(d) anticipated launch dates for applicable countries in the Territory;

(e) any global commercialization activities that are designed to benefit the Licensed Product in the Field in both the Territory and the Excluded Territory [\*\*\*\*\*];

(f) market and sales forecasts for the Licensed Products in the Field in the Territory in a form to be agreed between the Parties;

(g) strategies for the detailing and promotion of Licensed Products in the Field in the Territory, including recommended sales force sizes in the countries in the Territory;

(h) anticipated major advertising, public relations and patient advocacy programs for Licensed Products in the Field in the Territory;

(i) reimbursement and patient assistance, including [\*\*\*\*\*];

(j) post-marketing clinical trials to support Commercialization of Licensed Products in the Field in the Territory that [\*\*\*\*\*], including any such clinical trials sponsored by Third Parties using Licensed Product supplied by the Parties (“Non-Approval Trials”);

(k) proposed use of Third Party sales representatives, Sublicensees (or Affiliates) and/or distributors in any country in the Territory;

(l) target incentive product weighting and performance goals for sales representatives detailing the Licensed Products in the Field in the Territory; and

(m) all other Marketing Guidelines.

7.3 Country/Region PDGF Commercialization Plans. Each Country/Region PDGF Commercialization Plan and all updates and amendments thereto will be consistent with the Territory PDGF Commercialization Plan and the principles of the Collaboration Purpose. The initial Country/Region PDGF Commercialization Plan for [\*\*\*\*\*] Australia and each Region will be prepared by Company, with Regeneron’s participation and input, and approved by the JCC at least [\*\*\*\*\*] before the Anticipated First Commercial Sale of the first Licensed Product in the applicable Country and/or Region. The Country/Region PDGF Commercialization Plan for each subsequent Contract Year shall be updated and approved by the JCC at least two (2) months prior to the end of the then current Contract Year and shall cover then Reporting Countries. Each Country/Region PDGF Commercialization Plan shall include (with sufficient detail, relative to time remaining to the Anticipated First Commercial

Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

- (a) the overall strategy for Commercializing Licensed Products in the Field in the applicable Reporting Country or the Region, as applicable, including Licensed Product branding, positioning, promotional materials, core messages, pricing strategies and competitive analyses;
- (b) the Country/Region PDGF Commercialization Budget;
- (c) anticipated launch dates for the Licensed Product in the Field in the applicable Reporting Country or the Region, as applicable;
- (d) market and sales forecasts for the Licensed Products in the Field in the applicable Reporting Country or the Region, as applicable, in a form to be agreed between the Parties;
- (e) strategies for the detailing and promotion of Licensed Products in the Field in the applicable Reporting Country or the Region, as applicable, including sales force and medical affairs field force sizes, the number and type of Licensed Product details to be performed by Company sales representatives and target opinion leaders in the applicable Reporting Country or the Region, as applicable;
- (f) FTE requirements and Shared Promotion Expenses to fulfill the requirements of the Country/Region PDGF Commercialization Plan;
- (g) advertising, patient advocacy programs, professional symposia, public relations, marketing, sales and promotion efforts for Licensed Products in the Field in the applicable Reporting Country or the Region, as applicable;
- (h) reimbursement and patient assistance, [\*\*\*\*\*]; and
- (i) Non-Approval Trials (based on JDC approved protocols), [\*\*\*\*\*] in support of the Licensed Products in the Field in the applicable Reporting Country.

7.4 HQ Plan and HQ Budget. At least [\*\*\*\*\*] prior to the Parties' mutually agreeing that Company shall incur any Company HQ Costs and/or Regeneron shall incur any Regeneron HQ Costs, the JCC and JFC shall prepare and the JSC shall review and approve the initial HQ Plan and an initial budget for the Company HQ Unit and the Regeneron HQ Unit for the first Contract Year in which such expenses and costs are to be incurred, which budget shall include, in reasonable detail, the Company HQ Costs, the Regeneron HQ Costs, and the number of FTEs to be utilized by the Company HQ Unit and the Regeneron HQ Unit, as applicable, in connection with the Commercialization of Licensed Products in the Field across the Territory (and to the extent agreed by Regeneron, globally) (such budget, the "HQ Budget"), which budget

shall, unless otherwise agreed by the Parties, remain fixed throughout such Contract Year. The Parties agree that the costs and expenses in the HQ Budget shall be explicitly allocated by the JCC and JFC as either Territory-specific costs and expenses or global costs and expenses. To the extent the Company HQ Costs and/or the Regeneron HQ Costs are (a) allocated to the Territory pursuant to the HQ Budget, such costs shall be considered Shared Promotion Expenses and shall be shared by the Parties pursuant to Section I of Schedule 2 and (b) allocated globally pursuant to the HQ Budget, such costs shall be considered Global HQ Costs and shall be shared by the Parties pursuant to Section III of Schedule 2. The HQ Plan and HQ Budget for each subsequent Contract Year shall be updated by the JCC and JFC and approved by the JSC at least two (2) months prior to the end of the then current Contract Year.

#### 7.5 Commercialization Activities; Sharing of Commercial Information.

(a) Company (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory and shall do so in accordance with the Territory PDGF Commercialization Plan and the Country/Region PDGF Commercialization Plans. Without limiting the foregoing, Company will, as necessary, build, train and apply a field force in the Territory necessary to Commercialize the Licensed Products in the Field in the Territory in accordance with the Territory PDGF Commercialization Plan and Country/Region PDGF Commercialization Plans.

(b) Company shall use reasonable efforts to provide Regeneron with full access to Company information directly relating to the Commercialization of the Licensed Products in the Field in the Territory, including, without limitation, information relating to anticipated launch dates, the development of sales targets by customer segment and territory, key market metrics, market research, sales forecasting and modeling, sales, prescription and patient data, reimbursement and pricing matters, and field force plans, goals, incentives and training.

(c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information from the Territory or the Excluded Territory, as the case may be.

(d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.

7.6 Pricing and Pricing Approvals in the Territory. [\*\*\*\*\*]. For the avoidance of doubt, Regeneron shall have sole authority for determining and establishing the price and terms of sale (including any rebates or discounts) of Licensed Products in the Excluded Territory.

7.7 Sales and Distribution in the Territory; Other Responsibilities. Company (or its Affiliate) shall invoice and book, and appropriately record, all sales of

the Licensed Products in the Field in the Territory. Company (or its Affiliate) also shall be responsible for (a) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates that are due and owing with respect to the Licensed Products in the Field in the Territory, (b) handling all returns of Licensed Product sold in the Field in the Territory under this Agreement and (c) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory. If Licensed Product sold in the Field in the Territory is returned to Regeneron, it shall promptly be shipped to a facility designated by Company. If Licensed Product sold in the Excluded Territory is returned to Company, it shall promptly be shipped to a facility designated by Regeneron. If Regeneron receives an order for Licensed Product in the Field in the Territory (or Company receives an order for Licensed Product in the Field in the Excluded Territory), the Party erroneously receiving the order shall refer such orders to the other Party.

7.8 Commercialization Efforts. Company's sales representatives in the Territory shall provide the FTE effort and promote and detail the Licensed Products in the Field in accordance with the approved Country/Region PDGF Commercialization Plan (if applicable), Territory PDGF Commercialization Plan and all applicable Laws. Company shall, at its own expense, comply with the training plan contained in any Country/Region PDGF Commercialization Plan. Beginning in the Quarter of the First Commercial Sale of the first Licensed Product in each Reporting Country, Company will provide Regeneron on a quarterly basis with reports of the activity within its field force in each such Reporting Country, which will include reasonable data from reports created by Company for its internal management purposes. Company (through its local Affiliates where appropriate) shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the determination of Sales Force Cost and Medical Affairs Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

7.9 Contract Sales Force. Company shall not use the services of a sales representative employed by a Third Party without Regeneron's prior written consent. Company will be responsible for (a) all costs associated with retaining any such contract sales force in excess of the expected Sales Force Cost if Company provided its own field force and for such Third Party's compliance with this Agreement, (b) ensuring such contract sales force's compliance with all applicable Laws and (c) ensuring that sales representatives in such contract sales force have minimum skill levels customary for sales representatives in the Field at major pharmaceutical companies in such country.

7.10 Promotional Materials.

(a) Company will be responsible, consistent with the Marketing Guidelines, the Territory PDGF Commercialization Plan and the Country/Region PDGF Commercialization Plans (as applicable), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities for Licensed Products in the



Field in the Territory. Upon request, Regeneron 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 Company for use in the Territory. Without limiting the provisions of Section 12.6, Company shall use its own corporate name and/or logo on Promotional Materials and Licensed Product labels in connection with Commercialization of Licensed Products in the Field in the Territory, unless otherwise mutually agreed by the Parties.

(b) The Parties shall jointly own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.

7.11 Promotional Claims/Compliance. Neither Company nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any 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), Company and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.

7.12 Restriction on Bundling in the Territory. If Company or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Company agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any such Licensed Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates or Sublicensees, as applicable, to such customer or (b) is inconsistent with the Collaboration Purpose.

7.13 Inventory Management. Company shall use Commercially Reasonable Efforts to manage, or cause to be managed, Licensed Product inventory on-hand at wholesalers or Sublicensees (or Affiliates) 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.

7.14 Medical and Consumer Inquiries. Company shall be responsible for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Licensed Products in the Field in the Territory. The Parties will work together to formulate responses to any such major medical or consumer inquiries, including any inquiry relating to EYLEA (whether as part of a Combination PDGF Product that is a Licensed Product or as a standalone product), which shall be used, if possible, by Company in the Territory and Regeneron in the Excluded Territory. If Regeneron receives questions about Licensed Products in the Field in a country in the Territory, it shall refer such questions to Company, and Company shall be responsible for responding thereto. If Company receives questions about Licensed Products in the Field in a country in the Excluded Territory (or about any Licensed

Product outside the Field), it shall refer such questions to Regeneron, and Regeneron shall be responsible for responding thereto.

7.15 Market Exclusivity Extensions. Subject to the provisions of Article XIV, 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 or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Licensed Product in the Field may be marketed in such country.

7.16 Post Marketing Clinical Trials. Subject to the provision of this Agreement, the Parties shall comply with any clinical trial obligations with respect to a Marketing Approval with respect to any use of a Licensed Product in the Field in any country in the Territory imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

7.17 Non-Compete; Activities Outside the Collaboration.

(a) Activities Outside the Collaboration. During the Term, except as set forth in this Agreement, neither a Party nor any of its Affiliates, either alone or through any Third Party, shall develop, commercialize or otherwise Exploit [\*\*\*\*\*]; *provided* that either Party can develop, commercialize or otherwise Exploit any [\*\*\*\*\*]. For the avoidance of doubt, except with respect to the license grants set forth in Article V, nothing in the preceding sentence or elsewhere in this Agreement shall limit or restrict either Party's right [\*\*\*\*\*], including, without limitation, Regeneron's and Aventis' activities under the Aventis Agreement or either Party's activities under the EYLEA Agreement.

(b) Non-Compete.

(i) In the event that (A) Regeneron terminates this Agreement pursuant to Sections 20.2, 20.3, 20.5, 20.7 or 21.18 or (B) this Agreement terminates pursuant to Sections 20.4, 20.6 (other than for Company's termination of the EYLEA Agreement pursuant to Section 19.3 or 19.4 of the EYLEA Agreement) or 20.7, then during the period (the "Company Non-Compete Period") until the earlier of (1) [\*\*\*\*\*] and (2) [\*\*\*\*\*], its Affiliates or Sublicensees in the Field in the Territory, Company (and its Affiliates or Sublicensees) shall not, directly or indirectly, commercialize any [\*\*\*\*\*], or develop or manufacture any [\*\*\*\*\*] for commercialization in the Field in the Territory; *provided* that either Party can develop, commercialize or otherwise Exploit any [\*\*\*\*\*].

(ii) In the event that (A) Regeneron exercises the Regeneron Opt-Out Exercise pursuant to Section 2.5(c) and Company

exercises its Opt-In Right pursuant to Section 2.7(c) or (B) Company terminates this Agreement pursuant to Section 20.2 or Section 20.3 or (C) this Agreement terminates pursuant to Section 20.6 for Company's termination of the EYLEA Agreement pursuant to Section 19.3 or 19.4 of the EYLEA Agreement, then during the period (the "Regeneron Non-Compete Period") until the earlier of (1) [\*\*\*\*\*] and (2) [\*\*\*\*\*], Regeneron (and its Affiliates or Sublicensees) shall not, directly or indirectly, commercialize [\*\*\*\*\*], or develop or manufacture any [\*\*\*\*\*] for commercialization in the Field in the Territory, other than [\*\*\*\*\*] as to which, as of the date notice of such termination is received by Regeneron, Regeneron has ownership of, or a license to; *provided* that either Party can develop, commercialize or otherwise Exploit any [\*\*\*\*\*].

(iii) Without limiting the foregoing, in the event that a PDGF Product is no longer being developed, manufactured or commercialized by or on behalf of a Party, its Affiliates or Sublicensees in the Field in the Territory, such Party shall, during any period in which the restrictions of this Section 7.17 remain in effect with respect to the other Party, provide written notice thereof to the other Party.

(c) A Party (the "Affected Party") shall not be considered in breach of this Section 7.17 solely by reason of (i) the acquisition by such Party of a Person with a Competing PDGF Product in the Field in the Territory or the acquisition of such Party by a Person with a Competing PDGF Product in the Field in the Territory or (ii) the determination by such Party that one of its or its Affiliates' internal product candidates would otherwise constitute a Competing PDGF Product in the Field or the acquisition by such Party or its Affiliate of rights to a product that would otherwise constitute a Competing PDGF Product in the Field from a Third Party, in each case ((i) and (ii)), (A) with respect to Regeneron as the Affected Party, if Regeneron makes available and the Parties agree to include the offending Competing PDGF Product(s) in the licenses granted to Company pursuant to this Agreement and (B) with respect to Company as the Affected Party, if Company makes available and the Parties agree to include the offending Competing PDGF Product(s) in the Collaboration on the same terms as if such Competing PDGF Product(s) were a Licensed Product(s) and as if Company had the rights and obligations of Regeneron hereunder with respect thereto and Regeneron had the rights and obligations of Company hereunder with respect thereto, or (C) if prior to the closing of such acquisition (or as of the date such Party makes a determination as to an internal product candidate), the Affected Party commits in writing to the other Party that, promptly following the closing of such acquisition (or the date such Party makes a determination as to an internal product candidate), it will divest itself of the offending rights and/or activity, and the Affected Party uses Commercially Reasonable Efforts to pursue such divestiture, and in the event that such divestiture is not completed within six (6) months of the closing of such acquisition, the Affected Party ceases all development, manufacturing and/or commercialization, as applicable, of the

offending Competing PDGF Product(s) in the Field or includes the offending Competing PDGF Product(s) in the licenses granted to the other Party pursuant to this Agreement.

7.18 Restriction on Commercialization Activities. Company agrees that it shall refrain from pursuing a policy of directly or indirectly selling, advertising, promoting or marketing [\*\*\*\*\*], and, in particular, engaging in any advertising, promoting or marketing of [\*\*\*\*\*]. Without limiting the foregoing, it is agreed that the Parties shall use Commercially Reasonable Efforts to [\*\*\*\*\*] and each Party shall use Commercially Reasonable Efforts to [\*\*\*\*\*]. Company further agrees that it shall refrain from pursuing a policy of directly or indirectly selling, advertising, promoting or marketing Licensed Products that it is Commercializing hereunder in the Field in the Territory for sale in the Excluded Territory. Each Party will use reasonable efforts to prevent the unauthorized importation of Licensed Products into the Territory or Excluded Territory, as the case may be.

7.19 Exports from the Territory to the Excluded Territory.

(a) Company shall supply the [\*\*\*\*\*] with Licensed Products in quantities that are appropriate to the size of such market (not including cross-border sales).

(b) The Parties shall discuss, as appropriate from time to time, through their respective representatives on the JSC, any concerns either Party may have with respect to the entry of Licensed Products into the Excluded Territory from the Territory, including [\*\*\*\*\*] (“Parallel Trade Concern”).

(c) No later than ninety (90) days after Regeneron raises a Parallel Trade Concern, the Parties hereby agree to negotiate in good faith to determine a method for the calculation of [\*\*\*\*\*] (the “Parallel Unit Sales”). Such Parallel Unit Sales shall be determined based on available data, as agreed by the Parties, measuring [\*\*\*\*\*]. Out-of-Pocket Costs associated with obtaining the data required to meet Company’s obligations under this Section 7.19 shall be treated as Shared Promotion Expenses.

(d) Within fifteen (15) days after the end of any Contract Year in which Regeneron raises a Parallel Trade Concern, Company shall provide a detailed written report, which shall include copies of all data used to generate such report (the “Parallel Trade Report”), to Regeneron. The Parallel Trade Report shall show the amount of Parallel Unit Sales of Licensed Products on a unit basis for each Licensed Product from Canada and/or Mexico into the Excluded Territory for the preceding Contract Year. The Parallel Trade Report shall [\*\*\*\*\*].

(e) Promptly following delivery of the Parallel Trade Report, the Parties will meet and make a good faith effort to agree upon [\*\*\*\*\*].

(f) Notwithstanding anything to the contrary contained herein, nothing contained in this Section 7.19 shall require any Party to take actions inconsistent with applicable Law.

## **ARTICLE VIII CLINICAL AND REGULATORY AFFAIRS**

### **8.1 Ownership of Approvals and Registration Filings.**

(a) Regeneron shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Development of Licensed Products in the Field in the Excluded Territory under the Global PDGF Development Plan and (ii) with respect to its manufacturing facilities anywhere in the world (including with respect to any applicable site license and the drug master file for the Licensed Products), and shall have the rights and obligations set forth in this Article VIII with respect thereto.

(b) During the Term, Company shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Licensed Products in the Field in each country in the Territory and (ii) with respect to its manufacturing facilities anywhere in the world (including with respect to any applicable site license), and shall have the rights and obligations set forth in this Article VIII with respect thereto.

(c) The Lead Regulatory Party shall, as reasonably necessary to permit the other Party to perform its obligations or exercise its rights under this Agreement, license, transfer, provide a letter of reference with respect to or take such other action as is necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

(d) The Lead Regulatory Party (as defined in the EYLEA Agreement) shall, as reasonably necessary to permit the other Party to perform its obligations or exercise its rights under this Agreement, license, transfer, provide a letter of reference with respect to or take such other action as is reasonably necessary to make available the EYLEA Regulatory Documentation to and for the benefit of the other Party.

### **8.2 Regulatory Coordination.**

(a) Under the direction and supervision of the Working Group, the Lead Regulatory Party shall oversee, monitor and coordinate all regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to the 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 VIII. 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 the Licensed Products 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 with respect to Licensed Products and EYLEA to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the development, manufacture and/or commercialization of the Licensed Products and EYLEA (pursuant to the EYLEA Agreement) in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities, (ii) to comply with Laws in connection with the development, manufacture and/or commercialization of the Licensed Products and EYLEA (pursuant to the EYLEA Agreement) in the Field anywhere in the world, including the Excluded Territory, and (iii) to comply with Laws with respect to the development, manufacture and/or commercialization of PDGF Products and EYLEA (pursuant to the EYLEA Agreement) outside the Field. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product or EYLEA (pursuant to the EYLEA Agreement) 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 Licensed Products in the Field in the Territory (including with respect to any regulatory strategies, material regulatory actions, communications and Regulatory Filings under the EYLEA Agreement with respect to EYLEA), and, subject to Section 3.6, with respect to the same in the Excluded Territory to the extent that such strategies, actions, and/or communications would reasonably be expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Field in the Territory.

(c) Subject to Sections 3.6 and 8.2(e), 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 in each case ((i), (ii) and (iii)) that directly pertain to the Development and/or Commercialization of a 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, without limitation, all annual and periodic safety reports for Licensed Products in the Field). Moreover, the Lead Regulatory Party shall consider in good faith requests from the other Party to have up to two (2) representatives from the other Party attend (but not participate in) all material, pre-scheduled meetings, telephone conferences and/or discussions with the Regulatory Authorities in the Territory or, to the extent such material meetings, telephone conferences and/or discussions pertain to the activities under the Global PDGF Development Plan, the Excluded Territory. 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 the avoidance of doubt, nothing in this Section 8.2 entitles Company to attend meetings with Regulatory Authorities in the Excluded Territory or review Registration Filings in connection with the Development of Licensed Products in the Excluded Territory, except as they relate to the performance of the Global PDGF Development Plan. Subject to its obligations hereunder, Regeneron, in its sole discretion, shall have the exclusive right (i) to seek and obtain all Registration Filings and Approvals with respect to the commercialization of Licensed Products in the Excluded Territory, (ii) to decide the final content of, and to prepare and submit, any Registration Filings for Marketing Approval for a Licensed Product in the Excluded Territory and (iii) to make any submissions or conduct any meetings or discussions with Regulatory Authorities in the Excluded Territory concerning Marketing Approval for a Licensed Product.

(e) [\*\*\*\*\*].

8.3 Regulatory Coordination with Third Parties. Company acknowledges and agrees that Regeneron has secured certain rights under the Aventis Agreement (a) to allow Company and its Affiliates to reference the filings, registrations, licenses and authorizations from or with any Regulatory Authority in connection with Regeneron's and Aventis' development, manufacture or commercialization of Regeneron VEGF Products outside the Field to support the development, manufacture or commercialization of Licensed Products (as defined in the EYLEA Agreement) in the Field in the Territory under the EYLEA Agreement and (b) to coordinate the exchange of information (including, without limitation, information pertaining to pharmacovigilance, development, manufacture and commercialization) related to Licensed Products (as defined in the EYLEA Agreement) inside and outside the Field between Regeneron, Company and Aventis (or any other Third Party licensee of Regeneron engaged in the development, manufacture or commercialization of Licensed Products (as defined in the EYLEA Agreement) outside the Field) in order to ensure compliance with applicable Laws. Regeneron shall use Commercially Reasonable Efforts under the Aventis Agreement to extend to Company substantially similar rights with respect to Licensed Products that contain Aflibercept under this Agreement as those rights identified in the previous sentence. It is agreed that Regeneron and its Affiliates and licensees of PDGF Products and Regeneron VEGF Products outside the Field (including, without limitation, Aventis) or outside the Territory shall have the right to reference the Registration Filings and/or Approvals of the Parties for the Licensed Products and EYLEA to support Regeneron's or its Affiliates' or such licensees' development, manufacture or

commercialization of PDGF Products and EYLEA (pursuant to the EYLEA Agreement) and/or Regeneron VEGF Products outside the Field or outside the Territory. Company and Regeneron shall work in good faith to coordinate the exchange of information (including, without limitation, pharmacovigilance information) related to PDGF Products, EYLEA and/or Regeneron VEGF Products inside and outside the Field (and inside and outside the Territory) between Regeneron, Company and Aventis (or any other Third Party licensee of a Party engaged in the development, manufacture or commercialization of PDGF Products or EYLEA (pursuant to the EYLEA Agreement) or Regeneron VEGF Products outside the Field or outside the Territory) in order to ensure compliance with applicable Laws. As between the Parties, Regeneron shall have the exclusive right to communicate with Regulatory Authorities with respect to Licensed Products outside the Field and, subject to Section 3.6, in the Excluded Territory.

8.4 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 that it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority in the Territory or Excluded Territory, that:

(a) raises any material concerns regarding the safety or efficacy of any 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 a Licensed Product in the Field under the Plans; *provided, however*, 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 Licensed Product in the Field in the Territory.

Information that shall be disclosed pursuant to this Section 8.4 shall include, but not be limited to:

(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 8.4;

(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 Licensed Product tampering, contamination, or mix-up (*e.g.*, wrong ingredients).

8.5 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints for its territory and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning drug safety surveillance and product complaint reporting in all countries in which the Licensed Products (both in the Field and out of the Field) and/or EYLEA are being developed, manufactured, or commercialized in the Territory or in the Excluded Territory. Without limitation to the foregoing, the Parties shall within ninety (90) days of the Opt-In Effective Date execute a Pharmacovigilance Agreement setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse drug experiences and product complaints with respect to Licensed Product and/or EYLEA to ensure timely communication to Regulatory Authorities and compliance with Laws.

8.6 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a 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 a 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 relate to or may be reasonably expected to adversely impact the 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 Licensed Products for use in the Field under this Agreement; *provided* that, to the extent feasible, such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.

8.7 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any 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 or delayed; *provided, however*, that nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action required by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a 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. Except to the extent any such recall, market withdrawal or other corrective action is due to a Party's fraud, gross negligence or willful misconduct, expenses associated with such recalls will be treated as Other Shared Expenses. For clarity, any expenses associated with a recall, market withdrawal or other corrective action due to a Party's fraud, gross negligence or willful misconduct shall not be treated as Other Shared Expenses and shall be the responsibility of the Party causing such recall, market withdrawal or other corrective action.

## **ARTICLE IX MANUFACTURING AND SUPPLY**

9.1 Formulated Bulk Product Supply in the Field in the Territory. Regeneron or its Affiliates will use Commercially Reasonable Efforts to provide an adequate and timely supply of any Formulated Bulk Product for Clinical Supply Requirements and Commercial Supply Requirements of Licensed Product in the Field in the Territory in accordance with the applicable Manufacturing Plan. Regeneron or its Affiliates may use its Manufacturing facilities or, subject to Company's prior written approval, such approval not to be unreasonably withheld or delayed, Company or Third Parties to Manufacture any Formulated Bulk Product. [\*\*\*\*\*] Any Formulated Bulk Product Manufactured by or on behalf of Regeneron or its Affiliates will be charged by Regeneron or its Affiliates at the Manufacturing Cost as a Clinical Supply Cost (for Clinical Supply Requirements) or Commercial Supply Cost (for Commercial Supply Requirements), as the case may be, in accordance with Schedule 1 and Schedule 2, or as otherwise agreed by the Parties.

9.2 Finished Product Supply in the Field in the Territory. The Parties, through the JSC, will identify which Party or Third Party will perform the filling, packaging, labeling and testing of the Formulated Bulk Product to supply Finished Product for Clinical Supply Requirements and Commercial Supply Requirements for use in the Field in the Territory under this Agreement. The Finished Product Manufactured by or on behalf of a Party or its Affiliates will be charged by such Party or its Affiliates at the Manufacturing Cost as a Clinical Supply Cost (for Clinical Supply Requirements) in

accordance with Schedule 1 or Commercial Supply Cost or COGS (for Commercial Supply Requirements) in accordance with Schedule 2, as the case may be.

9.3 Supply Agreement. Within six (6) months after the Opt-In Effective Date, the Parties shall 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 [\*\*\*\*\*] prior to the Anticipated First Commercial Sale of the first Licensed Product in the Territory, the Parties (or their Affiliates) 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 of such Licensed Product, in a form substantially consistent with the EYLEA Commercial Supply 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.

9.4 Manufacturing Plans. The Parties (or their Affiliates), through the JSC, will develop and update as necessary on an annual basis, the Licensed Product Manufacturing plan (the initial plan and each such updated plan, a "Manufacturing Plan") providing for the Manufacturing (including testing and specifications), distribution, and forecasting of Clinical Supply Requirements under the Development Plans and Commercial Supply Requirements under the Territory PDGF Commercialization Plan, including, if applicable, the choice of Third Party manufacturers, fillers, packagers, and labelers. Notwithstanding the foregoing, Regeneron or its Affiliates will have the right to make all decisions with respect to Manufacturing Formulated Bulk Product for Licensed Products, subject to Company's prior written approval, such approval not to be unreasonably withheld or delayed. Each Manufacturing Plan shall be updated, reviewed and approved by the Parties, through the JSC, on an annual basis and shall set forth the Licensed Product requirements over an ensuing period of at least three (3) Contract Years. Each Manufacturing Plan shall be approved by the JSC at least [\*\*\*\*\*], except that the initial Manufacturing Plan shall be approved by the JSC within [\*\*\*\*\*]. Each Manufacturing Plan will include [\*\*\*\*\*] The Parties shall design Manufacturing Plans to ensure an adequate supply of Licensed Product and shall use Commercially Reasonable Efforts to perform their responsibilities in accordance with the approved Manufacturing Plans.

9.5 Manufacturing Shortfall. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it or its Affiliates will not be able to supply the agreed upon demand forecast for the Licensed Products set forth in a Manufacturing Plan. Upon such notification, the matter will be referred to the JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product should be utilized. In case of Finished Product or Formulated Bulk Product shortages, available supplies will be allocated as

between the Parties on a pro rata basis based on their forecasted requirements for Licensed Product in the Field in the Territory and the Excluded Territory over the relevant period; [\*\*\*\*\*]. Notwithstanding the foregoing, Company shall maintain an appropriate level of safety stock of Formulated Bulk Product and Finished Product. Company shall exert Commercially Reasonable Efforts to maintain the following target safety stocks based on Company's most recent Territory or applicable country forecast reviewed with Regeneron or the Joint Commercialization Committee: [\*\*\*\*\*]. The safety stock in other countries shall be determined by Company (and reviewed with Regeneron) and shall be commensurate with the level of safety stock necessary to assure uninterrupted supply of Finished Product in the relevant country.

9.6 Manufacturing Compliance. Each Party and its Affiliates will use diligent efforts to Manufacture Formulated Bulk Product and Finished Product supplied under this Article IX 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 or delayed, for any Manufacturing changes for any Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party and its Affiliates shall have the right to conduct inspections and audits of the other Party's or its Affiliates' facilities involved in the Manufacture of 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 and its Affiliates will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Aventis, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

## **ARTICLE X PERIODIC REPORTS; PAYMENTS**

10.1 Upfront Payment, Milestone Payments, Opt-In Payment, Aventis Royalties. In consideration of the rights granted to Company with respect to the Opt-In Right under Article II, Company shall be required to make the following payments to Regeneron:

(a) Upfront Payment. Within ten (10) Business Days from the receipt of an invoice from Regeneron on or after the Effective Date, Company shall pay to Regeneron the non-refundable, non-creditable amount of Twenty-Five Million Five Hundred Thousand U.S. Dollars (US \$25,500,000) (which shall not, subject to Section 21.9, be reduced by any withholding or similar taxes).

(b) Regeneron Development Milestone Payment. Company shall pay to Regeneron the non-refundable, non-creditable milestone payment set forth in Section I of Schedule 3 (such payment, the “Regeneron Development Milestone Payment”) within ten (10) Business Days from the receipt of an invoice from Regeneron related to the achievement of the Regeneron Development Milestone, which shall not, subject to Section 21.9, be reduced by any withholding or similar taxes.

(c) Aventis Development Milestone Payments. Company shall pay its applicable share of each Aventis Development Milestone Payment as set forth in Section 2.1 to Regeneron within ten (10) Business Days from the receipt of an invoice from Regeneron related to the achievement of the applicable Aventis Development Milestone, which, in each case, shall be non-refundable and non-creditable and shall not, subject, however, to Section 21.9, be reduced by any withholding or similar taxes.

(d) Opt-In Payment; Supplemental Option Payment; Additional Antibody Payment.

(i) In the event that Company elects to exercise its Opt-In Right pursuant to Section 2.7, Company shall make a non-refundable, non-creditable payment to Regeneron of US \$20,000,000 (such payment, the “Opt-In Payment”) pursuant to Section 2.7, which payment shall be made in accordance with Sections 10.7 and 10.8 and shall not, subject to Section 21.9, be reduced by any withholding or similar taxes.

(ii) In the event that Regeneron incurs Additional Development Costs, then following (A) the Parties’ agreement to amend the Initial Development Plan and Initial Development Budget to include an additional Phase 2 Trial pursuant to Section 2.7(b) or (B) Company’s exercise of its Opt-In Right, Regeneron shall issue an invoice to Company for the Supplemental Option Payment following such agreement to amend the Initial Development Plan and Initial Development Budget or Company’s exercise of its Opt-In Right, and Company shall pay to Regeneron the Supplemental Option Payment within ten (10) days of receipt of such invoice from Regeneron, subject to the terms of Sections 10.7, 10.8, 10.9 and 10.10.

(iii) In the event that Company exercises its Opt-In Right and elects to acquire rights to Additional PDGF Receptor Antibodies pursuant to Section 2.6, Regeneron shall issue an invoice to Company for the Additional Antibody Payment following Company’s exercise of its Opt-In Right, and Company shall pay to Regeneron the Additional Antibody Payment within ten (10) days of receipt of such invoice from Regeneron, subject to the terms of Sections 10.7, 10.8, 10.9 and 10.10. For clarity, the payment of the Additional Antibody Payment (and the Supplemental Option Payment, if applicable) shall be payable pursuant to

this Section 10.1 and shall not be subject to the Quarterly True-Up mechanism set forth in Article X and Schedule 2.

(e) Aventis Royalties. Following the Opt-In Effective Date, Company shall pay to Regeneron the Aventis Royalties (as described in Section III of Schedule 3) due with respect to a given Quarter during the PDGF Royalty Term within forty-five (45) days after the end of such Quarter for so long as Regeneron is obligated to pay such Aventis Royalties to Aventis under the Aventis Letter Agreement. Each payment of Aventis Royalties due to Regeneron shall be accompanied by a report specifying, on a Licensed Product-by-Licensed Product and country-by-country basis, any information necessary to calculate the Aventis Royalties or which Regeneron is required to report to Aventis under the Aventis Letter Agreement, including, without limitation, (i) the total gross invoiced amount from sales of each Licensed Product, (ii) all relevant deductions from gross invoiced amounts to calculate Net Sales (as defined in the Aventis Letter Agreement), (iii) the amount of Net Sales (as defined in the Aventis Letter Agreement) in local currency and United States Dollars and (iv) the Aventis Royalties payable for such Quarter, in each case ((i) - (iv)), as set forth in the Aventis Letter Agreement (each such report, an "Aventis Royalty Report"). Without limiting the generality of the foregoing, Company shall require its Affiliates and Sublicensees to account for their Net Sales and to provide such reports with respect thereto, as if such sales were made by Company.

## 10.2 Development Costs.

### (a) Initial Development Plan.

(i) Company shall be responsible for reimbursing Regeneron for (A) twenty-five percent (25%) of all Development Costs incurred under the Initial Development Plan and the Initial Development Budget, as each may be amended, that are not specific to the Territory and (B) fifty percent (50%) of all Development Costs incurred under the Initial Development Plan and the Initial Development Budget, as each may be amended, that are specific to the Territory; *provided; however*, in the event Company exercises the Company Opt-Out Exercise pursuant to Section 2.9, Company shall only be responsible for further payments of Development Costs and wind-down costs to the extent provided in Section 2.9.

(ii) In the event Company exercises the Company Opt-In Right pursuant Section 2.7(c) following Regeneron's exercise of the Regeneron Opt-Out Exercise, Regeneron shall only be responsible for further payments of Development Costs and wind-down costs to the extent provided in Section 2.8(b).

(iii) Regeneron shall issue an invoice to Company within twenty (20) days after the end of each Quarter for Company's applicable share of the Development Costs incurred under the Initial

Development Plan and/or wind-down costs, as applicable, for such Quarter, and Company shall pay to Regeneron its share of such Development Costs and/or wind-down costs, as applicable, within ten (10) days of receipt of such invoice from Regeneron, subject to the terms of Sections 10.7, 10.8, 10.9 and 10.10.

(iv) Without limiting the foregoing, Company shall pay to Regeneron pursuant to Section 10.1 its applicable share of all Aventis Development Milestone Payments when and as such payments become due.

(v) For clarity, the Development Costs incurred under the Initial Development Plan (and the associated Initial Development Budget) include Development Costs incurred by Regeneron thereunder beginning on January 1, 2014.

(b) Global PDGF Development Plan. Commencing on the Opt-In Effective Date and continuing during the Term, (i) Company shall be responsible for paying twenty-five percent (25%) of all Development Costs incurred under the Global PDGF Development Plan and (ii) Regeneron shall be responsible for paying seventy-five percent (75%) of all Development Costs incurred under the Global PDGF Development Plan, in each case ((i) and (ii)), by or on behalf of Company, Regeneron and their respective Affiliates in accordance with Schedule 2 and the other terms of this Agreement. Company shall also provide Development Cost reporting under the Global PDGF Development Plan in United States Dollars and, if applicable and to the extent available and generated by Company's and its Affiliates' internal reporting systems, local currency.

(c) Territory PDGF Development Plan. Commencing on the Opt-In Effective Date and continuing during the Term, each of Company and Regeneron shall be responsible for paying fifty percent (50%) of all Development Costs incurred under the Territory PDGF Development Plan by or on behalf of Company, Regeneron and their respective Affiliates in accordance with Schedule 2 and the other terms of this Agreement. Company shall also provide Development Cost reporting under the Territory PDGF Development Plan in local currency and United States Dollars. For clarity, in the event that Regeneron elects to cease all development of a Licensed Product in the Field in the Excluded Territory pursuant to Section 2.7(a) or Section 3.6, all Development Costs incurred by the Parties (or their Affiliates) under the Territory PDGF Development Plan after the Opt-In Effective Date in Developing such Licensed Product in the Field under this Agreement shall be considered Territory-specific Development Costs and shall be shared equally by the Parties pursuant to this Section 10.2(c).

(d) Allocation. With respect to Section 10.2(b) and 10.2(c), each Party shall be responsible in the first instance for bearing any Development Costs incurred by it and such expenses shall be allocated between the Parties pursuant to the Global True-Up, except as otherwise may be agreed by the Parties.

10.3 Periodic Reports. Company 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 Section 6.5;
- (b) Prior to the end of each Quarter, Company shall deliver electronically to Regeneron in a format to be agreed upon by the Parties (i) a high-level forecast of the Territory Profit for that Quarter to the extent reasonably available and (ii) a quarterly forecast of the Territory Profit for the remaining Quarters of the Contract Year. This forecast will include for each Reporting Country, the Regions, and the Company HQ Unit, as applicable, a minimum of Net Sales, COGS, Shared Promotion Expenses, Other Shared Expenses, and Company HQ Costs in United States Dollars and, if applicable and to the extent available and generated by Company's and its Affiliates' internal reporting systems, for each Reporting Country in local currency.
- (c) Within twenty (20) days following the end of each month, Company shall deliver electronically to Regeneron (i) a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars and (ii) the monthly Net Sales reports that are generated by Company's and its Affiliates' internal reporting systems for each country in the Territory in local currency;
- (d) Within forty-five (45) days following the end of each Quarter, Company shall deliver electronically to Regeneron a written report setting forth, on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales in local currency and United States Dollars;
- (e) Within thirty (30) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses incurred by such Party in such Quarter, including whether any such expenses are also included in the reports delivered pursuant to clause (g) below;
- (f) Within forty-five (45) days following the end of each Quarter, Company shall provide to Regeneron, in electronic form, a Country PDGF Commercialization Report for each country in the Territory;
- (g) Within thirty (30) days following the end of each Quarter, each Party that has incurred any Shared Promotion Expenses in that Quarter either in a Reporting Country or by the Company HQ Unit or by the Regeneron HQ Unit, as applicable, shall deliver electronically to the other Party a preliminary written report setting forth in reasonable detail the Shared Promotion Expenses incurred by such Party



in such Quarter (including a detailed breakdown of the Commercial Overhead Charge included in Shared Promotion Expenses in a format agreed upon by the JFC and JCC) in United States Dollars for each such Reporting Country and Company HQ Unit or Regeneron HQ Unit, as applicable. Company shall also provide the reports that are generated by Company's or its Affiliates' internal reporting system of the Shared Promotion Expenses incurred by Company for each applicable Reporting Country or HQ Unit, as applicable, in local currency;

(h) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Shared Promotion Expenses (by Reporting Country, the Regions, the Company HQ Unit and the Regeneron HQ Unit) in that Quarter shall deliver electronically to the other Party a final written report setting forth in reasonable detail the Shared Promotion Expenses (including a detailed breakdown of the Commercial Overhead Charge included in Shared Promotion Expenses in a format agreed upon by the JFC and JCC) incurred by such Party in such Quarter in United States Dollars;

(i) Within thirty (30) days following the end of each Quarter, each Party that has incurred any Global HQ Costs in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Global HQ Costs incurred by such Party in such Quarter in local currency and United States Dollars;

(j) Within forty-five (45) days after the end of each Quarter, Company shall provide to Regeneron, in electronic form, an HQ Report;

(k) Within forty-five (45) days following the end of each Quarter, each Party (if applicable) shall deliver electronically to the other Party a written report setting forth Commercial Supply Costs incurred by such Party for such Quarter in United States Dollars and, if applicable, for each Reporting Country in local currency; and

(l) Within sixty (60) days following the end of each Quarter, Company shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to Section 6.5 and this Section 10.3 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 Section 10.4 and, if applicable, providing for the netting of such payments; and

(m) At least six (6) months prior to the end of the then current Contract Year, Company will provide Regeneron with a high-level five (5)-year forecast to the extent available for each Reporting Country, the Regions, and the Company HQ Unit, as applicable, of Net Sales, COGS, Shared Promotion Expenses, Other Shared Expenses, and Company HQ Costs in United States Dollars and, if applicable and to the

extent available and generated by Company's and its Affiliates' internal reporting systems, local currency.

All reports referred to in this Section 10.3 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars. For all financial reports described in clauses (f), (g), (h), (i) and (j) above, Company shall also provide written explanations of variances to any JSC approved Territory PDGF Commercialization Budget or Country/Region PDGF Commercialization Budget and latest reforecast.

#### 10.4 Quarterly True-Up Payments; Funds Flow.

(a) The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Company is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section 10.11, make such payment to Regeneron within ten (10) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section 10.11, make such payment to Company within ten (10) days after its receipt of such Consolidated Payment Report from Company. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Company shall pay Regeneron [\*\*\*\*\*] of the amount of license fees, royalties or other amounts payable under any Existing License or New License (to the extent attributable to the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party and provide such supporting documentation required by such Existing License and/or New License, as the case may be. For clarity, Company's payment of the [\*\*\*\*\*] (x) shall not be governed by the provisions of this Section 10.4, but rather, in the case of the [\*\*\*\*\*], shall be governed by the provisions of Section 10.1(c) and 10.1(e) respectively and (y) shall not be included as part of the Quarterly True-Up payments to be made by the Parties pursuant to this Article X and Schedule 2.

(b) Notwithstanding anything in this Agreement to the contrary, no cost, expense, amount or sum allocable or chargeable to the Parties' activities under this Agreement shall be allocated or charged more than once (whether, for example, chargeable as a Development Cost, Shared Promotion Expense, Commercial Overhead Charge, Company HQ Cost, or Regeneron HQ Cost or as a deduction for purposes of calculating Net Sales).

10.5 Payments Related to Commercialization of Licensed Products in Japan. Notwithstanding anything to the contrary in this Agreement, within thirty (30) days of the Effective Date, the Parties shall meet to discuss in good faith [\*\*\*\*\*]. In the event [\*\*\*\*\*].

10.6 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.

10.7 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. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon 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 Quarter to which such payment relates, as reported in *The Bloomberg Professional*, a service of Bloomberg LP, or in the event *The Bloomberg Professional* does not have data available for the Quarter, then in Thomson Reuters Eikon and by a method of conversion consistent with Company's customary and usual procedures used for currency conversion in its financial statements.

10.8 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 the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, plus [\*\*\*\*\*] (such sum being referred to as the "Default Interest Rate").

10.9 Taxes. Subject to Section 21.9, 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, however*, that the withholding Party shall promptly furnish to the other Party proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party 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, Company agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on Regeneron's behalf the benefit of any available Treaty on the Avoidance of Double Taxation that applies to any payments hereunder.

10.10 Adjustments to FTE Rates. Notwithstanding anything herein to the contrary, upon the request of either Party (such request to occur not more than once every three (3) years for any country), the Parties shall meet to review the accuracy of an applicable FTE rate in any country (*e.g.*, Sales Force FTE Rate, Medical Affairs FTE

Rate, Development FTE Rate, HQ 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.

10.11 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this Article X (other than, for clarity, an Audit Dispute), 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 referred to the JSC in accordance with Section 4.10(a). 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.

10.12 Development Budget Overruns. Except as otherwise set forth in Section 2.2(a), neither Party shall be required to pay any Development Costs for a Contract Year that are in excess of [\*\*\*\*\*] of the total amounts that are in the JSC approved Global PDGF Development Budget (or Territory PDGF Development Budget) for such Contract Year (as such budget may be adjusted to include any Non-Incurred Amounts from prior years pursuant to Section 6.4) ("Development Overruns"), unless such Development Overruns have been approved by both Parties' representatives on the JSC. Otherwise, the Party responsible for the Development activities that caused the overrun shall be responsible for bearing [\*\*\*\*\*] of the costs and expenses of such Development Overrun not otherwise approved by the JSC, or, if both Parties contributed toward the overrun, they shall bear those excess expenses in the same proportion as their contributions to the Development Overrun.

10.13 Commercialization Budget Overruns.

(a) Major Market Country / HQ Commercialization Overruns. Regeneron shall not be required to pay (i) any Shared Promotion Expenses with respect to any individual Major Market Country or the Company HQ Unit for a Contract Year that for such Major Market Country or the Company HQ Unit are in excess of [\*\*\*\*\*] of the total amounts that are in the JSC approved Territory PDGF Commercialization Budget (or Country PDGF Commercialization Budget) for such Major Market Country or the HQ Budget for the Company HQ Unit for such Contract Year; and (ii) any Shared Promotion Expenses with respect to the aggregate of all Major Market Countries plus the Company HQ Unit for a Contract Year that collectively are in excess of [\*\*\*\*\*] of the total amounts that are in the JSC approved Territory PDGF Commercialization Budget (and Country PDGF Commercialization Budget) for all the Major Market Countries and the HQ Budget for the Company HQ Unit for such Contract Year. Any Shared Promotion Expenses that are not paid pursuant to Section

10.13(a)(i) shall be excluded from the Shared Promotion Expenses used in calculating the limits set forth in Section 10.13(a)(ii).

(b) Region Commercialization Overruns. Regeneron shall not be required to pay (i) any Shared Promotion Expenses with respect to any individual Region that are in excess of [\*\*\*\*\*] of the total amounts that are in the JSC approved Country/Region PDGF Commercialization Budget for such individual Region for a Contract Year; and (ii) any Shared Promotion Expenses with respect to the aggregate of all Regions that collectively are in excess of [\*\*\*\*\*] of the total amounts that are in the JSC approved Country/Region PDGF Commercialization Budget for all the Regions collectively for a Contract Year. Any Shared Promotion Expenses that are not paid pursuant to Section 10.13(b)(i) shall be excluded from the Shared Promotion Expenses used in calculating the limits set forth in Section 10.13(b)(ii).

(c) Non-Incurred Amounts. In the event that, during any Contract Year, any Shared Promotion Expenses expressly provided for in the JSC approved Country/Region PDGF Commercialization Budget or HQ Budget to be incurred during such Contract Year are not incurred during such Contract Year, then such budgeted amounts not yet incurred shall be automatically included in the Country/Region PDGF Commercialization Budget or HQ Budget, as applicable, for such succeeding Contract Year(s) (as such budgets may be adjusted to include any budgeted amounts not yet incurred from prior Contract Years).

(d) Company Responsibility for Commercialization Overruns. Each such overrun described in clauses (a) and (b) above shall be considered a “Commercialization Overrun” and shall be the sole responsibility of Company, unless such Commercialization Overrun has been approved by both Parties’ representatives on the JSC.

(e) Development and Commercialization Overruns. Any such Development Overruns or Commercialization Overruns that are not approved by both Parties’ representatives on the JSC shall not be included in the calculation of the Regeneron Reimbursement Amount, Global True-Up, or Territory Profit Split, as applicable. For clarity, the Parties shall share, to the extent provided in this Agreement, Development Costs and Shared Promotion Expenses that are over the budgeted amounts in the Plans up to (but not including) the amounts otherwise triggering a Development Overrun or Commercialization Overrun, as applicable.

## **ARTICLE XI DISPUTE RESOLUTION**

11.1 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 to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

11.2 Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article IV (“Governance Disputes”) shall be resolved pursuant to Article IV and, to the extent any such Governance Dispute constitutes a Technical Development Matter or an Audit Dispute, pursuant to Section 11.4 (subject to, and without limitation of, the proviso in Section 4.10(a)(iii)), except to the extent any such Governance Dispute constitutes a Legal Dispute, in which event the provisions of Section 11.3 shall apply. For the avoidance of doubt, Legal Disputes arising under Section 20.2 hereof shall be governed under such section.

11.3 Legal Disputes. The Parties agree that, subject to Sections 11.5 and 17.4, they shall use 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. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days 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 the time period set forth in Section 4.10(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 21.1 and Section 21.15. For the avoidance of doubt, Legal Disputes arising under Section 20.2 hereof shall be governed under such section.

#### 11.4 Expert Panel

(a) In the event of a dispute between the Parties concerning a Technical Development Matter or an Audit Dispute that cannot be resolved by the Executive Officers pursuant to Section 4.10(b) (other than a Legal Dispute or any dispute concerning any proposed amendment to the Initial Development Plan or the Initial Global PDGF Development Plan), 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 11.4. 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. For disputes referred to the Expert Panel arising under Section 4.10(a)(iii), the Expert Panel in resolving the dispute shall balance the relative benefits and harm to each Party from the matter in dispute in connection with the applicable Licensed Product in the Territory and Excluded Territory. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.

(b) Within fifteen (15) days of the responding Party’s response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case

of an Audit Dispute, expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) 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 (iii) 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 (i) through (iii) 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.

(c) Within fifteen (15) days of the appointment of the second 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 expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) 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.

(d) Within seven (7) days of the appointment of the third 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 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.

(e) 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, however*, 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.

(f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.

11.5 No Waiver. Nothing in this Article XI 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 XII TRADEMARKS AND CORPORATE LOGOS**

12.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

12.2 Selection of Product Trademarks. [\*\*\*\*\*]. Each Licensed Product in the Field shall be promoted and sold in the Territory, and if applicable pursuant to Section 4.4(b)(i), in the Excluded Territory, under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

12.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 12.4 and 12.5, Company (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names, and all goodwill related thereto in all countries in the Territory. It is understood and agreed that Regeneron shall own and retain all right, title and interest in the Product Trademark(s) for Licensed Products, together with all associated domain names and all goodwill related thereto in the Excluded Territory.

12.4 Prosecution and Maintenance of Product Trademark(s). Company will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Company elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Regeneron shall have the right, but not the obligation, to assume the prosecution or maintenance of such Product Trademark(s) on behalf of Company for use



with Licensed Products, subject to consultation and cooperation with Company. All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Product Trademark(s) in the Territory shall be shared by the Parties as part of Other Shared Expenses.

12.5 License and Use of the Product Trademark(s) and EYLEA Trademark(s). Company hereby grants to Regeneron (1) a co-exclusive (with Company and its Affiliates) sublicensable license to use the Product Trademark(s) and (2) a non-exclusive sublicensable license to use the EYLEA Trademark(s), both licenses for use in the Territory for the Licensed Products solely for the purposes of Regeneron's (a) Development and Manufacturing, and (b) if agreed to by Company or set forth in any Plans, Commercialization activities pursuant to this Agreement and subject to the terms and conditions of this Agreement. Regeneron shall utilize the Product Trademark(s) and/or EYLEA Trademark(s), if applicable, only on approved Promotional Materials or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Regeneron or its Affiliates or Sublicensees of the Product Trademark(s) and/or EYLEA Trademark(s), if applicable, 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). Regeneron 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) and/or EYLEA Trademark(s), if applicable, or take any other action that damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s) and/or EYLEA Trademark(s), if applicable, in each case, in the Territory. Company shall utilize the Product Trademark(s) and/or EYLEA Trademark(s), if applicable, only on approved Promotional Materials or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Company or its Affiliates or Sublicensees of the Product Trademark(s) and/or EYLEA Trademark(s), if applicable, 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). Company 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) and/or EYLEA Trademark(s), if applicable, or take any other action that damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s) and/or EYLEA Trademark(s), if applicable, in the Territory or the Excluded Territory. Each Party shall be entitled to use the EYLEA Trademarks (1) in any manner as specified in the EYLEA Agreement except as otherwise expressly provided in this Agreement and (2) in connection with the Licensed Products for the Development, Manufacturing and Commercialization of Licensed Products in the Field in the Territory as specified in this Agreement. 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 12.5.

12.6 Use of Corporate Names. Company (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials exclusively related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product) in the Major Market Countries, unless to do so would be prohibited under applicable Laws; *provided, however*, in the case of multi-product materials that refer to a Licensed Product in the Field in the Major Market Countries as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the 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 Licensed Product in the Field in the Territory during the Term and to the extent that a Party has a continuing right to use or sell existing inventory of Licensed Product and Promotional Materials for a maximum period of three (3) years thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples solely to the extent necessary to exhaust the existing inventory of 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 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 XIII NEWLY CREATED INVENTIONS**

#### 13.1 Ownership of Newly Created Intellectual Property.

(a) Each Party (or each Party's designated Affiliates) shall exclusively own all right, title and interest in and to any and all intellectual property (including, without limitation, Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with the Collaboration solely by or on behalf of such Party (or its Affiliates or its or their Sublicensees) ("Sole Inventions"). Sole Inventions made solely by or on behalf of Company (or its Affiliates or its or their Sublicensees) (other than Regeneron and its Affiliates) are referred to herein as "Company Sole Inventions." Sole Inventions made solely by or on behalf of Regeneron (or its Affiliates or its or their Sublicensees) (other than Company and its Affiliates) 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 each own an equal, undivided interest in any and all intellectual property (including, without limitation, Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with the Collaboration after the Opt-In Effective Date during the Term that is discovered, invented, authored or otherwise created jointly by an individual or individuals having an obligation to assign such intellectual property to Company or its Affiliates (or for which ownership vests in Company or its Affiliates by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliates (or for which ownership vests in Regeneron or its Affiliates by operation of law), 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 Inventions.

(c) Notwithstanding the foregoing in Section 13.1(b), (i) for purposes of determining whether a patentable invention is a Company 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 Company 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 Company 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 or its Affiliates, 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 so 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 is governed by the terms and conditions of this Agreement, including the terms of Article V and shall be governed as follows: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or part, by each Party without the consent of the other Party (unless otherwise prohibited by this Agreement); *provided, however* 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 V, (ii) each Party agrees not to transfer any of its ownership interests in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 13.1(e) and the other terms of this Agreement that relate to the Joint Intellectual Property and (iii) nothing in this Article XIII shall relieve a Party or its Affiliates of their obligations under Article XVII with respect to confidential Party Information provided by or on behalf of the other Party or such other Party's Affiliates. Neither Party hereto shall have the duty 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. Subject to the provisions of Article XIV, each of the Parties (or its Affiliates), 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. The provisions governing Joint Inventions set forth in this Section 13.1(e) shall survive the expiration or termination of this Agreement.

### 13.2 Prosecution and Maintenance of Patents.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights in the Territory and shall confer with and keep Company 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 the Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights in the Territory: (i) Regeneron shall use Commercially Reasonable Efforts to provide to Company 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 consider in good faith any comment from Company; (ii) Regeneron shall provide Company promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Company promptly following the filing of the priority Patent applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent applications and (iv) Regeneron shall consult with Company a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Regeneron Collaboration Patent Rights or Regeneron Licensed Patent Rights in the Territory in the Field (including but not limited to 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 Collaboration Patent Rights or Regeneron Licensed Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Company 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 Collaboration Patent Rights or Regeneron

Licensed Patent Rights with the applicable patent office) and, subject to any rights granted to Aventis under the Aventis Agreement, Company shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Regeneron's name, unless, with respect to any such Patent applications that are unpublished, Regeneron notifies Company that Regeneron would prefer to maintain the subject matter of such Patent applications as a trade secret.

(b) Company shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Company Collaboration Patent Rights in the Territory and the Excluded Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Company shall have the following obligations with respect to the filing, prosecution and maintenance of the Company Collaboration Patent Rights in the Territory and the Excluded Territory: (i) Company 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 and/or the Excluded Territory at least thirty (30) days prior to the filing of any such priority Patent application by Company and consider in good faith any comment from Regeneron; (ii) Company shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Company shall consult with Regeneron promptly following the filing of the priority Patent applications in the Territory and/or the Excluded Territory to mutually determine in which countries in the Territory and the Excluded Territory it shall file convention Patent applications and (iv) Company 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 Company Collaboration Patent Rights in the Territory or the Excluded Territory in the Field (including but not limited to 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 Company desires to abandon any Company Collaboration Patent Rights in the Territory or the Excluded Territory, Company 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 Company Collaboration Patent Rights 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 Company's name in the Territory and in Regeneron's name (and at Regeneron's cost) in the Excluded Territory and upon Regeneron's request, Company shall assign such Company Collaboration Patent Right in the Excluded Territory to Regeneron without additional consideration and such Patent shall thereafter cease to be a Company Collaboration Patent Right (provided, without limiting Company's obligations under Section 7.17, Regeneron hereby grants Company (effective upon any such assignment), a non-exclusive license to all rights under such Patent except to the extent that Company grants Regeneron exclusive rights under the Company Collaboration Patent Rights (A) in Section 5.2 or (B) solely upon termination of this Agreement under Schedule 7, Schedule 8 or Schedule 9, as applicable, unless, with respect to any such

Patent applications that are unpublished, Company notifies Regeneron that Company would prefer to maintain the subject matter of such Patent applications as a trade secret.

(c) The Parties shall consult with each other regarding the filing, prosecution and maintenance of any Joint Patent Rights in the Territory and the Excluded Territory, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of any Joint Patent Rights in the Territory and the Excluded Territory: (i) the Controlling Party shall use Commercially Reasonable Efforts to provide the non-Controlling 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 Controlling Party and consider in good faith any comment from the non-Controlling Party; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent application to mutually determine in which countries it shall file convention Patent applications; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) the Controlling Party shall provide the non-Controlling 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 (including but not limited to 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), 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, with notice of such proposed action or inaction so that the non-Controlling 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 Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling 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-Controlling Party to do so and (ii) sixty (60) days prior to the expiration of any period during which the Controlling Party is required to file such Patent application in order to maintain its rights in such Patent application, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof (and will undertake such filings, prosecutions and maintenance in such Party's name). Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Joint Patent Rights on thirty (30) days' prior 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 Joint Patent Rights with

the applicable patent office), providing the non-Controlling Party the right to assume the prosecution or maintenance thereof.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights and Joint Patent Rights pursuant to this Section 13.2, including, without limitation, 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 13.2(c). The JCC, with the approval of the JSC, will determine which of the Company Collaboration Patent Rights, Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights and Joint Patent Rights for which to seek an extension of term in the Territory and the applicable Party will file for said patent term extension, and Regeneron will determine which of the Company Collaboration Patent Rights, Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights and Joint Patent Rights for which to seek an extension of term in the Excluded Territory and will file for said patent term extension.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Company Collaboration Patent Rights, Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights and Joint Patent Rights, in each case, in the Territory, and any extensions thereof, pursuant to this Section 13.2 shall be shared by the Parties as part of Other Shared Expenses. Notwithstanding the foregoing, (i) each Party shall be responsible for its own costs and expenses incurred in the filing, prosecution and maintenance of any Company Collaboration Patent Rights, Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights (and any extensions thereof) in the Excluded Territory and (ii) the Parties will share equally all costs and expenses incurred in the filing, prosecution and maintenance of any Joint Patent Rights (and any extensions thereof) in the Excluded Territory (*provided* that if a Controlling Party abandons the prosecution or maintenance of any Joint Patent Right in the Excluded Territory and the other Party elects to continue the prosecution and maintenance thereof, then such other Party shall be responsible for the costs and expenses of such prosecution and maintenance); *provided, however*, that if the non-Controlling Party fails to pay its share of all costs and expenses incurred in the filing, prosecution and maintenance of any Joint Patent Rights (and any extensions thereof) in the Excluded Territory, such Joint Patent Right shall cease to be a Joint Patent Right and the non-Controlling Party shall assign to the Controlling Party, without additional consideration, all of its right, title and interest in and to such Joint Patent Right in the Excluded Territory.

### 13.3 Interference, Opposition and Reissue.

(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 or reexamination relating to Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights, in each case, in the Territory and, solely with respect to Company Collaboration Patent Rights and Joint Patent Rights, in the Excluded Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. 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, will be made (i) with respect to Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights, by Regeneron in consultation with Company, (ii) with respect to Company Collaboration Patent Rights, by Company in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties. Regeneron may have certain obligations under Section 12.3 of the Aventis Agreement with respect to any such proceeding described in this Section 13.3(a) and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights and/or Joint Patent Rights, in each case, in the Territory pursuant to this Section 13.3 shall be shared by the Parties as part of Other Shared Expenses. Notwithstanding the foregoing, (i) each Party shall be responsible for its own costs and expenses incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, and/or Company Collaboration Patent Rights and (ii) the Parties will share equally all costs and expenses incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Joint Patent Rights in the Excluded Territory.

13.4 Coordination with IP Provisions in the EYLEA Agreement. To the extent any Patent Right or invention with respect to a Licensed Product is implicated by both the intellectual property ownership and litigation provisions of this Agreement and this EYLEA Agreement, Article XIII and Article XIV shall govern if such Patent Right or invention is related primarily to a PDGF Product (including, for clarity, a Combination PDGF Product) and Article XII and Article XIII of the EYLEA Agreement shall govern if such Patent Right or invention is related primarily to EYLEA.

## **ARTICLE XIV INTELLECTUAL PROPERTY LITIGATION**

### 14.1 Enforcement of Patents and Product Trademarks.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual or suspected infringement or unauthorized use, as applicable,



of a Company Collaboration Patent Right, a Regeneron Collaboration Patent Right, a Regeneron Licensed Patent Right, a Joint Patent Right or any Product Trademark, in each case, by a Third Party's activities (an "Infringement"), the Party that became aware of such Infringement shall promptly notify the other Party in writing and shall provide such other Party with all available evidence supporting such Infringement.

(b) If the Infringement is with respect to (i) a Company Collaboration Patent Right, a Regeneron Collaboration Patent Right, a Regeneron Licensed Patent Right, or a Joint Patent Right in the Field in the Territory, (ii) Joint Patent Rights outside of the Field, (iii) Company Collaboration Patent Rights or Joint Patent Rights in the Field in the Excluded Territory or (iv) except as set forth in Section 14.1(d), Company Collaboration Patent Rights outside the Field, as soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC 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 with respect to such Infringement, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any such Infringement described in this Section 14.1 and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder. Final decisions on whether to initiate a proceeding with respect to such Infringement, and the course of action in such proceeding, including whether to prosecute any such Infringement as a defense or counterclaim in connection with any Third Party infringement claims pursuant to Section 14.3 or any settlement negotiations and terms, will be made with respect to (i) Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights in the Field in the Territory, Company Collaboration Patent Rights and Joint Patent Rights in the Field in the Excluded Territory, Joint Patent Rights outside the Field and, except as set forth in Section 14.1(d), Company Collaboration Patent Rights outside the Field, by Regeneron in consultation with Company, (ii) Company Collaboration Patent Rights in the Field in the Territory by Company in consultation with Regeneron and (iii) Joint Patent Rights in the Field in the Territory by the Controlling Party in consultation with the other Party. Without limiting the preceding sentence, any disagreement between the Parties concerning the enforcement specified above shall be referred to the Executive Officers for resolution. The Party controlling the prosecution of any Infringement pursuant to this Section 14.1 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 action, and if required by Law, will join in the action. 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. Subject to any obligations under any New License or Existing License, the amount of any recovery from any such Infringement action (whether by way of settlement or otherwise) shall be retained as follows: (i) for (A) Company Collaboration Patent Rights or Joint Patent Rights in the Field in the Excluded Territory, (B) Joint

Patent Rights that relate to a PDGF Product outside the Field in the Excluded Territory and (C) Company Collaboration Patent Rights that relate to a PDGF Product outside the Field in the Excluded Territory, by Regeneron, and (ii) for (A) Company Collaboration Patent Rights, Regeneron Collaboration Patent Rights or Regeneron Licensed Patent Rights in the Field in the Territory, (B) Joint Patent Rights in the Field in the Territory, (C) Joint Patent Rights outside the Field in the Territory, (D) Joint Patent Rights that relate to a product that is not a PDGF Product and (E) except as set forth in Section 14.1(d), Company Collaboration Patent Rights outside the Field in the Territory, shall be shared equally by the Parties; *provided, however*, that notwithstanding anything to the contrary in this Section 14.1(b), any recoveries for lost sales or profits of a product from any Infringement action hereunder shall be paid solely to or retained solely by the Party that is selling (or has the right to sell) such product.

(c) With respect to any actual or suspected Infringement of (i) Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights outside the Field, (ii) Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights in the Excluded Territory, and/or (iii) Regeneron Non-Collaboration Patent Rights, Regeneron shall have sole discretion and control of any actions taken with respect to such Infringement. Company shall promptly notify Regeneron in writing of any such Infringement of which it or any of its Affiliates becomes aware and shall provide Regeneron with all available evidence supporting such Infringement. Company shall, at Regeneron's cost, provide reasonable assistance to Regeneron in prosecuting any action with respect to such infringement, and if required by Law, will join in the action. The amount of any recovery from any such infringement action (whether by way of settlement or otherwise) shall be retained solely by Regeneron, subject to any obligations under any New License or Existing License.

(d) With respect to any actual or suspected infringement of (i) Company Collaboration Patent Rights outside the Field that relate to a product that is not a PDGF Product and/or (ii) Company Non-Collaboration Patent Rights, Company shall have sole discretion and control of any actions taken with respect to such infringement. Regeneron shall promptly notify Company in writing of any such infringement of which it or any of its Affiliates becomes aware and shall provide Company with all available evidence supporting such infringement. Regeneron shall, at Company's cost, provide reasonable assistance to Company in prosecuting any action with respect to such infringement, and if required by Law, will join in the action. The amount of any recovery from any such infringement action (whether by way of settlement or otherwise) shall be retained solely by Company, subject to any obligations under any New License or Existing License.

(e) All Out-of-Pocket Costs incurred in connection with any Infringement litigation under Section 14.1(b) with respect to (i) Company Collaboration Patent Rights, Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights or Joint Patent Rights in the Field in the Territory or (ii) Company Collaboration Patent Rights and Joint Patent Rights outside the Field in the Territory shall be shared by the

Parties as part of Other Shared Expenses. All internal and out-of-pocket costs and expenses incurred by Regeneron in connection with any infringement litigation under Section 14.1(c) or any Infringement litigation under Section 14.1(b) with respect to (i) Company Collaboration Patent Rights or Joint Patent Rights in the Field in the Excluded Territory, (ii) Joint Patent Rights outside the Field in the Excluded Territory or (iii) except as set forth in Section 14.1(d), Company Collaboration Patent Rights outside the Field in the Excluded Territory shall be the responsibility of Regeneron. All internal and out-of-pocket costs and expenses incurred by Company in connection with any Infringement litigation under Section 14.1(d) shall be the responsibility of Company.

(f) For the avoidance of doubt, neither Party will enter into any settlement of any Infringement suit referenced in this Section 14.1 that materially adversely affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory or the Excluded Territory or the commercialization of EYLEA in the Field in the Territory or the Excluded Territory pursuant to the EYLEA Agreement without the other Party's prior written consent.

14.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.

14.3 Third-Party Infringement Claims; New Licenses.

(a) If either Party or its Affiliates becomes aware of an allegation that the Development, Manufacture or Commercialization of any 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 and control the defense of any such action naming it as a defendant at its sole cost and expense, using counsel of its own choice; *provided, however*, that 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 and/or settlement of any such claim; *provided further* that any counterclaim or defense alleging Infringement (or infringement) shall be governed by Section 14.1. The rights and obligations in this Section 14.3 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 and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any allegation described in this Section 14.3 and,

notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(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 14.3 shall be shared by the Parties as Other Shared Expenses.

(c) For the avoidance of doubt, neither Party will enter into any settlement of any suit involving Licensed Products that materially adversely affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory or the Excluded Territory or the commercialization of EYLEA in the Field in the Territory or the Excluded Territory pursuant to the EYLEA Agreement without the other Party's prior written consent. Furthermore, neither 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 Licensed Products in the Field in the Territory under this Agreement (or with respect to Company, in the Field in the Excluded Territory) without the other Party's prior written consent.

(d) License fees, royalties and other payments under Existing Licenses and New Licenses to the extent attributable to, and based on, the Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be shared by the Parties as Other Shared Expenses.

#### 14.4 Invalidity or Unenforceability Defenses or Actions.

(a) In the event that a Third Party asserts, as a defense or as a counterclaim in any Infringement action (or infringement action) under Section 14.1, that any Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights are invalid or unenforceable, then the Party first becoming aware of such claim shall promptly give written notice to the other Party. Subject to the assistance and coordination provisions described in Sections 14.1(b) through 14.1(d), the Party having the final decision-making authority on responding to such defense or defending against such counterclaim (as applicable), including the right to settle or otherwise compromise such claim, will be made by the Party controlling and/or having final decision-making authority with respect to the Infringement action (or infringement action) as set forth in Sections 14.1(b) through 14.1(d), in consultation with the other Party.

(b) If a Third Party asserts, in a declaratory judgment action or similar action or claim filed by such Third Party, that any Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights, in each case, in the Territory or the Excluded Territory are invalid or unenforceable, then the Party first becoming aware of such action or claim shall promptly give written notice to the other Party. The Party having the final decision-making

authority on controlling the defense of such action or claim, including settlement negotiations and terms, will be (i) with respect to Company Collaboration Patent Rights and Joint Patent Rights in the Excluded Territory, and Regeneron Collaboration Patent Rights and Regeneron Licensed Patent Rights, Regeneron in consultation with Company, (ii) with respect to Company Collaboration Patent Rights in the Territory, Company in consultation with Regeneron, and (iii) with respect to Joint Patent Rights in the Territory, the Parties jointly. Any such Party controlling the defense against any such action or claim in the Territory shall use legal counsel mutually agreeable by the Parties, and 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 and/or settlement of any such claim.

(c) All Out-of-Pocket Costs incurred in connection with responding to or defending against any action or claim that any Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights are invalid or unenforceable pursuant to this Section 14.4 shall be shared by the Parties in the same way the Parties share costs with respect to Infringement (or infringement) litigation as specified in Section 14.1(e).

(d) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 14.4 that materially adversely affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory or the Excluded Territory, including admitting the invalidity or unenforceability of any Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights, or the commercialization of EYLEA in the Field in the Territory or the Excluded Territory without the other Party's prior written consent.

## **ARTICLE XV**

### **BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS**

15.1 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 GAAP or IAS/IFRS) 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 15.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party 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 to 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.

## 15.2 Audits and Adjustments.

(a) Each Party shall have the right (at its costs), 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 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 receipt thereof. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit (each such dispute, an "Audit Dispute") shall be subject to dispute resolution in accordance with Section 11.4 (subject to, and without limitation of, the proviso in Section 4.10(a)(iii)), except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 11.3 shall apply. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than ten percent (10%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article XVII.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then, unless the result of the audit is to be contested pursuant to Section 15.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 15.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section 15.2.

15.3 GAAP/IAS/IFRS. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with GAAP or IAS/IFRS as generally and consistently applied.

**ARTICLE XVI**  
**REPRESENTATIONS AND WARRANTIES**

16.1 Due Organization, Valid Existence and Due Authorization. Each Party hereto represents and warrants to the other Party, as of the Effective 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) no action by any other person is necessary to enter into this Agreement; (d) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (e) 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); (f) 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 V; and (g) 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. Company additionally represents and warrants to Regeneron that it has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement.

16.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective 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 Governmental Authority or arbitrator 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 pending or threatened actions or proceedings described in this Section 16.2.

16.3 Additional Regeneron Representations and Warranties. Regeneron additionally represents and warrants to Company that, as of the Effective Date:

(a) Regeneron has the right and authority to grant the rights and licenses granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that remain in effect that conflict with the rights and licenses granted herein;

(b) Except as set forth in Schedule 6A, (i) Regeneron is the sole owner of the Regeneron Licensed Patent Rights existing as of the Effective Date, (ii) to Regeneron's knowledge, its title in and to the Regeneron Licensed Patent Rights is free

and clear of all liens, security interests and other encumbrances (other than unilateral creditor filings, as to which this representation and warranty is made only to Regeneron's knowledge), and (iii) except for the joint owner identified in Schedule 6 (and with respect to the Existing Licenses, the Third Party licensors referred to in Schedule 4), no Third Party has any right, title or interest in the Territory in the Field with respect to the Regeneron Licensed Patent Rights existing at the Effective Date;

(c) [\*\*\*\*\*] Regeneron has no knowledge that the making, using or selling of REGN 2176 and REGN 2176-3 in the Field in the Territory would infringe any valid claims of the Patents of any Third Party in the Territory, nor does it have knowledge that any Third Party is infringing or misappropriating any of the Regeneron Licensed Intellectual Property;

(d) There are no judgments or settlements against or owed by Regeneron with respect to the Regeneron Licensed Intellectual Property that is owned by Regeneron;

(e) There are no announced investigations, actions or other proceedings pending before or, to Regeneron's knowledge, threatened by any Regulatory Authority or other government agency with respect to the Licensed Products, and Regeneron has not received written notice threatening any such investigation, action or other proceeding;

(f) To the knowledge of Regeneron, the development, manufacture and commercialization of the PDGF Product in the Field that has been conducted by Regeneron and its Affiliates and its subcontractors was conducted in compliance in all material respects with applicable Laws; and

(g) To Regeneron's knowledge, each Existing License is in full force and effect as of the Effective Date. Regeneron has, to the extent contractually permitted, provided to Company, or allowed Company access to review, a true and complete copy of each Existing License. Regeneron will devote Commercially Reasonable Efforts to maintain the Existing Licenses in full force and effect and to perform its obligations thereunder and to keep Company informed of any material development pertaining thereto that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement. Regeneron shall not, without the prior written approval of Company, (i) amend any provision of an Existing License that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement or (ii) make any election or exercise any right or option to terminate in whole or in part any Existing License to the extent such election or exercise would reasonably be expected to have a material adverse effect on Company's rights under this Agreement.

(h) [\*\*\*\*\*].



16.4 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, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

16.5 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date as follows:

(a) it will not during the Term grant any right or license to any Third Party that would conflict with 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) it will not use the Patents or Know-How of the other Party outside the scope of the licenses and rights granted to it by the other Party under this Agreement; and

(c) in the course of the Development or Commercialization of a 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 pursuant to Section 306 of the FFDCa in the Excluded Territory or by a Regulatory Authority in the Territory under applicable Law or, to the best of such Party's knowledge, is or has been the subject of a conviction described in Section 306 of the FFDCa or debarment proceedings by a Regulatory Authority in the Territory. It shall inform the other Party in writing immediately if it or any Person who is performing activities hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCa or under other applicable Law, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party's knowledge, is threatened, relating to the debarment or conviction of such Party or any Person performing activities hereunder.

## **ARTICLE XVII CONFIDENTIALITY**

17.1 Confidential Information. Each of Company and Regeneron acknowledges (subject to the further provisions of this Article XVII and the provisions of Article XX) 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, in the case of Company, Party Information provided to it under the confidentiality agreement between the Parties dated December 20, 2012, as subsequently amended) is

confidential and proprietary to such other Party. Furthermore, each of Company and Regeneron acknowledges (subject to the further provisions of this Article XVII) 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 XVII, during the Term and for a period of ten (10) years thereafter each of Company and Regeneron shall (a) maintain in confidence and not disclose to any Third Party the Party Information of the other Party (or its Affiliates) and all New Information and (b) use the Party Information of the other Party (or its Affiliates) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Company and Regeneron covenants that during the Term and for a period of ten (10) years thereafter neither it nor any of its respective Affiliates shall disclose any Party Information of the other Party (or its Affiliates) or New Information to any Person except (x) to its employees, agents or any other Person under its authorization; *provided* such employees, agents or Persons are subject in writing to substantially the same confidentiality obligations as the Parties as set forth in this Article XVII, (y) as approved by both Parties in writing or (z) as expressly permitted pursuant to Section 17.3 or elsewhere in this Agreement. Company shall not during the Term and for a period of ten (10) years thereafter disclose and/or use any Company Collaboration Intellectual Property, Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, Joint Intellectual Property and/or New Information in connection with the research, development, manufacture, commercialization or other exploitation of any compound or product in the Field in the Territory or the Excluded Territory (other than Licensed Products in the Field in the Territory as permitted under this Agreement) or any PDGF Product outside the Field in the Excluded Territory.

17.2 Exclusions. Notwithstanding anything provided above, the confidentiality and non-use restrictions provided in this Article XVII shall not apply to Party Information or New Information that was or is (and such information shall not be considered confidential or proprietary under this Agreement):

- (a) 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 its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information;
- (b) 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, however*, that this exception shall not apply with respect to New Information;
- (c) 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; or
- (d) similar in nature to the purported Party Information or New Information but has been independently created outside of this Agreement, as evidenced

by written or electronic documentation, without any aid, application or use of the Party Information or New Information.

### 17.3 Permitted Disclosures and Uses.

(a) Each Party may use or disclose Party Information of the other Party and New Information to the extent that such use or disclosure is:

(i) necessary or useful to file, prosecute or defend Patents for which the Party has the right to assume filing, prosecution, defense or maintenance pursuant to this Agreement; *provided, however*, that reasonable measures shall be 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 (including the rules or 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. Moreover, either Party may use Party Information and New Information to enforce the terms of this 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

(iii) to the Regulatory Authorities as required in connection with any filing, application or request for Approval of a Licensed Product in the Territory pursuant to the terms of this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law.

(b) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any

New Information or Party Information of Company, in each case, related to the Licensed Products (including the Manufacture or use thereof):

(i) to Aventis or any other Third Party licensee or contractor of Regeneron engaged in, and for use in connection with, the Exploitation of PDGF Products outside the Field under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years;

(ii) in connection with Regeneron's Exploitation of PDGF Products outside the Field, including, without limitation, to existing or potential distributors, Sublicensees, Affiliates, or collaboration partners, under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years;

(iii) in connection with Regeneron's Exploitation of PDGF Products in the Field in the Excluded Territory, including, without limitation, to existing or potential distributors, Sublicensees, Affiliates, or collaboration partners, under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years; or

(iv) to the Regulatory Authorities as required in connection with any filing, application or request for regulatory approval in the Excluded Territory; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law.

17.4 Injunctive Relief. Each Party acknowledges that damages resulting from breach of this Article XVII or Section 3.7 would not be an adequate remedy and that, notwithstanding the provisions of Article XI, in the event of any such disclosure or any indication of an intent to disclose such Party Information or New Information or Confidential Property and Information in breach of this Article XVII, or breach of Section 3.7, the Party owning such Party Information (or each Party with respect to New Information) or Regeneron (in the case of Confidential Property and Information) shall be entitled to obtain, by way of private litigation, injunctive relief, whether preliminary or permanent, specific performance in addition to any other rights or remedies (which may include reasonable royalties, notwithstanding anything to the contrary in Section 21.15) to which such non-breaching Party may be entitled in law or equity, and reasonable attorneys' fees. In any such action for equitable relief in a court of competent jurisdiction, both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm.

17.5 Publication of New Information. During the Term, if either Company or Regeneron (the “Publishing Party”) desires to disclose any New Information in scientific journals, publications or scientific presentations, 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 prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary (a) to prevent any specific, material adverse effect to it or any Licensed Product as a result of the publication or disclosure or (b) to enable the Parties to obtain patent protection if either Party deems it necessary (such recommendation of changes to include a description of the specific material adverse effect or patentability issues, as applicable) to which the Publishing Party shall give due consideration and shall not unreasonably reject such comments. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).

17.6 Other Publications or Disclosures.

(a) The Parties will mutually agree upon the contents of a joint press release with respect to the execution of this Agreement that shall be issued simultaneously by both Parties on the Effective Date. During the Term, Company 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 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 use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that 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 which information 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 or, after the Opt-In Effective Date, the Collaboration (*e.g.*, that the Collaboration is ongoing in accordance with the terms of this Agreement).

(b) 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, 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 XVII without the prior written consent of the other Party, which consent shall not be unreasonably withheld 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 Licensed Products in the Field. Company acknowledges that Regeneron, as a publicly traded company, is legally obligated to make timely disclosures of all material events relating to Licensed Products. 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 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 this 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.

17.7 Disclosure of Collaboration Know-How and Joint Inventions. During the Term and any applicable wind-down or transition periods after termination hereunder, Company shall disclose and/or make available to Regeneron any Company Collaboration Know-How and Joint Inventions as may be reasonably requested by Regeneron. After the Opt-In Effective Date during the Term, Regeneron shall disclose and/or make available to Company any Regeneron Collaboration Know-How and Joint Inventions as may be reasonably requested by Company.

## **ARTICLE XVIII INDEMNITY**

### 18.1 General Indemnity.

(a) Company will defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees, (sub)licensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Damages"), arising from a Third Party's claim, action, suit, judgment or settlement (a "Third Party Claim") against a Regeneron Indemnatee that is due to or based upon the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law in the performance of, or material breach of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement by or of any Company Indemnatee, including, without limitation, in connection with its Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that such Damages arise out of, and are allocable to, the gross negligence,

recklessness, bad faith, intentional wrongful acts or omissions or violations of Law in the performance of this Agreement or breach of this Agreement committed by Regeneron or any other Regeneron Indemnitee.

(b) Regeneron will defend, indemnify and hold harmless Company, its Affiliates and its and their respective officers, directors, employees, Sublicensees and agents (“Company Indemnitees”) from and against all Damages arising from a Third Party Claim against a Company Indemnitee that is due to or based upon the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law in the performance of, or material breach of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement by or of any Regeneron Indemnitee, including, without limitation, in connection with its Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that such Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law in the performance of this Agreement or breach of this Agreement committed by Company or any other Company Indemnitee.

#### 18.2 Additional Indemnity.

(a) In the event of any Third Party Claim alleging that the Development and/or Manufacture of any Licensed Product in the Excluded Territory or the Territory under this Agreement and/or the Commercialization of any Licensed Product in the Field in the Territory under this Agreement, in each case, infringes a Patent of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for [\*\*\*\*\*] of all Damages therefrom, and during the Term such Damages shall be treated as Other Shared Expenses; *provided*, that with respect to any Damages attributable to the Manufacture of Licensed Product in the Excluded Territory, such Damages shall be allocated between the Territory and the Excluded Territory (i) if such Damages are allocable between the Territory and the Excluded Territory pursuant to a formula or mechanism expressly set forth in the applicable settlement agreement or judgment (e.g., as a result of a royalty based on net sales or a flat fee per unit manufactured), then pursuant to such formula or mechanism and (ii) otherwise, as agreed by the Parties and in the absence of agreement, such matter shall be referred to the Executive Officers for resolution pursuant to Section 4.10(b).

(b) Without limiting Company’s obligations under Section 18.1(a), Company shall defend, indemnify and hold harmless the Regeneron Indemnitees from and against all Damages arising from a Third Party Claim arising from Company’s or its Affiliates’ or Sublicensees’ Commercialization of Licensed Products in the Field in the Territory, except that Regeneron shall indemnify Company Indemnitees under Section 18.1(b) for all such claims arising from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law in the performance of this Agreement or breach of this Agreement committed by Regeneron or any other Regeneron Indemnitee.

(c) Without limiting Regeneron's obligations under Section 18.1(b), Regeneron shall defend, indemnify and hold harmless the Company Indemnitees from and against all Damages arising from a Third Party Claim arising from Regeneron's or its Affiliates' or Sublicensees' commercialization of Licensed Products in the Field in the Excluded Territory, except that Company shall indemnify Regeneron Indemnitees under Section 18.1(a) for all such claims arising from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law in the performance of this Agreement or breach of this Agreement committed by Company or any other Company Indemnitee.

(d) In the event that Company exercises its Opt-In Right pursuant to Section 2.7, Damages from Third Party Claims arising from the Development of any Licensed Product in the Field under this Agreement for which neither Party is entitled to indemnification under this Article XVIII shall be treated as Development Costs.

(e) Notwithstanding anything to the contrary in this Article XVIII, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Company 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 IX; *provided, however*, that nothing in this Section 18.2(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 IX.

(f) Notwithstanding anything to the contrary herein, in the event that Company exercises the Company Opt-Out Exercise, Regeneron shall defend, indemnify and hold harmless the Company Indemnitees from and against all Damages arising from a Third Party Claim against a Company Indemnitee arising from Regeneron's (or its Affiliates' or Sublicensees') Development prior to the effective date of the Company Opt-Out Exercise of any Licensed Product in the Field to the extent attributable to a Discretionary Amendment not agreed to by Company.

(g) In the event that Company exercises its Opt-In Right pursuant to Section 2.7(c), (i) Company shall defend, indemnify and hold harmless the Regeneron Indemnitees from and against all Damages arising from a Third Party Claim against a Regeneron Indemnitee that is due to or based upon the Development (solely with respect to Licensed Product administered after the Opt-In Effective Date), Manufacture and Commercialization of any Licensed Product in the Field in or for the Territory, except that Regeneron shall indemnify Company Indemnitees under Section 18.1(b) for all such claims arising from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of



Law in the performance of this Agreement or breach of this Agreement committed by Regeneron or any other Regeneron Indemnitee; and (ii) Regeneron shall defend, indemnify and hold harmless the Company Indemnitees from and against all Damages arising from a Third Party Claim against a Company Indemnitee that is due to or based upon the Development (solely with respect to Licensed Product administered after the Opt-In Effective Date), Manufacture and commercialization of any Licensed Product in the Field in or for the Excluded Territory, except that Company shall indemnify Regeneron Indemnitees under Section 18.1(a) for all such claims arising from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law in the performance of this Agreement or breach of this Agreement committed by Company or any other Company Indemnitee.

(h) In the event that this Agreement terminates pursuant to the terms hereof (including as a result of Company's exercise of the Company Opt-Out Exercise), Regeneron shall defend, indemnify and hold harmless the Company Indemnitees from and against all Damages arising from or occurring as a result of a Third Party Claim against a Company Indemnitee that is due to or based upon a Licensed Product that is sold, or in connection with Development, Manufacture or commercialization of such Licensed Product administered solely after the effective date of termination of this Agreement, except that Company shall indemnify Regeneron Indemnitees under Section 18.1(a) for all such claims arising from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law in the performance of this Agreement or breach of this Agreement committed by Company or any other Company Indemnitee.

18.3 Insurance. Immediately upon First Commercial Sale of the first Licensed Product in the Territory, during the Term and thereafter for a period of five (5) years after the expiration of this Agreement or the earlier termination thereof, each Party shall use Commercially Reasonable Efforts to obtain and/or maintain (either directly or as a named insured on a Third Party insurance policy or policies), at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts, respectively, that are reasonable and customary for comparable products in the pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party; *provided, however*, that Regeneron shall not be required to obtain or maintain such insurance in an amount greater than [\*\*\*\*\*] per incident and in the aggregate. Such product liability insurance or self-insured arrangements shall insure against personal injury, physical injury or property damage arising out of, for Regeneron, the Manufacture of Licensed Products (if applicable) and sale, distribution and/or marketing of Licensed Products in the Excluded Territory, and for Company, the sale, distribution and/or marketing of Licensed Products in the Territory.

18.4 Indemnity Procedure. The Party entitled to indemnification under this Article XVIII (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of

becoming aware 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, however*, 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 its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 18.4 shall not apply to claims for which each Party indemnifies the other Party [\*\*\*\*\*] of all Damages under the terms of Section 18.2(a).

(a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such 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, however*, that the Indemnifying Party may not enter into any compromise or settlement without the Indemnified Party's prior written consent, not to be unreasonably withheld or delayed, 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) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in 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 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 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 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 18.4 and shall bear its own costs and expenses with respect to such participation; *provided, however*, 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.

(c) Regardless of whether the Indemnifying Party assumes the defense of any claim pursuant to this Section 18.4, the Indemnified Party shall and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access 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 XVIII, the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection with providing such assistance.

(d) The amount of any Damages for which indemnification is provided under this Article XVIII will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.

(e) If an Indemnified Party receives an indemnification payment pursuant to this Article XVIII and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article XVIII and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article XVIII.

#### **ARTICLE XIX 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, without limitation, 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 provided that 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 XX TERM AND TERMINATION**

### 20.1 Term/Expiration of Term.

(a) The “Term” of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated as provided hereafter, shall end at such time as neither Party, nor either Party’s Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent; *provided*, that if at any time during the Term after the Opt-In Effective Date Company loses the exclusive legal right to Commercialize Licensed Product in the Field in any Major Market Country, whether due to expiration of Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Joint Patent Rights or Company Collaboration Patent Rights, or expiration of any statutory marketing exclusivity period for Licensed Product in such Major Market Country, the Parties shall meet to discuss and attempt to enter into an amendment to this Agreement for the purpose of simplifying the governance structure hereunder.

(b) Upon expiration of the Term, except as set forth in this Agreement (including Sections 20.8 and 20.9), all licenses and rights granted by a Party to the other Party hereunder shall automatically terminate and revert to the granting Party.

20.2 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 20.2, this Agreement shall be terminable by a Party in its entirety if the 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 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 so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured at the end of such one hundred eighty (180) day period, 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 Commercially Reasonable Efforts to cure such breach), *provided* that (a) the Parties shall meet within fifteen (15) Business Days after delivery of such notice to the breaching Party to discuss in good faith such alleged breach and (b) in the event the Parties are unable to resolve such dispute within twenty (20) Business Days of meeting to discuss

such dispute, either Party may require that the matter be submitted to the Executive Officers for resolution, and the Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within fifteen (15) Business Days of receiving such written notification for a period of fifteen (15) Business Days. Should such Executive Officers fail to resolve the dispute within the appointed time, then, without limiting the foregoing, either Party may pursue any and all legal and equitable remedies available to it under applicable Law, subject to Sections 21.1 and 21.15. In the case of breach of a payment obligation hereunder, the ninety (90)-day period referred to in the second sentence of this Section 20.2 shall instead be thirty (30) days (and the immediately preceding parenthetical clause in such sentence shall not apply). For purposes of this Section 20.2, the term “material breach” shall mean a substantial violation of any material provision of this Agreement that would materially adversely affect the non-breaching Party.

20.3 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, (b) the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) the other Party shall make a general assignment for the benefit of creditors.

20.4 Termination for Company’s Opt-Out Exercise. In the event Company exercises the Company Opt-Out Exercise pursuant to the terms of Section 2.9, this Agreement shall terminate and the provisions of Section 20.8(c) shall apply, which such termination shall become effective at the end of the Opt Out Notice Period.

20.5 Termination for Breach of Standstill. Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, effective immediately, upon written notice to Company, if Section 21.16 of this Agreement shall have been breached by Company or any of its Affiliates. For the avoidance of doubt, Company or its Affiliates will not be deemed to have breached Section 21.16, and Regeneron shall not have the right to terminate this Agreement, as a result of an inadvertent breach of Section 21.16 arising from (a) any discussion with any Third Parties that are initiated by such Third Parties, are not publicly disclosed and do not result in any actions referred to in paragraphs (a) through (g) of Section 21.16 or (b) any informal discussions covering general corporate or other business matters the purpose of which is not to effectuate or lead to any of the actions referred to in paragraphs (a) through (g) of Section 21.16.

20.6 Termination for Termination of EYLEA Agreement. In the event that the EYLEA Agreement is terminated for any reason, this Agreement shall automatically terminate upon the effective date of the termination of the EYLEA

Agreement and the provisions of Section 20.8(e) shall apply. For clarity, the termination of this Agreement for any reason shall not automatically terminate the EYLEA Agreement.

20.7 Other Termination. [\*\*\*\*\*].

(a) [\*\*\*\*\*].

(b) [\*\*\*\*\*].

20.8 Effect of Termination.

(a) Except as set forth in Section 2.10, 20.7, 20.8(b), 20.8(c), 20.8(d), 20.8(e) and 21.18 below, upon termination of this Agreement other than pursuant to Section 20.6 prior to expiration of the Term or pursuant to Section 20.6 as a result of any termination of the EYLEA Agreement, other than Company's termination of the EYLEA Agreement pursuant to Section 19.3 or 19.4 of the EYLEA Agreement, the provisions of Schedule 7 shall apply, and except to the extent required by Company to fulfill its obligations pursuant to Schedule 7, (i) all licenses and rights granted by Regeneron to Company hereunder shall automatically terminate, and revert to Regeneron, and (ii) the licenses and rights granted by Company and its Affiliates to Regeneron in Sections 5.2(b), 5.2(c), 5.2(d), and 12.5 shall survive the termination of this Agreement; *provided, however*, the licenses under Section 12.5 shall be expanded to cover the rights to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products inside and outside the Field on a worldwide basis and those licenses in Section 5.2(b)(ii) shall be expanded to include the Territory. If Regeneron terminates this Agreement pursuant to Section 20.2, 20.3, or 20.5 or this Agreement terminates pursuant to Section 20.6 (other than for Company's termination of the EYLEA Agreement pursuant to Section 19.3 or 19.4 of the EYLEA Agreement) or Section 20.7(a) or Section 21.18 (only where Company is the subject party under Section 21.18), then Company shall pay to Regeneron, in addition to any other amount payable by Company to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to (i) twenty-five percent (25%) of the Development Costs incurred by Regeneron under the Global PDGF Development Plan and (ii) fifty percent (50%) of the Development Costs incurred by Regeneron under the Territory PDGF Development Plan, during the period commencing on the effective date of such termination of this Agreement pursuant to Section 20.2, 20.3, 20.5, 20.6, 20.7(a) or 21.18 (only where Company is the subject party under Section 21.18), as applicable, and ending on the six (6)-month anniversary of such date. Without limiting Section 20.9, to the extent this Section 20.8(a) is applicable, the following provisions of this Agreement shall survive the termination of this Agreement and shall continue to be enforceable: Article XIII and Article XIV, *provided that* Regeneron shall have the same rights, but not the obligation to prosecute, maintain, enforce and defend (and settle claims with respect thereto) the Company Collaboration Patent Rights (except as set forth in Section 14.1(d)), Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights and Joint Patent Rights in the Territory and outside the Field on the same terms as Regeneron has

with respect to the prosecution, maintenance, enforcement and defense of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights and Joint Patent Rights, as applicable, in the Field in the Excluded Territory under Article XIII and Article XIV, *mutatis mutandis*, provided that (A) any costs and expenses in connection with the prosecution and maintenance (including any interference, opposition or reexamination) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights or the defense of any claim that any of the foregoing are invalid or unenforceable shall be treated as follows: (1) to the extent they are incurred with respect to Regeneron Collaboration Patent Rights or Regeneron Licensed Patent Rights, such costs and expenses shall be the responsibility of Regeneron; (2) to the extent they are incurred with respect to Company Collaboration Patent Rights, such expenses shall be shared equally in the Territory and the responsibility of Company in the Excluded Territory, provided that if Company decides not to prosecute, maintain or defend any Company Collaboration Patent Right, then Regeneron shall have the right to take over the prosecution, maintenance and defense of such Company Collaboration Patent Right and upon Regeneron's request Company shall assign such Company Collaboration Patent Right to Regeneron without additional consideration and Regeneron hereby grants Company (effective upon any such assignment), a non-exclusive license to all rights under such Patent except to the extent that Company grants in (A) Section 5.2 or (B) Schedule 7 exclusive rights to Regeneron under the Company Collaboration Patent Rights; and (3) to the extent they are incurred with respect to Joint Patent Rights, the cost shall be shared equally unless the Controlling Party decides not to prosecute, maintain or defend any such rights, then the non-Controlling Party shall have the right to take over the prosecution, maintenance and defense of such Joint Patent Rights, and upon the non-Controlling Party's request the Controlling Party shall assign its interest in such Joint Patent Right to the non-Controlling Party without additional consideration and (B) any costs and expenses in connection with the enforcement (and any resulting recoveries) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights shall be the responsibility of the enforcing Party and the enforcing Party shall retain all recoveries with respect thereto; *provided, however*, that notwithstanding anything to the contrary in this Section 20.8(a), any recoveries for lost sales or profits of a product from any Infringement action hereunder shall be paid solely to or retained solely by the Party that is selling (or has the right to sell) such product.

(b) Upon termination of this Agreement by Company pursuant to Section 20.2 or 20.3 or the termination of this Agreement pursuant to Section 20.6 as a result of Company's termination of the EYLEA Agreement pursuant to Section 19.3 or 19.4 of the EYLEA Agreement, the provisions of Schedule 8 shall apply and the licenses from Company and its Affiliates to Regeneron referred to in Schedule 8 shall come into full force and effect, and all other licenses and rights granted (i) by Company to Regeneron hereunder shall automatically terminate and revert to Company (*provided, however*, that the licenses and rights with respect to the EYLEA Trademark(s) granted by Company and its Affiliates to Regeneron in Section 12.5 shall survive the termination of

this Agreement (*provided, however*, the licenses under Section 12.5 shall be expanded to cover the rights to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products inside and outside the Field on a worldwide basis) and (ii) by Regeneron to Company hereunder shall automatically terminate (except to the extent required by Company to fulfill its obligations pursuant to Schedule 8), and revert to Regeneron. Without limiting Section 20.9, the following provisions of this Agreement shall survive the termination of this Agreement by Company pursuant to Section 20.2, or 20.3 or the termination of this Agreement pursuant to Section 20.6 as a result of Company's termination of the EYLEA Agreement pursuant to Section 19.3 or 19.4 of the EYLEA Agreement and shall continue to be enforceable: Section 7.17(b)(ii), Article XIII and Article XIV, *provided that* (A) Regeneron shall have the same rights, but not the obligation to prosecute, maintain, enforce and defend (and settle claims with respect thereto) the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights and Joint Patent Rights in the Territory and outside the Field on the same terms as Regeneron has with respect to the prosecution, maintenance, enforcement and defense of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, and Joint Patent Rights, as applicable, in the Field in the Excluded Territory under Article XIII and Article XIV, *mutatis mutandis*, and (B) the Parties shall have the same rights, but not the obligation to prosecute, maintain, enforce and defend (and settle claims with respect thereto) the Company Collaboration Patent Rights in the Field in the Territory on the same terms as the Parties have with respect to the prosecution, maintenance, enforcement and defense of the Company Collaboration Patent Rights in the Field in the Excluded Territory under Article XIII and Article XIV, *mutatis mutandis*, *provided that* (1) any costs and expenses in connection with the prosecution and maintenance (including any interference, opposition or reexamination) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights or the defense of any claim that any of the foregoing are invalid or unenforceable shall be treated as follows: (X) to the extent they are incurred with respect to Regeneron Collaboration Patent Rights or Regeneron Licensed Patent Rights, such costs and expenses shall be the responsibility of Regeneron; (Y) to the extent they are incurred with respect to Company Collaboration Patent Rights, such expenses shall be the responsibility of Company, *provided that* if Company decides not to prosecute, maintain or defend any Company Collaboration Patent Right, then Regeneron shall have the right to take over the prosecution, maintenance and defense of such Company Collaboration Patent Right and upon Regeneron's request Company shall assign such Company Collaboration Patent Right to Regeneron without additional consideration and Regeneron hereby grants Company (effective upon any such assignment) a non-exclusive license to all rights under such Patent except to the extent that Company grants in (A) Section 5.2 or (B) Schedule 8 exclusive rights to Regeneron under the Company Collaboration Patent Rights; and (Z) to the extent they are incurred with respect to Joint Patent Rights, the cost shall be shared equally unless the Controlling Party decides not to prosecute, maintain or defend any such rights, then the non-Controlling Party shall have the right to take over the prosecution, maintenance and defense of such Joint Patent Rights, and upon the non-Controlling Party's request the Controlling Party shall assign its interest in such Joint Patent Right to the non-Controlling Party without additional consideration and (2) any



costs and expenses in connection with the enforcement (and any resulting recoveries) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights shall be the responsibility of the enforcing Party and the enforcing Party shall retain all recoveries with respect thereto; *provided, however*, that notwithstanding anything to the contrary in this Section 20.8(b), any recoveries for lost sales or profits of a product from any Infringement action hereunder shall be paid solely to or retained solely by the Party that is selling (or has the right to sell) such product.

(c) Upon termination of this Agreement by Company pursuant to Section 20.4 or Section 20.7(a), the provisions of Schedule 9 shall apply, and, the licenses from Company and its Affiliates to Regeneron referred to in Schedule 9 shall come into full force and effect. Notwithstanding the foregoing provisions of this Section 20.8(c), the following provisions of this Agreement shall survive or, as applicable, come into effect on, the termination of this Agreement by Company pursuant to Section 20.4 or Section 20.7(a) and shall continue to be enforceable: Sections 2.4 (solely with respect to a termination pursuant to Section 20.4), 2.9 (solely with respect to a termination pursuant to Section 20.4), 2.10 (solely with respect to a termination pursuant to Section 20.4), 7.17(b)(i), 8.1(d), 8.2(b) (solely to the extent related to EYLEA), 12.5 (*provided, however*, the licenses under Section 12.5 shall be expanded to cover the rights to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products inside and outside the Field on a worldwide basis), 20.8(c), and 20.9 and Article XIII (other than Sections 13.2(e) (first sentence only) and 13.3(b) (first sentence only)), Article XVII, and Article XXI. Notwithstanding the foregoing, Article XIV (other than Sections 14.1(e) (first sentence), 14.3(b), 14.3(d), and 14.4(c) (first sentence)) shall become effective, or if the Agreement is terminated pursuant to Section 20.7(a), shall survive the termination of this Agreement and continue to be enforceable, *provided* that Regeneron shall have the same rights, but not the obligation, to prosecute, maintain, enforce and defend (and settle claims with respect thereto) the Company Collaboration Patent Rights (except as set forth in Section 14.1(d)), Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights and Joint Patent Rights in the Field in the Territory and outside the Field on the same terms as Regeneron has with respect to the prosecution, maintenance, enforcement and defense of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights and Joint Patent Rights, as applicable, in the Field in the Excluded Territory under Article XIII and Article XIV, *mutatis mutandis*; provided, that that (A) any costs and expenses in connection with the prosecution and maintenance (including any interference, opposition or reexamination) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights or the defense of any claim that any of the foregoing are invalid or unenforceable shall be treated as follows: (1) to the extent they are incurred with respect to Regeneron Collaboration Patent Rights or Regeneron Licensed Patent Rights, such costs and expenses shall be the responsibility of Regeneron; (2) to the extent they are incurred with respect to Company Collaboration Patent Rights, such expenses shall be shared equally in the Territory and the responsibility of Company in the Excluded Territory, provided that if Company decides not to prosecute, maintain or

defend any Company Collaboration Patent Right, then Regeneron shall have the right to take over the prosecution, maintenance and defense of such Company Collaboration Patent Right and upon Regeneron's request Company shall assign such Company Collaboration Patent Right to Regeneron without additional consideration and Regeneron hereby grants Company (effective upon any such assignment), a non-exclusive license to all rights under such Patents except to the extent that Company grants in (A) Section 5.2 or (B) Schedule 9 exclusive rights to Regeneron under the Company Collaboration Patent Rights to use such to the extent it does not violate Regeneron's licenses; and (3) to the extent they are incurred with respect to Joint Patent Rights, the cost shall be shared equally unless the Controlling Party decides not to prosecute, maintain or defend any such rights, then the non-Controlling Party shall have the right to take over the prosecution, maintenance and defense of such Joint Patent Rights, and upon the non-Controlling Party's request the Controlling Party shall assign its interest in such Joint Patent Right to the non-Controlling Party without additional consideration and (2) any costs and expenses in connection with the enforcement (and any resulting recoveries) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights shall be the responsibility of the enforcing Party and the enforcing Party shall retain all recoveries with respect thereto; provided, however, that notwithstanding anything to the contrary in this Section 20.8(c), any recoveries for lost sales or profits of a product from any Infringement action hereunder shall be paid solely to or retained solely by the Party that is selling (or has the right to sell) such product.

(d) Upon Company's exercise of the Company Opt-In Right pursuant Section 2.7(c), (i) the provisions of Schedule 10 shall apply, (ii) the licenses from Regeneron and its Affiliates to Company referred to in Schedule 10 shall come into full force and effect (*provided* that Regeneron shall retain rights under the Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, Regeneron EYLEA Intellectual Property and Regeneron's interest in the Joint Intellectual Property to develop and Manufacture PDGF Products in the Field in the Territory solely in support of the commercialization of PDGF Products in the Excluded Territory and, to the extent agreed by the Parties, in the Territory) and the licenses from Company and its Affiliates to Regeneron referred to in Schedule 10 shall come into full force and effect; (iii) the licenses from Company to Regeneron in Sections 5.2 and 12.5 shall become effective (and the license grants in Section 5.2(a) shall be non-exclusive in the Field in the Territory (and further used only in the Field in the Territory in support of the development and commercialization of PDGF Products in the Excluded Territory) (and the license grants in Section 12.5 with respect to the EYLEA Trademark(s) shall be used only in the Field in the Territory in support of the development and commercialization of Licensed Products in the Excluded Territory); (iv) all costs and expenses (including all Other Shared Expenses) payable under this Agreement from and after the Opt-In Effective Date shall be borne solely by Company (other than that portion of the Development Costs and wind-down costs that are to be borne by Regeneron pursuant to Section 2.8(b)); and (v) this Agreement shall become effective in its entirety as of the Opt-In Effective Date, except as otherwise provided in this Section 20.8(d) and except for the following

provisions, which shall terminate and be of no further force and effect: Sections 5.1, 7.17(a), 8.7, 10.2(b), 10.2(c), 10.2(d), 10.3, 10.4, 10.5, 10.6, 10.10, 10.12, 11.2, 11.3, 11.4, 12.2, 12.5 (second and fourth sentences), 12.6, 18.2(a) through (e) (except to the extent related to Licensed Product sold, or in connection with the Development of such Licensed Product, administered on or prior to the Opt-In Effective Date), 18.2(f), 18.3 (with respect to Regeneron), 20.4, and Article II (other than Section 2.8(b)), Article III (other than Section 3.2, the first and third sentences of Section 3.6), Article IV, Article VI (other than Company's obligation to use Commercially Reasonable Efforts to Develop Licensed Products in the Field), Article VII (other than Sections 7.17(b) and 7.17(c), 7.18, 7.19, and Company's obligation to use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory), and Article IX. Notwithstanding the foregoing, Section 5.3 (any consent not to be unreasonably withheld in any country including any Major Market Country), 8.1 (without regard to the Global PDGF Development Plan), 8.2 (to the extent necessary for the Parties to fulfill their ongoing obligations), Article XIII and Article XIV shall become effective, *provided* that (A) in the event that Regeneron desires to abandon any Regeneron Collaboration Patent Rights or Regeneron Licensed Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Company 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 Collaboration Patent Right or Regeneron Licensed Patent Right, as applicable, with the applicable patent office) and Company shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Company's name in the Territory and Regeneron shall assign such Regeneron Collaboration Patent Right or Regeneron Licensed Patent Right, as applicable, to Company and such Patent shall thereafter cease to be a Regeneron Collaboration Patent Right or Regeneron Licensed Patent Right, as applicable, (provided, without limiting Regeneron's obligations under Section 7.17, Company hereby grants Regeneron (effective upon any such assignment), a non-exclusive license to all rights under such Patent except to Commercialize Licensed Products in the Field in the Territory; (B) Section 13.2(e)(ii) shall apply with respect to Joint Patent Rights in the Territory as well as in the Excluded Territory; (C) any costs and expenses in connection with the prosecution and maintenance (including any interference, opposition or reexamination) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights or the defense of any claim that any of the foregoing are invalid or unenforceable that would have been included in Other Shared Expenses shall be treated as follows: (1) to the extent they are incurred with respect to Regeneron Collaboration Patent Rights or Regeneron Licensed Patent Rights, such costs and expenses shall be shared equally, provided that if Regeneron decides not to pursue or defend any Regeneron Collaboration Patent Right or Regeneron Licensed Patent Right, then Company shall have the right to take over the prosecution, maintenance and defense of such Regeneron Collaboration Patent Right or Regeneron Licensed Patent Right, as applicable and upon Company's request Regeneron shall assign such Regeneron Collaboration Patent Right or Regeneron Licensed Patent Right, as applicable, to Company without additional consideration and the applicable non-exclusive license to Regeneron under such Patent as specified in clause (A) above

shall and is hereby granted to Regeneron effective upon such assignment; (2) to the extent they are incurred with respect to Company Collaboration Patent Rights, such expenses shall be the responsibility of Company; and (3) to the extent they are incurred with respect to Joint Patent Rights, the cost shall be shared equally unless the Controlling Party decides not to prosecute, maintain or defend any such rights, then the non-Controlling Party shall have the right to take over prosecution, maintenance and defense of such Joint Patent Rights and upon the non-Controlling Party's request the Controlling Party shall assign its interest in such Joint Patent Right to the non-Controlling Party without additional consideration; and (D) any costs and expenses in connection with the enforcement (and any resulting recoveries) of the Regeneron Collaboration Patent Rights, Regeneron Licensed Patent Rights, Company Collaboration Patent Rights or Joint Patent Rights shall be treated as follows: (1) to the extent incurred with respect to the Field in the Territory, such costs shall be the responsibility of Company and Company shall retain all recoveries with respect thereto and (2) to the extent incurred outside the Field in the Territory, such costs and recoveries shall be shared equally by the Parties; *provided, however*, that notwithstanding anything to the contrary in this Section 20.8(d), any recoveries for lost sales or profits of a product from any Infringement action hereunder shall be paid solely to or retained solely by the Party that is selling (or has the right to sell) such product.

(e) Upon termination of this Agreement pursuant to Section 20.6, (i) the provisions of Section 20.8(b) shall apply in the event that the EYLEA Agreement was terminated by Company pursuant to Section 19.3 or 19.4 of the EYLEA Agreement and (ii) the provisions of Section 20.8(a) shall apply in the event that the EYLEA Agreement was terminated for any other reason.

20.9 Survival of Obligations. Except as otherwise provided in this Article XX, Schedule 7, Schedule 8 or Schedule 9, 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 notwithstanding any expiration or termination of this Agreement:

(a) neither Company nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, 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);

(b) subject to the provisions of this Article XX, including Schedule 7, Schedule 8 and Schedule 9 to the extent applicable, the following provisions shall survive the expiration or termination of this Agreement and shall continue to be enforceable: Sections 5.4, 7.17(b), 7.17(c) (excluding clauses (A) and (B)), 8.1(c) (solely with respect to Regeneron and, insofar as necessary to fulfill its ongoing regulatory obligations, Company), 8.5, 10.7, 10.8, 10.9, 10.11 and 11.3 (*provided* that the Parties shall use reasonable efforts to resolve any Legal Disputes themselves, not through the

JSC, prior to escalation to the Executive Officers), 11.4 (solely with respect to Audit Disputes), 12.1, 15.1, 15.2, 20.8, 20.9 and Article XVII (excluding Section 17.5, Section 17.6(a) and the second sentence of Section 17.7), Article XVIII (other than Section 18.2(a) through (e), which shall survive solely to the extent related to Licensed Product sold, or in connection with the Development of such Licensed Product, administered on or prior to the effective date of the termination of this Agreement), Article XXI, and solely with respect to Joint Inventions and Joint Patent Rights, Article XIII and Article XIV, and any other provisions that by their nature are intended to survive any such expiration or termination; and

(c) such expiration or termination and this Article XX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

## **ARTICLE XXI MISCELLANEOUS**

21.1 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 XI, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the courts of general jurisdiction of the State of New York and the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding (other than appeals therefrom) arising out of or in connection with this Agreement, and agree not to commence any action or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action or proceeding brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 21.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

21.2 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.

21.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 11 attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

21.4 Entire Agreement. This Agreement contains 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.

21.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Company and Regeneron.

21.6 Headings. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.

21.7 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.

21.8 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is or may be 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 17.6. 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 such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

21.9 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Company or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Company or (b) the prior written consent of Company in the case of an assignment by Regeneron, except in each case ((a) or (b)), (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, 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; *provided*, that in each case ((i) or (ii)), (X) [\*\*\*\*\*] and (Y) the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment and any such Affiliate or other party to whom this Agreement is assigned shall agree in writing to be bound by the terms of this Agreement. Any attempted assignment in violation hereof shall be void.

21.10 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 Company Indemnitees to the extent provided in the last sentence of Section 21.13.

21.11 Affiliates. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Without limiting the foregoing, each Party shall take reasonable efforts to ensure that each of its Affiliates engaged in the development or commercialization of ophthalmic products or technologies and that have know-how or technologies that are materially useful for the Development or Commercialization of Licensed Products, engage in the Development or Commercialization of Licensed Products or otherwise license their Know-How under this Agreement. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party prompt 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, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) that such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product or will otherwise license its Know-How 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 that 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.

21.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but that together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

21.13 Third-Party Beneficiaries. 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 XVIII is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Company Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

21.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Company 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 Company, and Company'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.

21.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR COMPANY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OR LOST 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. HOWEVER, NOTHING IN THIS SECTION 21.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD PARTY CLAIMS.

21.16 Standstill Agreement. During the period commencing on the Effective Date and expiring on the date which is five (5) years after the end of the Term, neither Company nor any of its Affiliates (for purposes of this Section 21.16, Company, together with such Affiliates, being referred to as the "Investor") shall:



(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock or any securities convertible into or exchangeable for Shares of Then Outstanding Capital Stock, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock, if after giving effect to such acquisition (and assuming the conversion of all convertible securities), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended) twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock; *provided, however*, that notwithstanding the provisions of this Section 21.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted in Investor's ownership totaling twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock;

(b) directly or indirectly, propose or nominate for election to the Board of Directors of Regeneron any Person whose nomination has not been approved by a majority of the Board of Directors of Regeneron, or vote or cause to be voted in favor of such Person for election to the Board of Directors of Regeneron any Shares of Then Outstanding Capital Stock;

(c) directly or indirectly, accept or support a tender, exchange or other offer or proposal by any other Person or group (an "Offeror") the consummation of which would result in a Change of Control of Regeneron (an "Acquisition Proposal");

(d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Securities Exchange Act) in opposition to the recommendation of a majority of the Board of Directors of Regeneron with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Capital Stock of Regeneron or any of its Affiliates;

(e) deposit any Shares of Then Outstanding Capital Stock in a voting trust or subject any Shares of Then Outstanding Capital Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Capital Stock;

(f) act in concert with any Third Party to take any action in clauses (a) through (e) above;

(g) request or propose that Regeneron or any of Regeneron's officers or its Board of Directors amend, waive, or consider the amendment or waiver of any provisions set forth in this Section 21.16; or

(h) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in clauses (a) through (g) above;

*provided* that the mere voting of any Shares of Then Outstanding Capital Stock held by the Company shall not constitute a violation of any of clauses (a) through (f) above.

21.17 Termination of Standstill. Provided Investor has not violated Section 21.16(d), (f) or (h) with respect to the Offeror referred to in this Section 21.17, the restrictions contained in Section 21.16 shall terminate upon the earlier to occur of (a) the public announcement by an Offeror of an Acquisition Proposal; (b) the acquisition by an Offeror (other than Dr. Leonard Schleifer or his Affiliates) of beneficial ownership of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by the Offeror, represents more than [\*\*\*\*\*] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock; (c) the issuance by Regeneron to a Third Party (other than an underwriter in a public offering which promptly distributes such shares to the public) of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by such Third Party, represents more than [\*\*\*\*\*] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock, if Regeneron does not enter into a standstill agreement with such Third Party for a time period and upon terms substantially similar to the provisions of Section 21.16; (d) a sale of all or substantially all of the assets of Regeneron (other than to a wholly owned subsidiary of Regeneron); or (e) a liquidation or dissolution of Regeneron, which would give rise to a termination of this Agreement pursuant to Section 20.3; *provided, however*, that if any of the transactions referred to in (a), (b) or (d) above terminates and Regeneron has not made a public announcement of its intent to solicit or engage in a transaction referred to in Section 21.16 (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of Regeneron, then the restrictions contained in Section 21.16 shall again be applicable.

21.18 Rejection of Agreement in Bankruptcy. In the event that this Agreement is 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(35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any Patents 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-subject 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

such rejection unless the non-subject Party fails to exercise its rights under Section 365(n)(1)(B) of the Bankruptcy Code (or its foreign equivalents). For clarity, if the non-subject 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 provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (y) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (z) if not delivered under clause (y) above, following the rejection of this Agreement by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy upon written request therefor by the non-subject Party.

21.19 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 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.

21.20 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the words "will" and "shall" shall have the same meaning. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. This Agreement has been prepared jointly and will not be construed against either Party.

21.21 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule means references to such Article, Section or Schedule of this Agreement, (b) references in any section to any clause are references to such clause of such section and (c) 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, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

IN WITNESS WHEREOF, Company and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

BAYER HEALTHCARE LLC

By /s/ R. Scott Meece  
Name: R. Scott Meece  
Title: General Counsel and Senior Vice President

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray Goldberg  
Name: Murray A. Goldberg  
Title: Senior Vice President, Administration

SCHEDULE 1

Manufacturing Cost

“Manufacturing Cost” as used in this Agreement shall mean (a) with respect to any Formulated Bulk Product and/or comparator agent or placebos, the Fully Burdened Manufacturing Cost and (b) with respect to Finished Product and/or comparator agent or placebos, the Cost of Finishing, as provided in this Schedule 1.

A. General Principles

1. Regeneron or its Affiliates shall supply Formulated Bulk Product for Clinical Supply Requirements and Commercial Supply Requirements at the “Fully Burdened Manufacturing Cost”, defined and calculated as described in Section B below.

2. To the extent that a Manufacturing Plan includes the use of Formulated Bulk Product, comparator agent or placebos or Finished Product that was Manufactured by Regeneron prior to the Effective Date or outside of the Collaboration (whether prior to or after the Effective Date), Regeneron or its Affiliates shall supply such Formulated Bulk Product, comparator agent, placebo or Finished Product at its actual average Fully Burdened Manufacturing Cost, calculated as described in Section B below, plus the Cost of Finishing, as described in Section C below.

3. [\*\*\*\*\*].

4. If a Manufacturing Plan calls for Regeneron or its Affiliates to reserve its facility to Manufacture Formulated Bulk Product and/or comparator agent or placebos, including, without limitation, purifying/processing the bulk drug substance, and the Parties subsequently amend the Manufacturing Plan such that the facility is not used as originally set forth therein, then Regeneron shall be reimbursed for what otherwise would have been its Fully Burdened Manufacturing Cost as if such facility had been used for Manufacturing as originally required in the Manufacturing Plan, except for such variable costs as are actually avoided or mitigated; *provided, however*, that Regeneron shall not be reimbursed hereunder if such amendment of the Manufacturing Plan has been agreed upon at least twelve (12) months prior to its effective date; *provided, further*, that Regeneron shall use its commercially reasonable efforts to minimize, avoid and/or mitigate the costs (e.g., by rescheduling production of other customers).

B. [\*\*\*\*\*]

1. [\*\*\*\*\*].

2. [\*\*\*\*\*]

(a) [\*\*\*\*\*]

(i) [\*\*\*\*\*]

(ii) [\*\*\*\*\*]

(iii) [\*\*\*\*\*]

(iv) [\*\*\*\*\*]

(b) [\*\*\*\*\*]

(i) [\*\*\*\*\*]

(ii) [\*\*\*\*\*]

(c) [\*\*\*\*\*]

3. [\*\*\*\*\*]

C. [\*\*\*\*\*]

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## 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”) equal to (a) the Territory Profit Split for such Quarter (as set forth in Part I), plus (b) the Regeneron Reimbursement Amount for such Quarter (as set forth in Part II), plus or minus (c) the Global True-Up (as set forth in Part III). In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Company to Regeneron in accordance with the terms set forth in Article X. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Company in accordance with the terms set forth in Article X. An example of the Quarterly True-Up is shown in Part V.

For clarity, the payment of (a) the Supplemental Option Payment, (b) the Additional Antibody Payment, and (c) any Development Costs and other amounts by a Party to a Proposing Party pursuant to Section 6.3, in each case ((a) - (c)), shall not be subject to the Quarterly True-Up mechanism set forth in Article X and this Schedule 2.

### I. TERRITORY PROFIT SPLIT

The “Territory Profit Split” shall mean fifty percent (50%) of Territory Profits in a Quarter. “Territory Profits” shall mean aggregate Net Sales in the Territory in the Quarter less the sum of aggregate COGS and aggregate Shared Promotion Expenses incurred by both Parties in the Territory in the Quarter.

An example of a calculation of the Territory Profit Split in a Quarter would be:

	Aggregate	Company	Regeneron	Territory Profit Split
Net Sales in the Territory	1000	1000		
COGS	(50)	(50)	0	
Shared Promotion Expenses	(350)	(300)	(50)	
Territory Profits	600			300

## II. REGENERON REIMBURSEMENT AMOUNT

The “Regeneron Reimbursement Amount” for a Quarter shall mean (a) Shared Promotion Expenses incurred by Regeneron in the Quarter (if any), plus (b) Commercial Supply Costs incurred by Regeneron in the Quarter (if any), plus (c) Development Costs incurred by Regeneron under the Territory PDGF Development Plan in the Quarter (if any).

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Promotion Expenses 50

Regeneron Commercial Supply Costs 15

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Regeneron Reimbursement Amount 65

## III. GLOBAL TRUE-UP

The “Global True-Up” for a Quarter shall mean:

(a) the sum of (i) fifty percent (50%) of the sum of (A) aggregate Development Costs incurred by both Parties under the Territory PDGF Development Plan in the Quarter (excluding Development Overruns in connection with the Territory PDGF Development Plan that were not approved by both Parties’ representatives on the JSC) and (B) aggregate Other Shared Expenses incurred by both Parties in the Quarter; and (ii) twenty-five percent (25%) of the sum of (A) aggregate Development Costs incurred by both Parties under the Global PDGF Development Plan in the Quarter (excluding Development Overruns in connection with the Global PDGF Development Plan that were not approved by both Parties’ representatives on the JSC) and (B) aggregate Global HQ Costs incurred by both Parties in the Quarter; minus

(b) one hundred percent (100%) of the sum of (i) Development Costs incurred by Company under the Territory PDGF Development Plan in the Quarter (excluding Development Overruns in connection with the Territory PDGF Development Plan that were not approved by both Parties’ representatives on the JSC); (ii) Other Shared Expenses incurred by Company in the Quarter; (iii) Development Costs incurred by Company under the Global PDGF Development Plan in the Quarter (excluding Development Overruns in connection with the Global PDGF Development Plan that were not approved by both Parties’ representatives on the JSC); and (iv) Global HQ Costs incurred by Company in the Quarter.

If the Global True-Up is a positive number, it shall be added in the calculation of the Quarterly True-Up and, if it is a negative number, the absolute value of such amount shall be subtracted in the calculation of the Quarterly True-Up.



An example of a calculation of the Global True-Up in a Quarter would be:

	Aggregate	Company	Regeneron	Global True-Up
<b>Development Costs under Territory</b>				
PDGF Development Plan	60	20	40	
Other Shared Expenses	40	30	10	
<i>Sub-Total</i>	100	50	50	—
<b>Development Costs under Global PDGF</b>				
Development Plan	120	40	80	
Global HQ Costs	20	10	10	
<i>Sub-Total</i>	140	50	90	(15)
<b>Total</b>	<b>240</b>	<b>100</b>	<b>140</b>	<b>(15)</b>

#### IV. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-up in a Quarter would be:

Territory Profit Split 300  
 Regeneron Reimbursement Amount 65  
 Global True-Up (15)

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Quarterly True-up 350

In this example, Company would pay Regeneron 350 in accordance with the terms set forth in Article X.

### SCHEDULE 3

#### Milestone Payments and Aventis Royalties

##### I. REGENERON DEVELOPMENT MILESTONE PAYMENT

Company shall pay to Regeneron the Regeneron Development Milestone Payment upon the achievement of the applicable milestone event set forth below (such milestone, the “Regeneron Development Milestone”) for the first Licensed Product to achieve such milestone pursuant to the terms of Section 10.1(b). For clarity, the Regeneron Development Milestone Payment shall be payable only upon the first achievement of the Regeneron Development Milestone and no amounts shall be due for subsequent or repeated achievements of such milestone, whether for the same or a different Licensed Product.

<b>Milestone</b>	<b>Payment</b>	<b>Milestone Event</b>
1.	US \$20,000,000	Receipt by either Party of the first Marketing Approval of the first Licensed Product by the EMA or in any Major Market Country.

##### II. AVENTIS DEVELOPMENT MILESTONE PAYMENTS

Subject to the following sentence, each Party shall be responsible for fifty percent (50%) of the following milestone payments that are attributable to the Development of Licensed Products in the Field in the Territory and payable pursuant to the Aventis Letter Agreement (each such payment, an “Aventis Development Milestone Payment” and collectively, the “Aventis Development Milestone Payments”). Company shall pay to Regeneron fifty percent (50%) of each Aventis Development Milestone Payment set forth below for which the corresponding milestone event is achieved on or prior to the date of the Company Opt-Out Exercise and twenty-five percent (25%) of each Aventis Development Milestone Payment for which the corresponding milestone event is achieved after the date of the Company Opt-Out Exercise, in each case, within ten (10) Business Days from the receipt of an invoice from Regeneron related to the achievement of the corresponding milestone event (each such milestone event, an “Aventis Development Milestone”) for the first Licensed Product to achieve such milestone, which, in each case, shall not be reduced by any withholding or similar taxes, subject, however, to Section 21.9, for so long as Regeneron is obligated to pay such Aventis Development Milestone Payments to Aventis under the Aventis Letter Agreement. For clarity, each Aventis Development Milestone Payment shall be payable only upon the first achievement of such Aventis Development Milestone and no amounts shall be due for subsequent or repeated achievements of such milestone, whether for the same or a different Licensed Product. Notwithstanding anything to the contrary in this Agreement (including this Section II of Schedule 3), Company shall be obligated to pay to Regeneron its applicable share of the Aventis Development Milestone Payments as and

when Regeneron is obligated to pay such Aventis Development Milestone Payments to Aventis pursuant to the terms of the Aventis Letter Agreement.

<b>Milestone</b>	<b>Payment</b>	<b>Milestone Event</b>
1.	US \$5,000,000	[*****]
2.	US \$5,000,000	[*****]
3.	US \$10,000,000	[*****]
4.	US \$20,000,000	[*****]

### III. AVENTIS ROYALTIES

Company shall pay to Regeneron a royalty on Net Sales of each Licensed Product in the Field in the Territory during each Quarter during the PDGF Royalty Term (all such royalties, the “Aventis Royalties”) for so long as Regeneron is obligated to pay such Aventis Royalties to Aventis under the Aventis Letter Agreement at the following rates:

<b>Licensed Product</b>	<b>Royalty Rate</b>
Monotherapy PDGF Product	[*****]
PDGF Product (other than a Monotherapy PDGF Product that is a Licensed Product)	[*****]

Company shall pay the Aventis Royalties to Regeneron pursuant to the terms of Section 10.1(e). Notwithstanding anything to the contrary in this Agreement (including this Section III of Schedule 3), Company shall be obligated to pay to Regeneron the Aventis Royalties as and when Regeneron is obligated to pay such Aventis Royalties to Aventis pursuant to the terms of the Aventis Letter Agreement.

SCHEDULE 4

Existing Licenses

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SCHEDULE 5

Initial Development Plan

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SCHEDULE 6

Regeneron Licensed Patent Rights

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## SCHEDULE 7

### General Termination Arrangements.

1. Company 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 of Regeneron and its Affiliates, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any New Information and Party Information of Regeneron and its Affiliates. In addition, at Regeneron's request, Company shall collect and transfer to Regeneron any remaining inventory of Licensed Product Promotional Materials, Licensed Product sales training materials, Licensed Product samples, and Licensed Product inventory. Regeneron and its Affiliates shall have the right to use and disclose any New Information or Party Information of Company, in each case, related to the Licensed Products (including the Manufacture or use thereof) in connection with Regeneron's Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory, including, without limitation, to existing or potential distributors, Sublicensees, Affiliates, or collaboration partners, under substantially the same confidentiality obligations as are set forth in Article XVII except that the confidentiality obligations shall have a term of at least five (5) years. Notwithstanding the foregoing, Company may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Company shall grant, and does hereby grant, to Regeneron and its Affiliates a worldwide, fully paid-up, royalty-free, (a) exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Collaboration Intellectual Property, Company's interest in the Joint Intellectual Property, the Product Trademark(s) to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products in the Field in the Territory; (b) co-exclusive (with Company and its Affiliates) right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Collaboration Intellectual Property, Company's interest in the Joint Intellectual Property and the Product Trademark(s) to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products that are not Licensed Products outside the Field in the Territory; and (c) non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under Company EYLEA Intellectual Property and EYLEA Trademark(s) to make, have made, develop, use, sell, offer to sell, have sold, import and export (1) PDGF Products in the Field in the Territory and (2) PDGF Products outside the Field in the Territory; and (d) non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under Company Future Non-Collaboration Rights to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products for use in the Field; *provided, however*, such license shall be limited only to Licensed Products that are (A) in substantially the form and

formulations and (B) for substantially the indications and using such modes of administration and (C) using substantially those Manufacturing processes as are used to Manufacture the Licensed Product, in each case ((A), (B) and (C)) as the Licensed Product existed on the earlier of (1) the first Marketing Approval anywhere in the world and (2) four (4) years after the termination date.

3. Company shall use Commercially Reasonable Efforts to provide 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 Licensed Products in the Field. 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, without limitation, the following:

(a) Company 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 Company or its Affiliates or any of its Sublicensees to the extent specifically relating to Licensed Products.

(b) Company shall assign and transfer to Regeneron (or its nominee) Company's entire right, title and interest in and to all Product Trademarks and Promotional Materials relating to Licensed Products; *provided* that nothing herein is intended to convey any rights in or to Company's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Company 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 Licensed Products in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to any Licensed Products in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Company, *provided* that all such information shall be in a format that is reasonably accessible to Regeneron using non-proprietary systems and Regeneron shall be responsible for any costs associated with Company converting such information into a format reasonably accessible to Regeneron.

(d) Company shall use Commercially Reasonable Efforts for a period up to twelve (12) months from the applicable date of termination (subject to extension as reasonably requested by Regeneron to the extent necessitated by regulatory delays outside Regeneron's reasonable control) to assign to Regeneron any applicable sublicenses to the extent related to any Licensed Product and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory, as reasonably requested by Regeneron and subject to the German Employee Invention Act.



(e) Without limitation of Company's other obligations under this Schedule 7, to the extent Company or its Affiliate is Manufacturing (in whole or in part) Licensed Products for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Company (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of Licensed Products, and Regeneron shall purchase such Licensed Products, at the same price, and on such other terms and conditions on which Company was supplying, or in the absence of termination would have been required to supply, such Licensed Products, [\*\*\*\*\*] of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Company that Regeneron is able to Manufacture or have Manufactured Licensed Products on comparable financial terms.

4. Company shall grant, and does hereby grant, to Regeneron and its Affiliates a worldwide, fully paid-up, royalty-free, right of reference and use, with the right to grant further rights of reference and use unless otherwise restricted by any Existing License or New License, under the EYLEA Regulatory Documentation to Exploit PDGF Products in the Territory and the Excluded Territory. In addition, Company shall permit Regeneron, upon Regeneron's reasonable notice and during regular business hours, to access and review and copy any EYLEA Regulatory Documentation and, to the extent not transferred pursuant to paragraph 3, information, data and materials of the types identified below that relate to Licensed Products. Without limiting the provisions of Section 20.9, the following provisions shall survive any termination of this Agreement triggering the application of this Schedule 7 and shall continue to be enforceable: Sections 8.1(d), 8.2(b) (solely to the extent related to EYLEA), and 8.3.

5. 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 Licensed Products in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

6. Notwithstanding anything to the contrary in this Schedule 7, Regeneron shall not be required to provide Company any consideration in exchange for the licenses, transfers, assignments or other rights granted to it pursuant to the provisions of this Schedule 7; *provided, however*, that Regeneron shall be solely responsible for paying (a) any royalties, fees or other consideration that Company 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 and (b) all amounts owed to Third Parties and all reasonable Out-of-Pocket Costs and FTE costs incurred by Company in meeting its obligations under any Existing Licenses or New Licenses, in each case, as a result of Company's (or its Affiliate's or Sublicensee's) Development, Manufacturing and Commercializing of Licensed Products in the Field in the Territory.

## SCHEDULE 8

### Company Termination Arrangements for Regeneron Breach or Insolvency

1. Company 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 of Regeneron and its Affiliates, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any New Information and Party Information of Regeneron and its Affiliates. In addition, at Regeneron's request, Company shall collect and transfer to Regeneron any remaining inventory of Licensed Product (other than Combination PDGF Products) Promotional Materials, Licensed Product (other than Combination PDGF Products) sales training materials, Licensed Product (other than Combination PDGF Products) samples, and Licensed Product (other than Combination PDGF Products) inventory. Regeneron and its Affiliates shall have the right to use and disclose any New Information or Party Information of Company, in each case, related to the Licensed Products (other than Combination PDGF Products) (including the Manufacture or use thereof) in connection with Regeneron's Development, Manufacture or Commercialization of Licensed Products (other than Combination PDGF Products) in the Field in the Territory, including, without limitation, to existing or potential distributors, Sublicensees, Affiliates, or collaboration partners, under substantially the same confidentiality obligations as are set forth in Article XVII except that the confidentiality obligations shall have a term of at least five (5) years. Notwithstanding the foregoing, Company may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Company shall grant, and does hereby grant, to Regeneron and its Affiliates (a) a fully paid-up, royalty-free, exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Collaboration Intellectual Property and Company's interest in the Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products (other than Combination PDGF Products) in the Field in the Territory and PDGF Products inside and outside the Field in the Excluded Territory, in each case, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (b) a fully paid-up, royalty-free, exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Collaboration Intellectual Property and Company's interest in the Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products (other than Combination PDGF Products) outside the Field in the Territory and Licensed Products inside and outside the Field in the Excluded Territory, in each case, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (c) a fully paid-up, royalty-free, co-exclusive (with Company and its Affiliates) right and license, with the right to sublicense unless otherwise restricted by

any Existing License or New License, under the Company Collaboration Intellectual Property and Company's interest in the Joint Intellectual to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products that are not Licensed Products outside the Field in the Territory, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (d) a fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under Company EYLEA Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products (other than Combination PDGF Products) inside and outside the Field in the Territory, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (e) a fully paid-up, royalty-free, exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under Company EYLEA Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products inside and outside the Field in the Excluded Territory, including, without limitation, for use with EYLEA and (f) a worldwide, fully paid-up, royalty-free, right of reference and use, with the right to grant further rights of reference and use unless otherwise restricted by any Existing License or New License, under the EYLEA Regulatory Documentation to Exploit PDGF Products (other than Combination PDGF Products in the Field in the Territory) inside and outside the Field in the Territory, and PDGF Products inside and outside the Field in the Excluded Territory, in each case, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Field in the Territory).

3. Company shall provide reasonable cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to Develop, Manufacture and Commercialize the Licensed Products (other than Combination PDGF Products) in the Field in the Territory including, without limitation, for use with EYLEA, for a period of six (6) months after the effective date of termination of this Agreement. 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, without limitation, the following:

(a) Company 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 Company or its Affiliates or any of its Sublicensees to the extent specifically relating to Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory).

(b) Company shall assign and transfer to Regeneron (or its nominee) Company's entire right, title and interest in and to all Product Trademarks and Promotional Materials relating to Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory); *provided* that nothing herein is intended to convey any rights in or to Company's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Company 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 Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to any Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Company.

(d) Company shall use Commercially Reasonable Efforts for a period up to twelve (12) months from the applicable date of termination (subject to extension as reasonably requested by Regeneron to the extent necessitated by regulatory delays outside Regeneron's control) to assign to Regeneron any applicable sublicenses to the extent related to any Licensed Product, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of any Licensed Product, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field in the Territory, as reasonably and promptly requested by Regeneron and subject to the German Employee Invention Act.

(e) Without limitation of Company's other obligations under this Schedule 8, to the extent Company or its Affiliate is Manufacturing (in whole or in part) Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Company (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory), and Regeneron shall purchase such Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory), at the same price, and on such other terms and conditions on which Company was supplying, or in the absence of termination would have been required to supply, such Licensed Products (other than Combination PDGF Products), [\*\*\*\*\*] of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Company that Regeneron is able to Manufacture or have Manufactured Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) on comparable financial terms.

4. In addition, Company shall permit Regeneron, upon Regeneron's reasonable notice and during regular business hours, to access and review and copy any EYLEA Regulatory Documentation and, to the extent not transferred pursuant to paragraph 3, information, data and materials of the types identified below that relate to

Combination PDGF Products; *provided, however*, that with respect to the Territory, Regeneron shall only have the right to use such information, data and materials to develop and commercialize Licensed Products that are not Combination PDGF Products and Regeneron shall not have the right to use such information, data and materials to develop and commercialize Combination PDGF Products in the Territory. Without limiting the provisions of Section 20.9, the following provisions shall survive any termination of this Agreement triggering the application of this Schedule 8 and shall continue to be enforceable: Sections 8.1(d), 8.2(b) (solely to the extent related to EYLEA), and 8.3 (*provided, however*, that nothing in Section 8.3 shall be intended to grant Regeneron rights to exploit Combination PDGF Products in the Territory).

5. Notwithstanding anything to the contrary in this Schedule 8, Regeneron shall not be required to provide Company any consideration in exchange for the licenses, transfers, assignments or other rights granted to it pursuant to the provisions of this Schedule 8; *provided, however*, that, except as otherwise provided in this Agreement, Regeneron shall be solely responsible for paying (a) any royalties, fees or other consideration that Company 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; and (b) all amounts owed to Third Parties and all reasonable Out-of-Pocket Costs and FTE costs incurred by Company in meeting its obligations under any Existing Licenses or New Licenses, in each case, as a result of Company's (or its Affiliate's or Sublicensee's) Development, Manufacturing and Commercializing of Licensed Products in the Field in the Territory.

6. 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 Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

## SCHEDULE 9

### Company Opt-Out and Safety Termination Arrangements

1. Company 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 of Regeneron and its Affiliates, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any New Information and Party Information of Regeneron and its Affiliates. In addition, at Regeneron's request, Company shall collect and transfer to Regeneron any remaining inventory of Licensed Product (other than Combination PDGF Products) Promotional Materials, Licensed Product (other than Combination PDGF Products) sales training materials, Licensed Product (other than Combination PDGF Products) samples, and Licensed Product (other than Combination PDGF Products) inventory. Regeneron and its Affiliates shall have the right to use and disclose any New Information or Party Information of Company, in each case, related to the Licensed Products (other than Combination PDGF Products) (including the Manufacture or use thereof) in connection with Regeneron's Development, Manufacture or Commercialization of Licensed Products (other than Combination PDGF Products) in the Field in the Territory, including, without limitation, to existing or potential distributors, Sublicensees, Affiliates, or collaboration partners, under substantially the same confidentiality obligations as are set forth in Article XVII except that the confidentiality obligations shall have a term of at least five (5) years. Notwithstanding the foregoing, Company may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Company shall grant, and does hereby grant, to Regeneron and its Affiliates (a) a fully paid-up, royalty-free, exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Collaboration Intellectual Property and Company's interest in the Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products (other than Combination PDGF Products) in the Field in the Territory and PDGF Products inside and outside the Field in the Excluded Territory, in each case, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (b) a fully paid-up, royalty-free, exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Collaboration Intellectual Property and Company's interest in the Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products (other than Combination PDGF Products) outside the Field in the Territory and Licensed Products inside and outside the Field in the Excluded Territory, in each case, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (c) a fully paid-up, royalty-free, co-exclusive (with Company and its Affiliates) right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Collaboration Intellectual

Property and Company's interest in the Joint Intellectual to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products that are not Licensed Products outside the Field in the Territory, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (d) a fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under Company EYLEA Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export (1) PDGF Products (other than Combination PDGF Products) inside and outside the Territory, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory); (e) a fully paid-up, royalty-free, exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under Company EYLEA Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products inside and outside the Field in the Excluded Territory, including, without limitation, for use with EYLEA; (f) a fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Non-Collaboration Patent Rights, Company Future Non-Collaboration Patent Rights and Party Information of Company to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products (other than Combination PDGF Products) in the Field in the Territory and Licensed Products in the Field in the Excluded Territory, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Territory), *provided, however*, that such license with respect to Company Future Non-Collaboration Patent Rights shall be limited to the Licensed Product (A) in substantially the form and formulation, (B) for substantially those indications and using such modes of administration and (C) using substantially those Manufacturing processes as are used to Manufacture the Licensed Product, in each case ((A), (B) and (C)), as Licensed Product existed on the earlier of (1) first Marketing Approval anywhere in the world and (2) four (4) years after the termination date; and (g) a worldwide, fully paid-up, royalty-free, right of reference and use, with the right to grant further rights of reference and use unless otherwise restricted by any Existing License or New License, under the EYLEA Regulatory Documentation to Exploit PDGF Products (other than Combination PDGF Products in the Field in the Territory) inside and outside the Field in the Territory, and PDGF Products inside and outside the Field in the Excluded Territory, in each case, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Field in the Territory).

3. Company shall provide 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 Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field. 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, without limitation, the following:

(a) Company 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 Company or its Affiliates or any of its Sublicensees to the extent specifically relating to Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory).

(b) Company shall assign and transfer to Regeneron (or its nominee) Company's entire right, title and interest in and to all Product Trademarks and Promotional Materials relating to Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory); *provided* that nothing herein is intended to convey any rights in or to Company's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Company 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 Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to any Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Company, *provided* that all such information shall be in a format that is reasonably accessible to Regeneron using non-proprietary systems and Regeneron shall be responsible for any costs associated with Company converting such information into a format reasonably accessible to Regeneron.

(d) Company shall use Commercially Reasonable Efforts for a period up to twelve (12) months from the applicable date of termination (subject to extension as reasonably requested by Regeneron to the extent necessitated by regulatory delays outside Regeneron's reasonable control) to assign to Regeneron any applicable sublicenses to the extent related to any Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of any Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field in the Territory, as reasonably requested by Regeneron and subject to the German Employee Invention Act.

(e) Without limitation of Company's other obligations under this Schedule 9, to the extent Company or its Affiliate is Manufacturing (in whole or in part) Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Company (or its



Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory), and Regeneron shall purchase such Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory), at the same price, and on such other terms and conditions on which Company was supplying, or in the absence of termination would have been required to supply, such Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory), [\*\*\*\*\*] of termination of this Agreement or such shorter period if Regeneron notifies Company that Regeneron is able to Manufacture or have Manufactured Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) on comparable financial terms.

4. In addition, Company shall permit Regeneron, upon Regeneron's reasonable notice and during regular business hours, to access and review and copy any EYLEA Regulatory Documentation and, to the extent not transferred pursuant to paragraph 3, information, data and materials of the types identified below that relate to Combination PDGF Products. Without limiting the provisions of Section 20.9, the following provisions shall survive any termination of this Agreement triggering the application of this Schedule 9 and shall continue to be enforceable: Sections 8.1(d), 8.2(b) (solely to the extent related to EYLEA), and 8.3.

5. 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 Licensed Products, including, without limitation, for use with EYLEA (other than Combination PDGF Products in the Territory) in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

6. Notwithstanding anything to the contrary in this Schedule 9, Regeneron shall not be required to provide Company any consideration in exchange for the licenses, transfers, assignments or other rights granted to it pursuant to the provisions of this Schedule 9; *provided, however*, that Regeneron shall be solely responsible for paying (a) any royalties, fees or other consideration that Company 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; and (b) all amounts owed to Third Parties and all reasonable Out-of-Pocket Costs and FTE costs incurred by Company in meeting its obligations under any Existing Licenses or New Licenses, in each case, as a result of Company's (or its Affiliate's or Sublicensee's) Development, Manufacturing and Commercializing of Licensed Products in the Field in the Territory.

## SCHEDULE 10

### Company Opt-In Arrangements Upon Regeneron Opt-Out

1. Regeneron shall grant, and does hereby grant, to Company and its Affiliates (a) a fully paid-up, royalty-free, co-exclusive (with Regeneron and its Affiliates and Sublicensees, subject to Section 20.8(d)) right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License (or any Existing License or New License (as such terms are defined in the EYLEA Agreement)), under the Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, Regeneron EYLEA Intellectual Property and Regeneron's interest in the Joint Intellectual Property to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products (other than Combination PDGF Products), including, without limitation, for use with EYLEA (but not as a Combination PDGF Product), in the Field in the Territory; (b) a fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License (or any Existing License or New License (as such terms are defined in the EYLEA Agreement)), under the Regeneron Collaboration Intellectual Property, Regeneron Licensed Intellectual Property, Regeneron EYLEA Intellectual Property and Regeneron's interest in the Joint Intellectual Property to make, have made, develop, use, import and export Licensed Products (other than Combination PDGF Products), including, without limitation, for use with EYLEA (but not as a Combination PDGF Product), in the Field in the Excluded Territory solely in support of the Development and Commercialization of Licensed Products in the Territory; (c) a fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Regeneron Non-Collaboration Patent Rights, Regeneron Future Non-Collaboration Patent Rights and Party Information of Regeneron to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products (other than Combination PDGF Products) in the Field in the Territory, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product), *provided, however*, that such license with respect to Regeneron Future Non-Collaboration Patent Rights shall be limited to the Licensed Product (A) in substantially the form and formulation, (B) for substantially those indications and using such modes of administration and (C) using substantially those Manufacturing processes as are used to Manufacture the Licensed Product, in each case ((A), (B) and (C)), as Licensed Product existed on the earlier of (1) first Marketing Approval in any country and (2) four (4) years after Regeneron Opt-Out Exercise; and (d) a fully paid-up, royalty-free, non-exclusive right of reference and use, with the right to grant further rights of reference and use unless otherwise restricted by any Existing License or New License (or any Existing License or New License (as such terms are defined in the EYLEA Agreement)), under (i) the EYLEA Regulatory Documentation and (ii) all regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its Sublicensees under this Agreement to the extent specifically relating to Licensed Products (other than Combination PDGF Products) in the Field in the Territory, in each case ((i) and (ii)), to make, have made, develop, use, sell, offer to sell,

have sold, import and export Licensed Products (other than Combination PDGF Products), including, without limitation, for use with EYLEA (but not as a Combination PDGF Product), in the Field in the Territory.

2. Company shall grant, and does hereby grant, to Regeneron and its Affiliates (a) a fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Future Non-Collaboration Rights (1) to make, have made, develop, use, sell, offer to sell, have sold, import and export Licensed Products in the Field in the Excluded Territory and (2) to make, have made, develop, use, import and export Licensed Products in the Field in the Territory for the sole purpose of developing and commercializing Licensed Products in the Field in the Excluded Territory, *provided, however*, that such license shall be limited to the Licensed Product (i) in substantially the form and formulation, (ii) for substantially those indications and using such modes of administration and (iii) using substantially those Manufacturing processes as are used to Manufacture the Licensed Product, in each case ((i), (ii) and (iii)), as Licensed Product existed on the earlier of (A) the first Marketing Approval anywhere in the world and (B) four (4) years after the termination date; and (b) a fully paid-up, royalty-free, non-exclusive right of reference and use, with the right to grant further rights of reference and use unless otherwise restricted by any Existing License or New License (or any Existing License or New License (as such terms are defined in the EYLEA Agreement)), under (i) the EYLEA Regulatory Documentation and (ii) all regulatory filings (including Registration Filings) made or obtained by Company or its Affiliates or any of its Sublicensees under this Agreement, in each case (i) and (ii), (1) to make, have made, develop, use, sell, offer to sell, have sold, import and export PDGF Products outside the Field in the Territory and PDGF Products inside and outside the Field in the Excluded Territory, including, without limitation, for use with EYLEA (but not as a Combination PDGF Product in the Field in the Territory) and (2) to make, have made, develop, use, import and export PDGF Products in the Field in the Territory for the sole purpose of developing and commercializing PDGF Products in the Field in the Excluded Territory.

3. Regeneron shall use Commercially Reasonable Efforts to provide cooperation and assistance reasonably requested by Company to enable Company (or its nominee) to assume with as little disruption as reasonably possible, the continued Development and Manufacture of the Licensed Products in the Field. The Parties shall discuss in good faith either the continuation of supply of Licensed Product by Regeneron or manufacturing technology transfer to Company.

4. For the avoidance of doubt, Company 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 10; *provided, however*, that Company shall be solely responsible for paying (a) 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 Company of such licenses or other rights and (b) all amounts owed to Third Parties and all reasonable Out-of-Pocket Costs and FTE costs incurred by Regeneron in meeting its

obligations under any Existing Licenses or New Licenses, in each case, as a result of Company's (or its Affiliate's or Sublicensee's) Development, Manufacturing and Commercializing of Licensed Products in the Field in the Territory (including, without limitation, the Aventis Development Milestone Payments and Aventis Royalties).

SCHEDULE 11

Notices

- (a) If to Company:  
Bayer HealthCare LLC  
100 Bayer Boulevard  
Whippany, New Jersey 07981-0915  
U.S.A.

With copy to:

Bayer HealthCare AG  
51368 Leverkusen, Germany  
Attention: 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

SCHEDULE 1.97

Licensed Products

REGN 2176

REGN 2176-3 (combination with EYLEA®)

EXHIBIT A

Opt-In Package

**The Opt-In Package will include the following information:**

**Clinical Data**

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**CMC Data**

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**Preclinical data (Research, Toxicology, DMPK)**

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**Regulatory**

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**Product Supply information**

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**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: May 8, 2014

/s/ Leonard S. Schleifer  
Leonard S. Schleifer, M.D., Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

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**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: May 8, 2014

/s/ Robert E. Landry  
Robert E. Landry  
Senior Vice President, Finance and Chief  
Financial Officer  
(Principal Financial Officer)

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**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 March 31, 2014 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)  
May 8, 2014

/s/ Robert E. Landry

Robert E. Landry  
Senior Vice President, Finance and Chief  
Financial Officer  
(Principal Financial Officer)  
May 8, 2014