#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT

#### Pursuant to Section 13 or 15(d) of

the Securities Exchange Act of 1934

Date of Report: January 9, 2017

#### **REGENERON PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of incorporation)

000-19034 (Commission

File Number)

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02. Results of Operations and Financial Condition.

On January 9, 2017, at the 35<sup>th</sup> Annual J.P. Morgan Healthcare Conference in San Francisco, California (the "2017 J.P. Morgan Healthcare Conference"), Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc. ("Regeneron") or the "<u>Company</u>"), is providing a corporate update. Dr. Schleifer's presentation includes information regarding the Company's preliminary (unaudited) U.S. net sales of EYLEA<sup>®</sup> (aflibercept) Injection of \$858 million and \$3.32 billion for the fourth quarter 2016 and the full year 2016, respectively, and the preliminary (unaudited) global sales of EYLEA of more than \$5 billion for the full year 2016.

#### Item 7.01. Regulation FD Disclosure.

The information set forth under Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 to this Current Report on Form 8-K is incorporated by reference herein.

On January 11, 2017, at a sell-side investor meeting at the 2017 J.P. Morgan Healthcare Conference, Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer of Regeneron, is giving a presentation entitled "2017 Financial Overview." A copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

The information included or incorporated in Item 2.02 and Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

#### Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Presentation by Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., at the 35th Annual J.P. Morgan Healthcare Conference.

99.2 Presentation by Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer of Regeneron Pharmaceuticals, Inc., entitled "2017 Financial Overview."

#### SIGNATURES

2

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.

Senior Vice President, General Counsel and Secretary

Date: January 9, 2017

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/s/ Joseph J. LaRosa Joseph J. LaRosa

#### EXHIBIT INDEX

Description

99.1 99.2

Numbe

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

> **10591-6707** (Zip Code)



JANUARY 2017

# NOTE REGARDING FORWARD-LOOKING STATEMENTS AND NON-GAAP FINANCIAL MEASURES

This presentation includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), a 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 int identify such forward-looking statements, although not all forward-looking statements, although not all forward-looking statements, and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA%[afilbercept] lipection, I (alirocumab) Injection, Dupxent% (dupilumab), saniumab, tREGN 2222, Regeneron's earlier-stage product candidates, Regeneron's immuno-oncology program, and the use of human genetics in Regeneron's products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials, the likelil timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, including without limitation EYLEA, Praluent, dupilumab, s fasinumab, and REGN 2222; ongoing regulatory and administrative governmental authorities which may delay or restrict Regeneron's and the evelop or commercialize Regeneron's products and product candidates, uncertainty of market acceptance and commercial success of Regeneron's products and product candidates, uncertainty of market acceptance and commercial auccess of Regeneron's products and product candidates, uncertainty of market acceptance and commercial acceptance and doministrative governis's products, uncertainty of market acceptance and commercial acceptance and doministrative governis's products and product candidates, uncertainty of market acceptance and commercial auccess

This presentation uses non-GAAP unreimbursed R&D and non-GAAP SG&A, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). These nu financial measures are computed by excluding certain non-cash and other items from the related GAAP financial measure. The Company believes that the presentation of these non-GAAP measures is useful to because they exclude, as applicable: (i) non-cash share-based compensation expresse, which fluctuates from period to period based on factors that are not within the Company's control, such as the Company's stock the dates share-based grants are issued; (ii) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control, and (iii) up-front payments related to lic collaboration agreements. Non-GAAP adjustments also include the income tax effect of reconciling items. Non-GAAP unreimbursed R&D expresses reduced by R&D expenses reduced by R&D expen

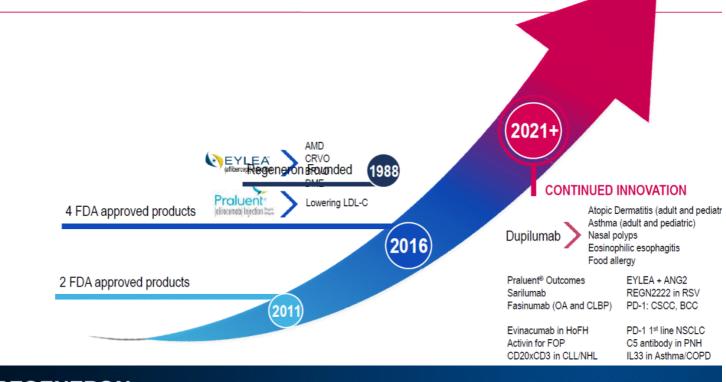
# DOING WELL BY DOING GOOD

Regeneron is committed to consistently and repeatedly bringing new medicines to patients with serious diseases

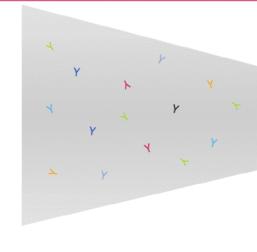


### REGENERON

# **REGENERON: GROWTH THROUGH INNOVATION**



# **INDUSTRY-LEADING PIPELINE**



- Program partnered with Sanofi
- rogram partnered with Bayer ex-U.S.
- Program partnered with Mitsubishi Tanabe (Asia) and Teva

This slide includes pipeline drug candidates currently undergoing clinical testing in a variety of diseases. The safety and efficacy of these drug candidates have not been evaluated by any regulatory authorities for the disease categories described here.

REGENERON

14.5

PHASE 1

REGN2810 (PD-1) Cancer ◆ REGN1979 (CD20 X CD3) Cance

**REGN 2810 + REGN 1979** 

(PD-1 + CD20 X CD3) Cane

REGN 3767 (LAG3) Cance

REGN1908-1909 (Feld1) Allergic

disease

REGN 3470-3471-3479 Ebola Virus

REGN 2477 (Activin antibody) FOP

REGN 3500 (IL-33) Inflammatory ◆

PHASE 2

DUPILUMAB (IL-4R) eosinophilic

SARILUMAB non-infectious uveitis

NESVACUMAB + Aflibercept (ANG2 +

REGN2810 (PD-1) Cutaneous squamous

TREVOGRUMAB (GDF8) Skeletal

EVINACUMAB (ANGPTL-3)

Cardiovascular and metabolic

EYLEA) Retinal disease

esophagitis

muscle disorders

cell carcinoma

PHASE 3

PRALUENT® (alirocumab)

DUPIXENT<sup>®</sup> (dupilumab, IL-4R) ◆

EYLEA Diabetic retinopathy without

Atopic dermatitis, asthma, nasal

FASINUMAB (NGF) Pain

REGN2222 (RSV) Respiratory

Hypercholestrolemia

Rheumatoid arthritis

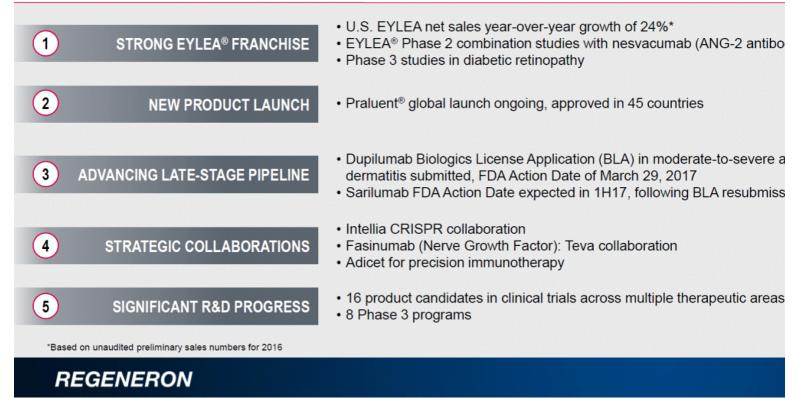
diabetic macular edema

Syncytial Virus

polyps

SARILUMAB (IL-6R)

# 2016: YEAR IN REVIEW

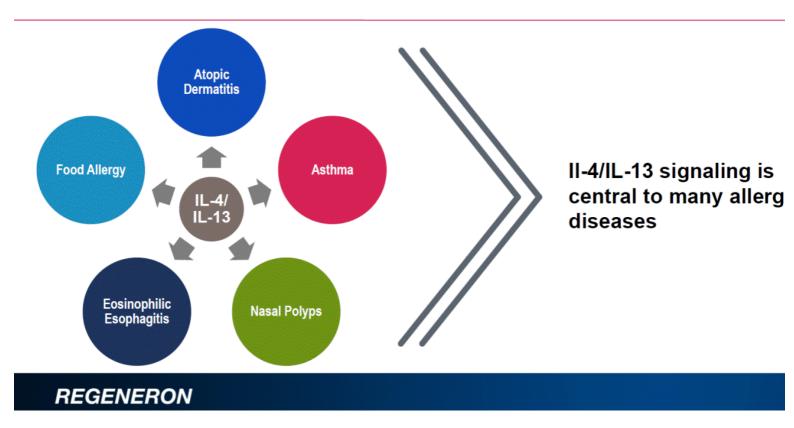


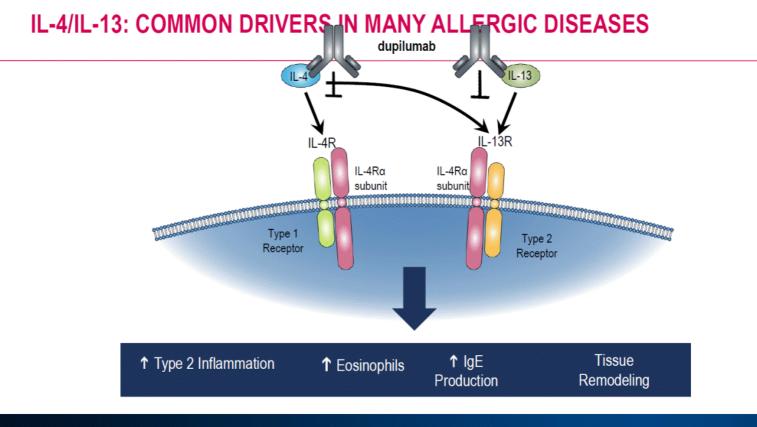
# SCIENCE IS THE ENGINE THAT DRIVES US



### REGENERON

# IL-4/IL-13: COMMON DRIVERS IN MANY ALLERGIC DISEASES





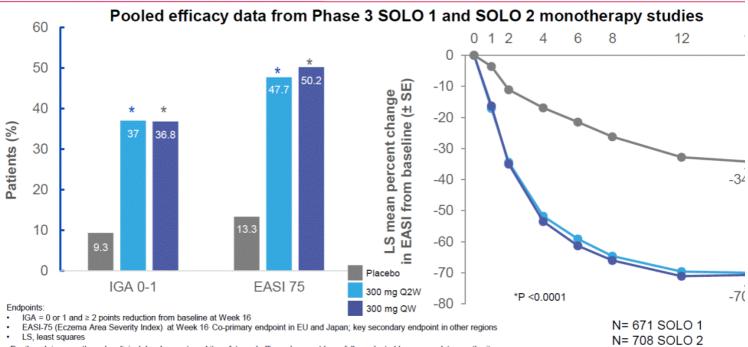
### REGENERON

# **DUPIXENT® (DUPILUMAB): OPPORTUNITIES IN MULTIPLE INDICATIONS**



DUPIXENT® has been conditionally accepted as tradename by the FDA and EMA

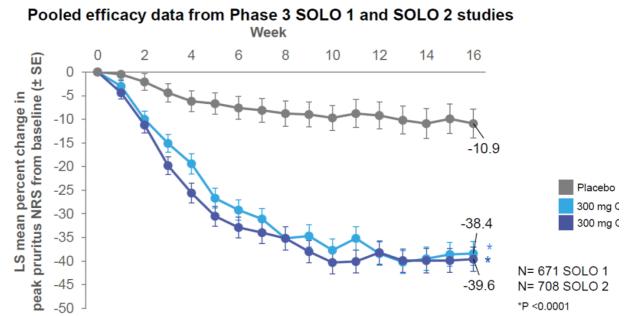
# DUPIXENT®: SIGNIFICANT IMPROVEMENTS OBSERVED IN SKIN CLEARING MEASURES IN PHASE 3 SOLO STUDIES



Dupilumab is currently under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority

#### REGENERON

## DUPIXENT®: SIGNIFICANT IMPROVEMENTS OBSERVED IN PRURITUS IN PHASE SOLO STUDIES



Adverse events that were noted to have a higher rate with dupilumab treatment across both studies included injection site reactions (10-20 percent dupilumab; 7-8 percent placebo) and conjunctivitis (7-12 dupilumab; 2 percent placebo); approximately 26 percent of patients in both studies reported a history of allergic conjunctivitis at study entry. No patient discontinued therapy due to injection site reactions a one patient discontinued therapy due to conjunctivitis



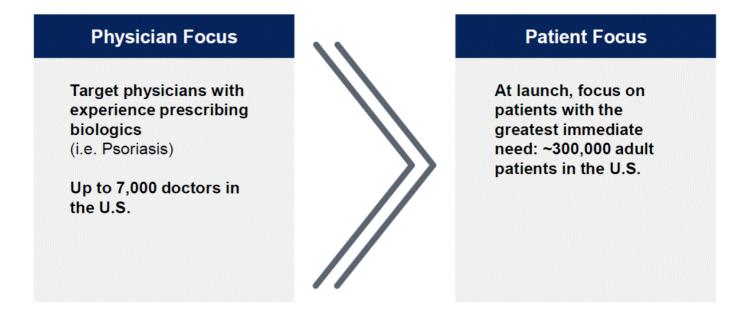
#### DUPIXENT®: SIGNIFICANT IMPROVEMENTS IN SKIN CLEARING OBSERVED IN COMBINATION WITH TOPICAL CORTICOSTEROIDS IN PHASE 3 LIBERTY-AD-CHRONOS STUDY



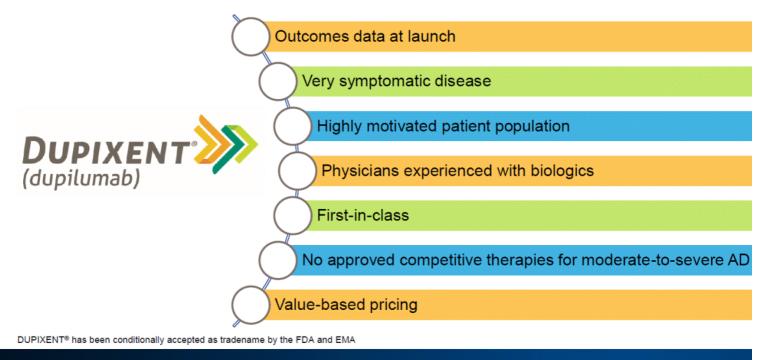
The overall rate of adverse events was comparable between the dupilumab with TCS groups (83 percent for the weekly dose (qw) and 88 percent for the every two weeks (q2w) dosing group) and the place TCS group (84 percent). The rate of serious adverse events was comparable between the dupilumab with TCS groups (3 (qw) and 4 percent (q2w)) and placebo with TCS group (5 percent). Serious and/or infections were numerically higher in the placebo with TCS group (1 percent in both dupilumab groups and 2 percent placebo). Adverse events that were noted to have a higher rate with dupilumab includec injection site reactions (20 (qw) and 16 percent (q2w) dupilumab; 9 percent placebo) and conjunctivitis (19 (qw) and 13 (q2w) percent dupilumab; 8 percent placebo); 22 percent of patients on placebo, and and 28 percent (q2w) of patients on dupilumab reported a history of allergic conjunctivitis at study entry

### REGENERON

# DUPIXENT®: UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS REPRESENTS A SIGNIFICANT UNMET NEED IN ADULTS

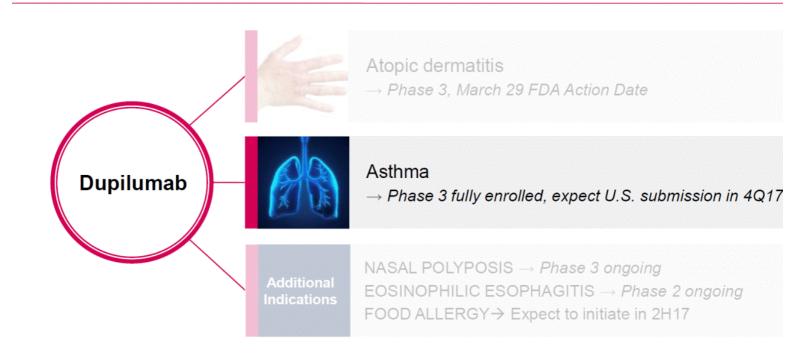


# **DUPIXENT®: STRONG PROFILE DESPITE CHALLENGING ACCESS LANDSCAPE**

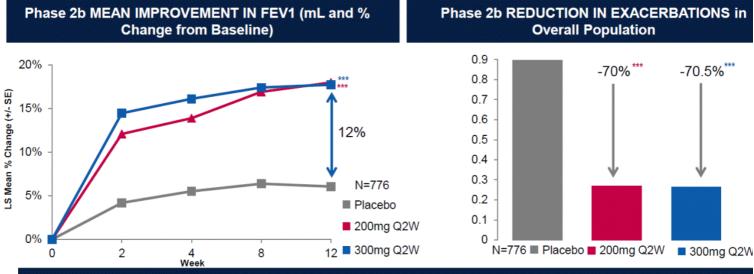


### REGENERON

# **DUPILUMAB: OPPORTUNITIES IN MULTIPLE INDICATIONS**



# DUPILUMAB ASTHMA PHASE 2B: SIGNIFICANT BENEFITS IN ALL PATIENTS WIT UNCONTROLLED PERSISTENT ASTHMA



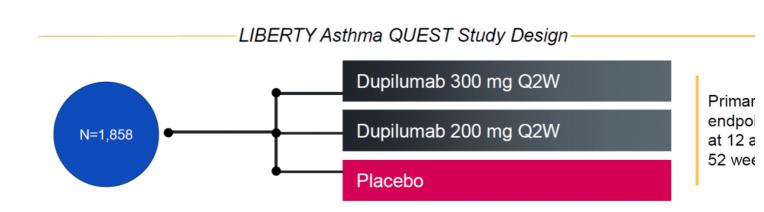
#### Completed Phase 2b study will be considered pivotal by FDA

Arrows represent percent change compared to placebo;\*\*\*P < 0.001 vs placebo. The most common adverse event was injection site reaction, which was more frequent in the dupilumab dose groups (13 to 25 percent) compared to placebo (12 percent).

Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high-dose inhaled corticosteroids plus a long-acting β2 agonist: a randomised double-blind placel controlled pivotal phase 2b dose-ranging trial. Lancet. 2016 Jul 2;388(10039):31-44. doi: 10.1016/S0140-6736(16)30307-5.

#### REGENERON

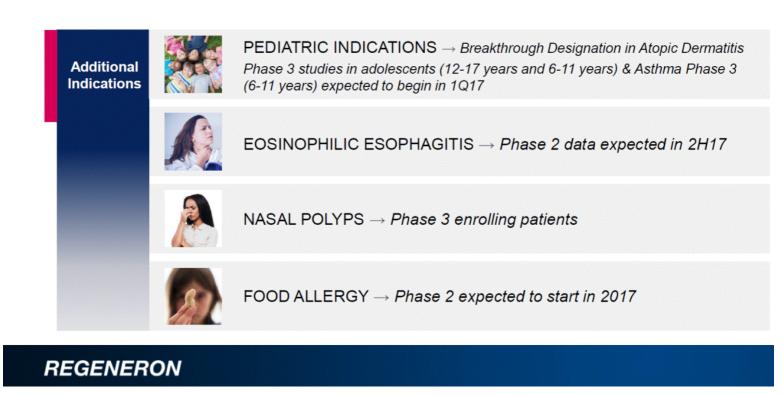
# DUPILUMAB: PHASE 3 IN ASTHMA FULLY ENROLLED



**Primary endpoints**: Absolute change from baseline in pre-bronchodilator forced expiratory volume in ( second (FEV1) at 12 weeks and annualized rate of severe exacerbation events at 52 weeks

Expect topline results and U.S. regulatory submission in 4Q17

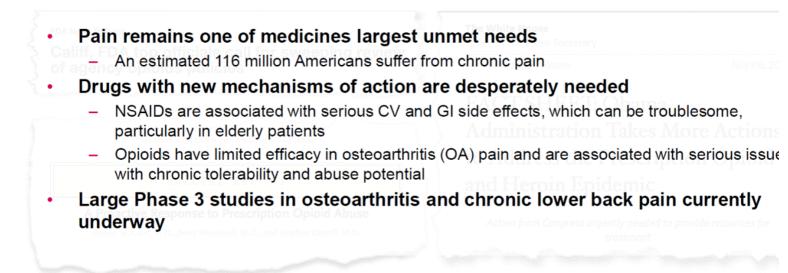
# DUPILUMAB: OPPORTUNITIES IN MULTIPLE INDICATIONS



# SARILUMAB: IL-6R ANTIBODY FOR RHEUMATOID ARTHRITIS

- Launch preparation activities ongoing
- Based on review of responses to the FDA 483 as well as proposed corrective actions, the FDA has reclassified the Le Trait "fill and finish" facility as "acceptable"
- Expect an FDA pre-approval inspection of Le Trait and re-submission of sarilumab BLA in 1Q17. Anticipate two-month review cycle, with Action Date 2Q17

# FASINUMAB: MAJOR OPPORTUNITY EXISTS FOR A NOVEL CLASS OF NON-OPIOID PAIN THERAPIES



Fasinumab is being developed in collaboration with Mitsubishi Tanabe (Asia) and Teva.

### REGENERON

# **REGN2222: PHASE 3 IN RESPIRATORY SYNCYTIAL VIRUS (RSV)**

#### **RSV Healthcare Burden**

**20 percent of infants <six months old** require medical attention for RSV<sup>(1)</sup> annually

**2.1 million children less than five years old** require medical attention for RSV<sup>(1)</sup> every year

**9 times more deaths** than influenza in infants<sup>(2)</sup> on an annual basis

### **RSV Prophylaxis Landscape**

One approved drug: Synagis<sup>®</sup> (palivizumab)

American Academy of Pediatrics guidelines recommend **use in gestational age of <29 weeks** or with preexisting conditions<sup>(3)</sup>

#### 3-5 monthly injections

#### Potential RSV Marke

>80 percent of premature infants are born between 2 and 35 weeks<sup>(4)</sup>

Majority of U.S. RSV cost are from full-term infants

Elderly/Adults

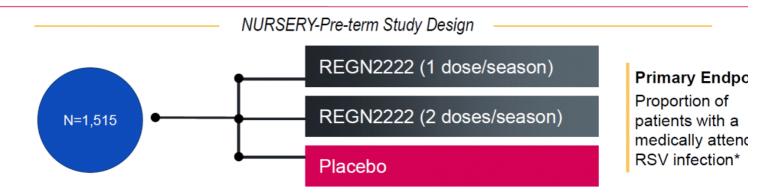
Hall et al N Engl J Med 2009;360:588-98
 Thomson et al IAMA 2003:289:179

- Thompson et al JAMA 2003;289:179
   American Academy of Perijatrics Committee on Infe
- (3) American Academy of Pediatrics Committee on Infection Diseases and Bronchiolifis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014;134(2) (4) Hamitton, B.E., et al. 'Births: Final Data for 2014.' <u>National Vital Statistics Reports</u> Vol. 64; No. 12.

Palivizumab is marketed as Synagis®



# **REGN2222: NURSERY-PRE-TERM PHASE 3 STUDY DESIGN**



#### KEY PHASE 3 PROGRAM DESIGN HIGHLIGHTS:

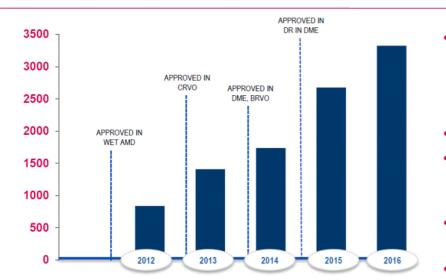
- Primary Endpoint: Medically attended RSV infection with either hospitalization or outpatient lower respiratory tract infection;
- Patient Population: Infants born at a gestational age of 35 weeks or less and are younger than 6 months in chronological aç that are not eligible for palivizumab
- Dosing: REGN2222 has the potential to be dosed once or twice an RSV season
- Top-line data expected 2H17
- Fast-Track designation in U.S

Palivizumab marketed as Synagis®

\*Hospitalization or outpatient lower respiratory tract infection during 150 days after the first dose of study drug

### REGENERON

# EYLEA® (AFLIBERCEPT) INJECTION : LEADERSHIP IN THE RETINAL FRANCHISI



EYLEA is the market-leading product among FDA-approved anti-VEGF agents for its approved indications

- Full-year 2016 U.S. EYLEA net sal of \$3.32 billion\*
  - 4Q16 U.S. EYLEA net sales of \$858
  - Global sales exceeded \$5Bn\* in 201
- Additional Studies Ongoing:
- Phase 2 study of EYLEA + Nesvacumab (ANG2 mAb) ongoing in DME (fully enroll and AMD
- PANORAMA: Ongoing Phase 3 study i
   Diabetic Retinopathy (DR)
- **PROTOCOL-W:** Ongoing Diabetic Retinopathy Clinical Research Network (DRCR.Net) -conducted study in DR

\*Unaudited, preliminary numbers \*\*Ex-U.S. EYLEA commercialized by Bayer

# PRALUENT®: LITIGATION UPDATE

- Sanofi and Regeneron will appeal the District Court's rulings in the Federal Circuit Court of Appeals, including requesting a stay of the injunction during pendency of the appeal
- Will vigorously defend our case through the appeal process as we believe th Amgen's asserted patent claims are invalid and the facts and controlling law support our position
- Praluent<sup>®</sup> continues to be available to patients

### REGENERON

# PRALUENT®: LAUNCH PROGRESSING GLOBALLY

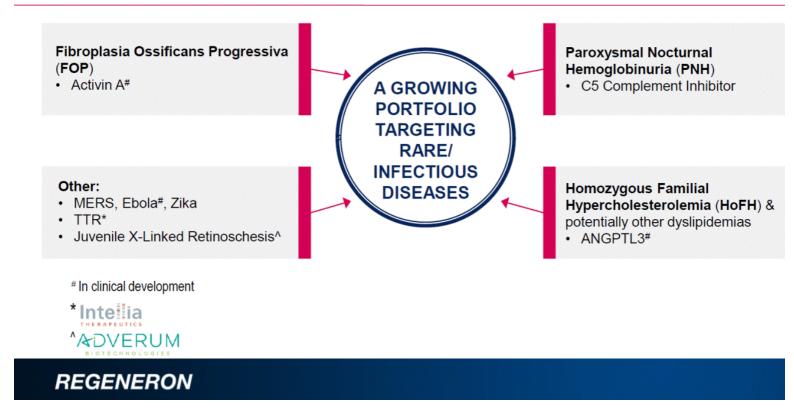
- PRALUENT<sup>®</sup> (alirocumab) Injection is the first FDA-approved PCSK9 inhibitor
  - Approved for use along with diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL) or atherosclerotic heart problems, who need additional lowering of LDL cholesterol
  - The effect of Praluent<sup>®</sup> on cardiovascular morbidity and mortality has not been determined
- 2016 global first 9 months net sales of \$75 million
  - Praluent® launched in Japan in September and available in 45 markets worldwide
- 18,000 patient ODYSSEY OUTCOMES study remains ongoing, with data expecte in 2H17

# MULTIPLE APPROACHES TO ADVANCE THE PROMISE OF IMMUNO-ONCOLOGY NEW I/O TARGETS

I/O TARGETS	<ul> <li>PD-1 antibody a foundation for combination therapies         <ul> <li>Potentially pivotal monotherapy study in cutaneous squamous cell carcinoma ongoing</li> <li>Phase 2 PD-1 study in non-small cell lung cancer to be initiated in 1H1</li> <li>Potentially pivotal study of PD-1 in basal cell carcinoma to be initiated 1H17</li> </ul> </li> <li>LAG-3 antibody (monotherapy and in combination with PD-1) in clinica development</li> </ul>
BISPECIFIC PLATFORM	<ul> <li>CD20 x CD3 bispecific data presented at ASH         <ul> <li>Clinical activity demonstrated at very dose levels relative to rituximab i a heavily pretreated/refractory patient population.</li> <li>Dose escalation/optimization continuing</li> </ul> </li> <li>Combo study of CD20 x CD3 + PD-1 in NHL enrolling patients         <ul> <li>ASH American Society of Hematology</li> </ul> </li> </ul>

### REGENERON

# EXPANDING RARE AND INFECTIOUS DISEASE DRUG PORTFOLIO



### REGENERON GENETICS CENTER: APPLICATION OF HUMAN GENETICS TO ACCELERATE NOVEL TARGET IDENTIFICATION AND CLINICAL DEVELOPMENT



Identify new drug targets and pathways

#### **De-risking**

Confirm lack of "on-target adverse side effects" in drug target loss-o function carriers

#### Indication Discovery

Identify new indications for drug targets and programs

#### Biomarker

Develop pharmacogenetic markers to predict drug response

- **30+** academic collaborations
- 150,000 exomes sequenced to date
- Leverage VelociSuite for rapid clinical development

REGENERON

# 2017 FINANCIAL GUIDANCE<sup>1,2</sup>

Non-GAAP Unreimbursed R&D:	\$950MM - \$1,025MM		
<b>Non-GAAP SG&amp;A:</b> This includes REGN incurred commercial-related expenses for Sanofi collaboration antibodies	\$1,175MM - \$1,250MM		
Sanofi Reimbursement of Regeneron Commercialization-Related Expenses	\$400MM - \$450MM		
Effective Tax Rate	32% - 38%		
Capital Expenditures	\$375MM - \$450MM		

The 2017 guidance, provided on January 9<sup>th</sup>, 2017, does not assume the completion of any significant business development transactions not completed as of January 9<sup>th</sup>, 20
 The 2017 guidance, provided on January 9<sup>th</sup>, 2017, assumes that Praluent<sup>®</sup> will remain on the market throughout 2017







# 2017 FINANCIAL OVERVIE

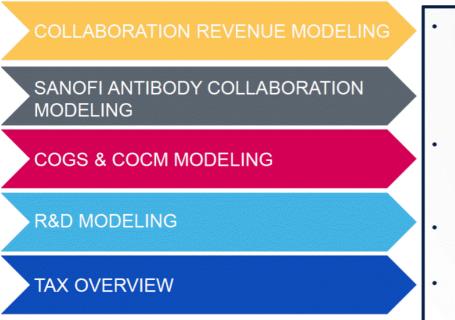
ROBERT LANDRY, SENIOR VICE PRESIDER - FINANCE AND CHIEF FINANCIAL OFFICEF JANUARY 11, 2017

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This presentation uses non-GAAP unreimbursed R&D and non-GAAP SG&A, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAA non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP financial measure. The Company believes that the presentation of these non-GAAP measu to investors because they exclude, as applicable: (i) non-cash share-based compensation expense, which fluctuates from period to period based on factors that are not within the Company's control; and (ii) up-fror company's stock price on the dates share-based grants are issued; (ii) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control; and (iii) up-fror related to license and collaboration agreements. Non-GAAP adjustments also include the income tax effect of reconciling items. Non-GAAP newsures from the Company's collaboration partners. Regeneron makes such adjustments for items the Company does not view as useful in evaluating its operating performance. Manag these non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additi non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of these and othe financial measures. Any non-GAAP financial measures for financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP.

# **2017 FINANCIAL OVERVIEW**



#### Review collaboration accounting

- Addition of Teva collaboration in September
- Expiration of Sanofi Antibody Discovery Collaboration funding on December 31, 2017 three-year tail
- Differentiate between 'Cost of Goods Sol (COGS) and 'Cost of Collaboration and Contract Manufacturing' (COCM)
- Unreimbursed and reimbursed R&D mod overview
- Review tax guidance following adoption ( ASU 2016-09 (stock compensation)

### REGENERON

# **COLLABORATION REVENUE MODELING**

#### Sanofi and Bayer Collaborations

- 2017 income statement modeling remains consistent with 2016 filings
- Sanofi collaboration revenue line will continue to encompass both the antibody and the I/O collaborations
- Reimbursement of Regeneron R&D for antibody collaboration will continue after discovery funding ends

#### **Teva Collaboration**

- Revenues related to the Teva collaboration will not be a separate line item on the income statement
- Revenues related to this collaboration will be included in the "Other" revenue line on the Income Statement
- These revenues will include R&D reimbursements, potential development milestones, as well as amortization of the \$250M upfront payment
- Quarterly filings will include detailed quantitative information

#### **Other Collaborations**

- Reimbursements from other collaborations will also flow i "Other" revenue line
  - Mitsubishi Tanabe Pł Corporation (MTPC)
  - Biomedical Advanced Research and Development Authori (BARDA)
- Potential development miles related to the MTPC collabor may be achieved in 2017

# SANOFI ANTIBODY COLLABORATION MODELING

- The Sanofi/Regeneron Antibody Discovery Collaboration Agreement expires on December 31, 201
  - Regeneron will receive up to \$130MM in Antibody Discovery funding in 2017, after which annual funding will be discontinued
  - Notwithstanding this expiration, Sanofi has the option to name specific targets on which they would like to continu
    discovery collaboration activities for an additional 3 years
    - o Sanofi will provide full funding for these continued efforts
    - o Targets must be identified by June 30, 2017
  - o Sanofi can then choose to opt-in to antibodies against these targets by December 31, 2020
  - Currently partnered clinical and commercial programs are not affected, and Sanofi will continue to reimburse Regeneron for programs previously opted into under the agreement
- The I/O Antibody Discovery and License Agreements are not affected by the expiration of the Antib Discovery Collaboration Agreement

Within the antibody collaboration, Sanofi is currently partnered with Regeneron on Praluent<sup>®</sup> (alirocumab) Injection, sarilumab, dupilumab, and REGN3500 (IL-33)

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# COGS AND COST OF COLLABORATION AND CONTRACT MANUFACTURING MODELING

#### **Cost of Goods Sold**

- Cost of goods sold primarily consists of costs in connection with producing EYLEA commercial supplies, and various start-up costs and unabsorbed overhead costs in connection with our Limerick, Ireland commercial manufacturing facility
- In May 2016, cost of goods sold decreased since our obligation to pay Genentech a royalty based on U.S. sales of EYLEA ended

#### Cost of Collaboration and Contract Manufact

- COCM primarily consists of the costs in connect with producing bulk commercial supplies for our collaborators
- When our collaborators complete sales of these products to third party customers:
  - We recognize the value that Sanofi and Bayer reir Regeneron for the costs in connection with product these commercial supplies in the "Other" line item found within their respective collaboration revenue
  - Our risk of inventory loss no longer exists, and we recognize our related manufacturing costs for the product as cost of collaboration manufacturing

Key Difference: COGS represents costs related to products for which we record sales directly in our P&L, and COCM is related to products sold by our collaborators

# **REIMBURSED R&D MODELING**

REIMBURSED R&D COMPONENTS – 2017 & BEYOND	Program	Phase	Collaborator	Collabo Funding		
Late-stage collaborated programs include	Praluent®	3	Sanofi	80%		
<ul> <li>Praluent<sup>®</sup> (Sanofi)</li> <li>Dupixent<sup>®</sup> (Sanofi)</li> </ul>	Dupilumab (Phase 3 indications)	3	Sanofi	80%		
<ul> <li>Sarilumab (Sanofi)</li> </ul>	Dupilumab (Phase 2 indications)	2	Sanofi	100%		
<ul> <li>Fasinumab (Teva, MTPC)</li> </ul>	Sarilumab	3	Sanofi	80%		
<ul> <li>PD-1 monotherapy program funded on a 50/50 basis</li> </ul>	Fasinumab	3	Teva, MTPC	50%		
	REGN2810 (PD-1)	2	Sanofi	50%		
<ul> <li>All other I/O molecules are funded by Regeneron and Sanofi on a 25/75 basis,</li> </ul>	Nesvacumab + EYLEA	2	Bayer	25%		
respectively, from discovery through Proof-of-	REGN3500 (IL-33)	1	Sanofi	100%		
<ul><li>Concept</li><li>CD20xCD3 is not included in the I/O</li></ul>	I/O Molecules <sup>(2)</sup>	1 Pre-clinical	Sanofi	~75%		
collaboration	<ol> <li>Only represents Development Funding and excludes any Development Milestones that may be payable by a collaborator.</li> <li>Combinations of I/O molecules with Sanoff and Regeneron proprietary molecules are funded outside of the collaboration.</li> </ol>					

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# **R&D MODELING**

#### FORECASTING R&D

- 'Project Costs' found in our quarterly filings, is a useful tool in determining how Regeneron's reimbursed and unreimbursed R&D may fluctuate year-over-year
- Provides insight into how spending for programs will increase or decrease with clinical advancement, the initiation of new trials, or the conclusion of pivotal trials

Project Costs		Nine Months Ended September 30,				Increase	
(In millions)	2016		2015		(Decrease)		
Praluent	\$	118.8	\$	195.2	\$	(76.4)	
Dupixent		373.7		269.2		104.5	
Sarilumab		36.7		67.4		(30.7)	
Fasinumab		124.4		24.7		99.7	
REGN2222		48.8		29.4		19.4	
REGN2810		80.1		25.9		54.2	
Other antibody candidates in clinical development		185.1		163.8		21.3	
Other research programs and unallocated costs		605.5		383.8		221.7	
Total research and development expenses	\$	1,573.1	\$	1,159.4	\$	413.7	
Source: Regeneron filings.					-		

# **TAX OVERVIEW**

#### EFFECTS OF POTENTIAL TAX REFORM AND NEWLY ADOPTED ACCOUNTING STANDARD

- · We believe potential tax reform proposals under discussion would be mostly positive for Regeneron
  - Lowering U.S. corporate tax rate would be beneficial, as the majority of Regeneron earnings are in the U.S.
  - o Repatriation provisions would not impact Regeneron, as we do not currently have overseas earnings
  - o Total impact of "border adjustment" proposal is unclear
- Adoption of ASU 2016-09 during 2Q16 fundamentally changed how we determined and provided guidance for ou effective tax rate
  - The new standard requires companies to recognize tax benefits in connection with employee exercises of sto options in the income statement
- · The new accounting standard will create volatility quarter-over-quarter in our effective tax rate
  - The new standard does not permit these items to be forecasted in our estimated annual effective tax rate, but rather recognized in the quarter of stock option exercises

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# **TARRYTOWN CAMPUS HEADQUARTERS TRANSACTION**

- Entered into a Purchase Agreement with affiliates of Biomed Realty, L.P. to purchase Corporate Heade
  - o 150 acres of adjacent office and lab space in the towns of Mount Pleasant and Greenburgh, N.Y.
  - Regeneron occupies 80% (1.2M ft<sup>2</sup>) / Tenants occupy 16% (0.24M ft<sup>2</sup>) / Common space 4% (0.07M ft<sup>2</sup>)
  - Gross Purchase Price of \$720MM with no financial condition
- Banc of America Leasing & Capital, LLC ("BAL") to use best efforts to arrange a \$720MM lease financ
- Intend to assign rights under the Purchase Agreement to an affiliate of BAL
  - BAL will become the legal owner of the facility ("Lessor")
- Regeneron to lease the facility for a term of five years
- At the end of the lease term, Regeneron has the option to:
  - Request to extend term of lease
  - Purchase the facility at a pre-determined amount
  - $_{\odot}\,$  Sell the facility to a third party on behalf of the lessor

# **TARRYTOWN CAMPUS HEADQUARTERS TRANSACTION**

Economics of Transaction <sup>(1)</sup>	
Estimated Average After-Tax Annual Cash Savings <sup>(2)</sup>	\$21MM
Estimated 5-Year After-Tax Net Present Value <sup>(2)</sup>	\$90MM
Favorable Tax Treatment	

Based on proposed transaction terms. Actual terms and economic impact may vary from those currently anticipated, and any such difference may be material.
 Includes \$14MM of one-time transactional fees.

- 2016 Capital Expenditures Guidance of \$480MM \$510MM remains in place
- Closing of transaction expected in First Quarter 2017
- Provides more economical expansion opportunities on existing campus

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# 2017 FINANCIAL GUIDANCE<sup>1,2</sup>

Non-GAAP Unreimbursed R&D:	\$950MM - \$1,025MM
<b>Non-GAAP SG&amp;A:</b> This includes REGN incurred commercial-related expenses for Sanofi collaboration antibodies	\$1,175MM - \$1,250MM
Sanofi Reimbursement of Regeneron Commercialization-Related Expenses	\$400MM - \$450MM
Effective Tax Rate	32% - 38%
Capital Expenditures	\$375MM - \$450MM

The 2017 guidance, provided on January 9<sup>th</sup>, 2017, does not assume the completion of any significant business development transactions not completed as of January 9<sup>th</sup>
 The 2017 guidance, provided on January 9th, 2017, assumes that Praluent will remain on the market throughout 2017.

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**APPENDIX** 

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Q&A

# **OVERVIEW OF SANOFI I/O COLLABORATION MODELING**

ANOFI WILL PROVIDE UP TO \$2.17 BILLION		onths Ende mber 30,
IVESTMENT	Sanofi Collaboration Revenue 2015	20
	Antibody:	
\$640 million in upfront payments is being amortized, currently, over eight years	Reimbursement of Regeneron research and development expenses \$ 205,114	5 S
	Reimbursement of Regeneron commercialization-related expenses 53,341	
\$1 billion of funding from discovery through proof of concept, is being split 75/25 between Sanofi and	Regeneron's share of losses in connection with commercialization of antibodies (74,865	i)
	Other 2,561	<u> </u>
Regeneron	Total Antibody 186,151	
\$650 million to fund development of PD-1, is being	Immuno-oncology:	
split 50/50	Reimbursement of Regeneron research and development expenses 18,584	i i
	Other 20,000	/
\$75M (\$15M in 2015 and \$30M in both 2016 and	Total Immuno-oncology 38,584	1
2017) transferred from antibody collaboration	ZALTRAP <sup>®</sup> :	
discovery funding to immuno-oncology collaboration	Regeneron's share of losses in connection with commercialization of ZALTRAP —	
	Reimbursement of Regeneron research and development expenses —	
	Other	
	Total ZALTRAP —	1
	\$ 224,735	s