

**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 12, 2016**

**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)

**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)

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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- 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 13, 2016, at the 34<sup>th</sup> Annual J.P. Morgan Healthcare Conference in San Francisco, California (the "2016 J.P. Morgan Healthcare Conference"), Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), is providing a corporate update. Dr. Schleifer's presentation includes on page 6 information regarding the Company's preliminary (unaudited) U.S. net sales of EYLEA<sup>®</sup> (afibercept) Injection for the full year 2015 and the preliminary global sales of EYLEA for the full year 2015. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 7.01. Regulation FD Disclosure.**

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

On January 13, 2016, at a sell-side investor meeting at the 2016 J.P. Morgan Healthcare Conference, Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer of Regeneron, is giving a presentation entitled "2016 Financial Overview." A copy of the relevant portion 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 34<sup>th</sup> Annual J.P. Morgan Healthcare Conference.

### SIGNATURES

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.

/s/ Joseph J. LaRosa

Joseph J. LaRosa

Senior Vice President, General Counsel and Secretary

Date: January 12, 2016

### EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
99.1	Presentation by Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., at the 34 <sup>th</sup> 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 “2016 Financial Overview.”

# REGENERON

## J.P. MORGAN 34<sup>TH</sup> ANNUAL HEALTHCARE CONFERENCE

JANUARY 2016

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

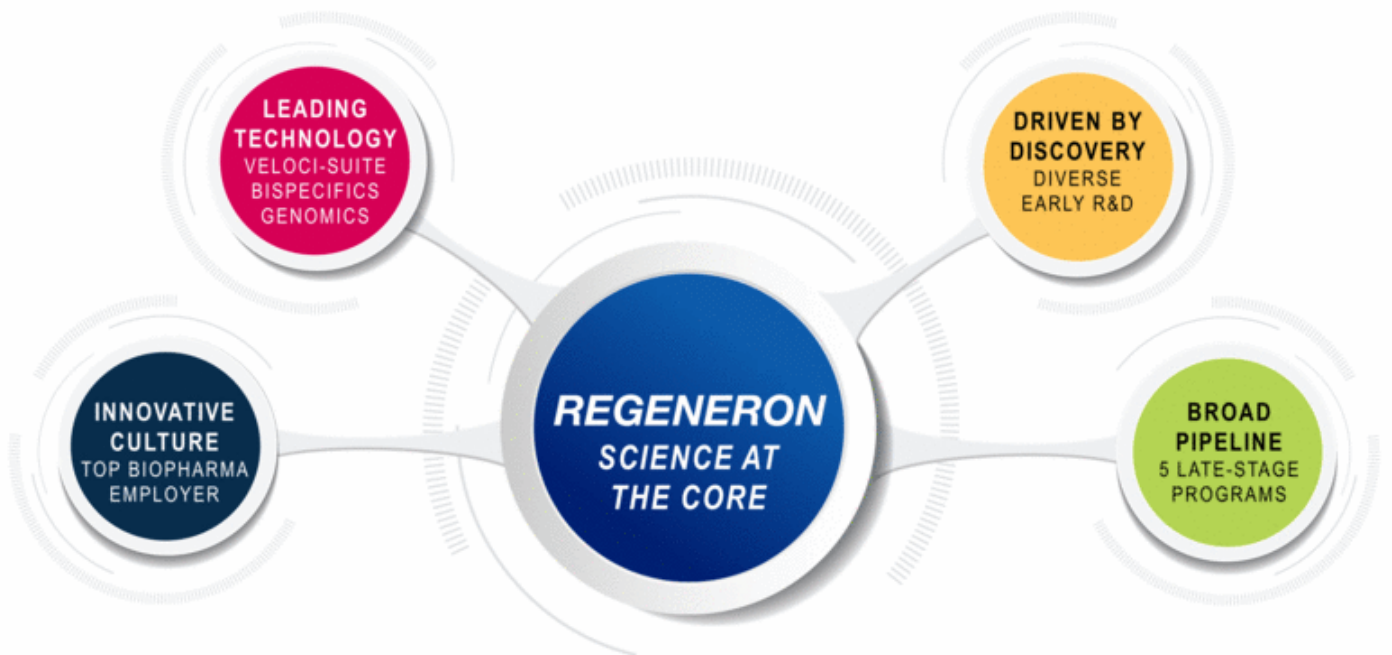
This presentation includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. 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 Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA<sup>®</sup>(aflibercept) Injection, Praluent<sup>®</sup>(alirocumab) Injection, sarilumab, dupilumab, fasinumab, REGN2222, and the immuno-oncology program; 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 Regeneron's product candidates in clinical trials; the likelihood and 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, sarilumab, dupilumab, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA and Praluent), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron 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; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance, including without limitation those relating to EYLEA U.S. net sales and the Company's expectations regarding non-GAAP unreimbursed R&D, non-GAAP SG&A, cash tax payments, non-GAAP pre-tax income, and capital expenditures; the potential for any license or collaboration agreement, including Regeneron's 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. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2014 and its Form 10-Q for the quarterly period ended September 30, 2015, in each case including in the sections thereof captioned "Item 1A. Risk Factors." Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

This presentation uses non-GAAP unreimbursed R&D, non-GAAP SG&A, and cash tax as a percentage of non-GAAP pre-tax income, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). Regeneron believes that the presentation of these non-GAAP measures is useful 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, such as the Company's stock price on the dates share-based grants are issued, (ii) non-cash interest expense related to the Company's convertible senior notes, since this is not deemed useful in evaluating the Company's operating performance, (iii) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control, and (iv) estimate of income tax expense that is not payable in cash, as there is a significant difference between the Company's effective tax rate and actual cash income taxes paid or payable. Non-GAAP unreimbursed R&D represents non-GAAP R&D expenses reduced by R&D expense reimbursements from the Company's collaboration partners. Non-GAAP pre-tax income represents GAAP pre-tax income less non-GAAP adjustments. Management uses 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. However, there are limitations in the use of these and other non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP.

REGENERON



**DR. ALFRED G. GILMAN:**  
1941-2015



**REGENERON IS COMMITTED TO CONSISTENTLY AND REPEATEDLY  
BRINGING NEW MEDICINES TO PATIENTS WITH SERIOUS DISEASES**

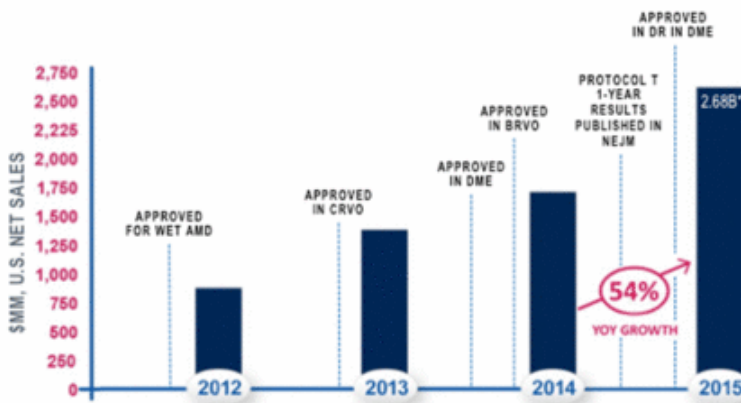
# A BROAD AND COMPELLING PIPELINE



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# U.S. EYLEA®: LEADERSHIP IN THE RETINAL FRANCHISE



**EYLEA is the market-leading product among FDA-approved anti-VEGF agents**

EYLEA full year U.S. net sales of \$2.68 billion\*

– EYLEA global sales of over \$4 billion\*

Phase 3 study of EYLEA in Diabetic Retinopathy to begin in 1Q16

Diabetic Retinopathy Clinical Research Network's Protocol-W study in DR expected to begin in early 2016

EYLEA + PDGFR-beta topline data from Phase 2 expected by year end

– Fast Track designation in wet age-related macular degeneration (wet AMD)

- EYLEA + ANG2 Phase 2 studies in wet AMD and Diabetic Macular Edema (DME) expected to begin in 1H16

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# PRALUENT®: APPROVED IN THE U.S. AND EU IN HIGH CARDIOVASCULAR RISK HYPERCHOLESTEROLEMIC PATIENTS\*



FDA approval granted on July 24, 2015

Indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL cholesterol (LDL-C)



Approved in EU on September 25, 2015

Indicated in adults with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidaemia, as an adjunct to diet in patients unable to reach their LDL-C goals with a maximally-tolerated statin and patients who are statin intolerant, or for whom a statin is contraindicated

\*The effect of Praluent® on CV morbidity and mortality has not been determined

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## PRALUENT® LAUNCH UNDERWAY

Education



Access

Global launch

Outcomes Study

### Building awareness and education

- Physician and patient education ongoing through field force efforts, medical conferences, publications, advertising
- Two approved doses—75 mg and 150 mg—resonating well with physicians



75 mg dose



150 mg dose

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## PRALUENT® LAUNCH UNDERWAY

Education

Access



Global launch

Outcomes Study

### Ensuring broad access for appropriate patients

- Sampling, bridging, and patient assistance programs through launch period
- Praluent coverage for ~150 MM lives in the U.S.
  - Stringent utilization management criteria
  - Contract rebating occurring
  - Parity access with Express Scripts, Prime Therapeutics\*
  - Exclusive status with United HealthCare
- Contract negotiations ongoing with additional payers, expect all coverage decisions to be made by mid-2016
  - >~47 MM lives under negotiation
  - Medicare coverage decisions expected by April 2016

\*ESRX includes commercial and Medicare, Prime Therapeutics includes only commercial lives

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## PRALUENT® LAUNCH UNDERWAY

Education

Access

Global launch

Outcomes Study



### Global launch ongoing

- Drug is available in Germany, UK, and Nordic Countries\*
- Expect Italy, Spain, France, Canada, and Japan to launch in 2016
- Pricing negotiations are ongoing in many EU countries

\*Not yet on national formularies

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Education

Access

Global launch

Outcomes Study



## Outcomes study likely to have impact on uptake

- ODYSSEY OUTCOMES study fully enrolled
- In 2016, expect interim futility analysis when approximately 50% of events have occurred and potentially also when 75% (for futility and overwhelming efficacy) of the targeted number of primary events have occurred

Additional details on ODYSSEY OUTCOMES can be found at American Heart Journal Volume 168, Issue 5, November 2014, Pages 682-689.e1

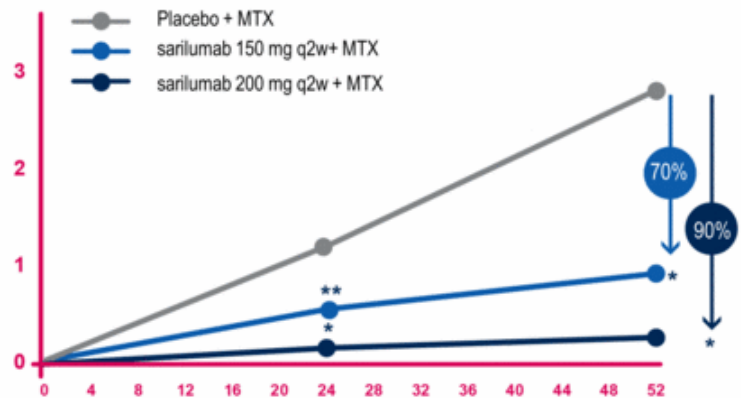
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## SARILUMAB FOR RHEUMATOID ARTHRITIS

- FDA action date of October 30, 2016
- Positive Phase 3 data demonstrated efficacy in methotrexate-inadequate responder (IR) and difficult-to-treat TNF-IR populations
- Phase 3 MONARCH study data of sarilumab vs. adalimumab expected in 2H16
- Launch preparation underway – co-promote with Sanofi in the U.S.

Change from Baseline in mTSS<sup>(1)</sup> Shows  
90% Inhibition of Bone Damage With Sarilumab 200 mg Q2W



\*p<0.0001, \*\*p=0.003  
<sup>1</sup>mTSS – Van der Heijde modified Total Sharp Score (mTSS)

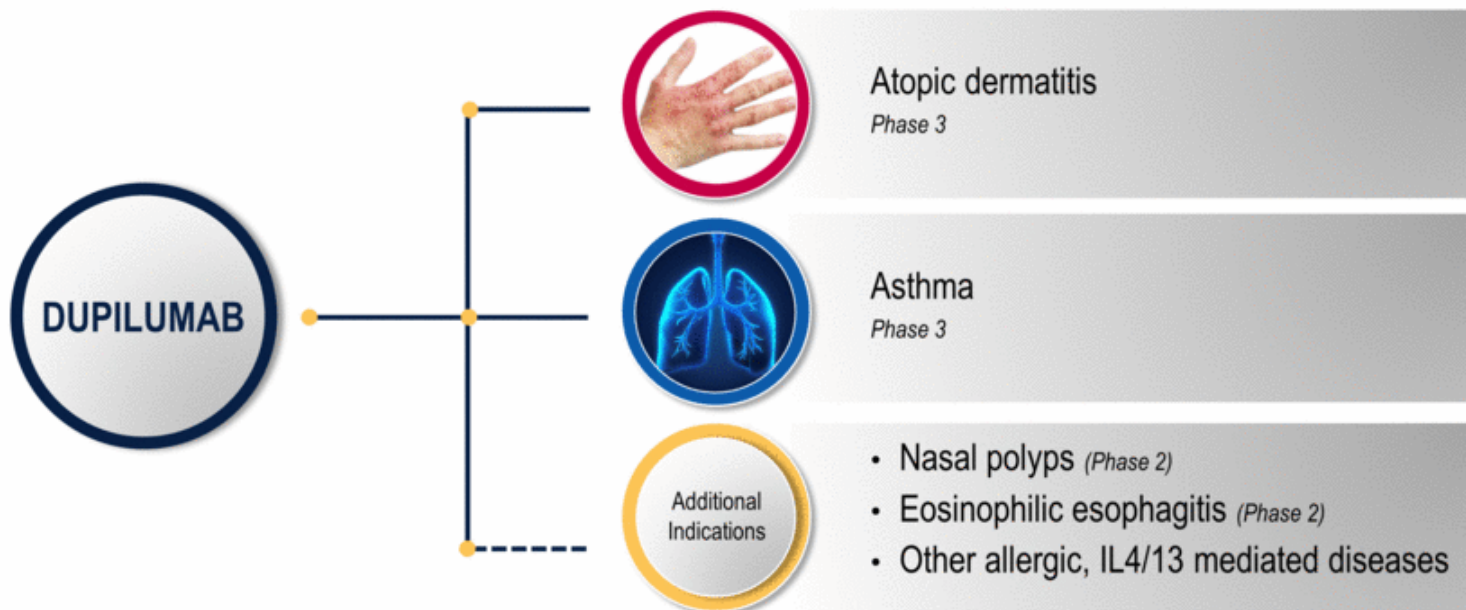
Humira® (adalimumab) is marketed by AbbVie  
 In the MOBILITY study, infections were the most frequently reported adverse events and were reported with a higher incidence in the sarilumab groups vs. placebo, all in combination with MTX (39.6% for 200 mg, 40.1% for the 150 mg group and 31.1% for pbo). The incidence of serious infections was 4.0% in the 200 mg + MTX group, 2.6% in the 150 mg + MTX group, and 2.3% in the placebo + MTX group  
 Q2W = every other week

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# DUPILUMAB: A PIPELINE IN A PRODUCT



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## DUPILUMAB: MAJOR UNMET MEDICAL NEED IN ATOPIC DERMATITIS (AD)

- Approximately 1 million adults estimated to have uncontrolled, moderate-to-severe atopic dermatitis in the U.S.
  - Only topical therapies approved by FDA (topical glucocorticoids, calcineurin inhibitors)
  - Systemic immuno-suppressants (e.g. cyclosporine) are used off-label but have significant side effects
- Burden of disease for moderate-to-severe adult patients is high
  - Patients have secondary infections<sup>1</sup>, increased sleep disturbance<sup>2</sup>, decreased work/school productivity<sup>2</sup>, decreased self-esteem<sup>3</sup>, increase in depression and suicidal ideation<sup>4</sup>
  - FDA Breakthrough Designation granted in adult AD indication
- Moderate-to-severe pediatric patients have a significant unmet medical need
  - March 9, 2015 FDA advisory committee highlighted unmet need and encouraged pediatric drug development<sup>5</sup>
  - Phase 2 pediatric study fully enrolled, data expected in 1H16. Phase 3 pediatric study to begin in 1H16

1. Pugliarello S, Cozzi A, Girolomoni G. Phenotypes of atopic dermatitis. JDDG 2011; 9:12-20

2. Murota H, Kitaba S, Tani M, Wataya-Kaneda M, Azukizawa H, Tanemura A, et al. Impact of sedative and non-sedative antihistamines on the impaired productivity and quality of life in patients with pruritic skin diseases. Allergol Int 2010 Dec;59(4):345-54

3. Torreló et al. Atopic Dermatitis: impact on quality of life and patients' attitudes toward its management. Eur J Dermatol 2012;22(1):97-105

4. Kimata H. Prevalence of suicidal ideation in patients with atopic dermatitis. Suicide Life Threat Behav 2006 Feb;36(1):120-4

5. <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DermatologicandOphthalmicDrugsAdvisoryCommittee/ucm431514.htm>

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# DUPILUMAB AD: PHASE 2B EFFICACY

## Phase 2b Study in AD – Responder Analyses at 16 Weeks

Parameter	Placebo	300mg Q2W	300mg QW
% EASI-50 <sup>1</sup> (50% improvement)	29.5%	78.1%	82.5%
% EASI-75 <sup>1</sup> (75% improvement)	11.5%	53.1%	60.3%
% EASI-90 <sup>1</sup> (90% improvement)	3.3%	29.7%	36.5%
<b>% IGA Responders<sup>2</sup></b>	<b>1.6%</b>	<b>29.7%</b>	<b>33.3%</b>

Primary endpoint of Phase 3 studies

p < 0.0001 vs placebo for all parameters

300mg QW and 300mg Q2W dose regimens being studied in Phase 3 program

EASI = Eczema Area Severity Index

(1) Proportion of patients achieving EASI-50/70/90

(2) Proportion of patients achieving IGA ≤ 1 (Investigator's Global Assessment score of 0 "clear" or 1 "almost clear"); Patients enrolled had IGA ≥ 3

QW = weekly, Q2W = every other week

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## DUPILUMAB AD: ILLUSTRATIVE EXAMPLE OF AN IGA RESPONDER FROM P2B TRIAL

### BASELINE



Images of patient before and after receiving dupilumab therapy for atopic dermatitis

Images from actual patient who received dupilumab in a Phase 2 clinical study. Results may vary. In this clinical study, all doses of dupilumab showed a dose-dependent improvement in the primary endpoint, the mean percent change in Eczema Area and Severity Index (EASI) score from baseline to week 16. The improvements in EASI score ranged from 74% to 45%, compared to 18% for patients receiving placebo (p<0.0001 for all doses). The most common adverse events in this study were nasopharyngitis. Injection site reactions and headaches were more frequent in the dupilumab group compared to placebo

### Investigator Global Assessment Scoring System (IGA)



Score	Grade	Definition
0	Clear	No Inflammatory signs of atopic dermatitis.
1	Almost Clear	Just perceptible erythema and just perceptible papulation induration.
2	Mild	Mild erythema and mild papulation induration. No oozing or crusting.
3	Moderate	Moderate erythema and moderate papulation induration. Oozing or crusting may be present.
4	Severe	Severe erythema and severe papulation induration. Oozing or crusting is present.

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# DUPILUMAB AD: ILLUSTRATIVE EXAMPLE OF AN IGA RESPONDER FROM P2B TRIAL

BASELINE	POST-TREATMENT	Improving System (IGA)
		<p>Atopic dermatitis.</p> <p>and just perceptible papulation</p> <p>ulation induration.</p> <p>oderate papulation induration. present.</p> <p>re papulation induration. Oozing</p>

Images of patient before and after receiving dupilumab therapy for atopic dermatitis  
 Images from actual patient who received dupilumab in a Phase 2 clinical study. Results may vary. In this clinical study, all doses of dupilumab showed a dose-dependent improvement in the primary endpoint, the mean percent change in Eczema Area and Severity Index (EASI) score from baseline to week 16. The improvements in EASI score ranged from 74% to 45%, compared to 18% for patients receiving placebo (p<0.0001 for all doses). The most common adverse events in this study were nasopharyngitis. Injection site reactions and headaches were more frequent in the dupilumab group compared to placebo

## DUPILUMAB AD: SAFETY FINDINGS

### Phase 2b Study in Moderate-to-Severe Atopic Dermatitis (Safety Data, N=380)

	Placebo	100 mg Q4W	300 mg Q4W	200 mg Q2W	300 mg Q2W	300 mg weekly
Nasopharyngitis	26%	31%	32%	26%	25%	25%
Headache	3.3%	10.8%	7.7%	14.8%	7.8%	12.7%
Injection site reaction	3.3%	4.6%	7.7%	6.6%	4.7%	9.5%

- Nasopharyngitis, the most common adverse event, balanced across dupilumab treatment groups vs. placebo
- Headache and injection site reactions more frequent with dupilumab

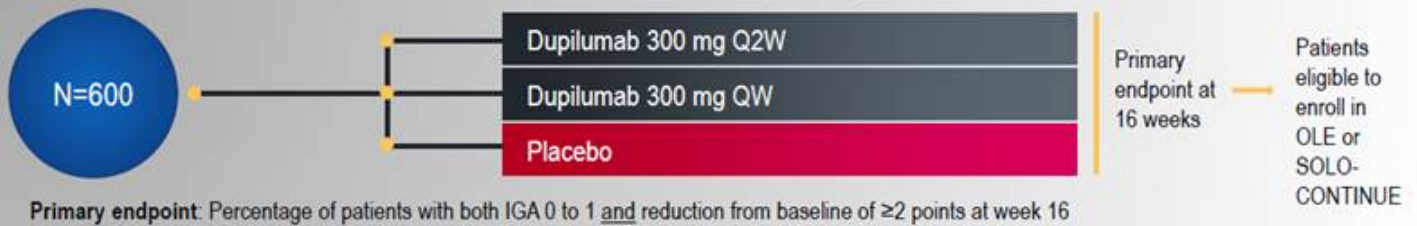
Ongoing follow-up period of 16 weeks after treatment

Q4W = every 4 weeks

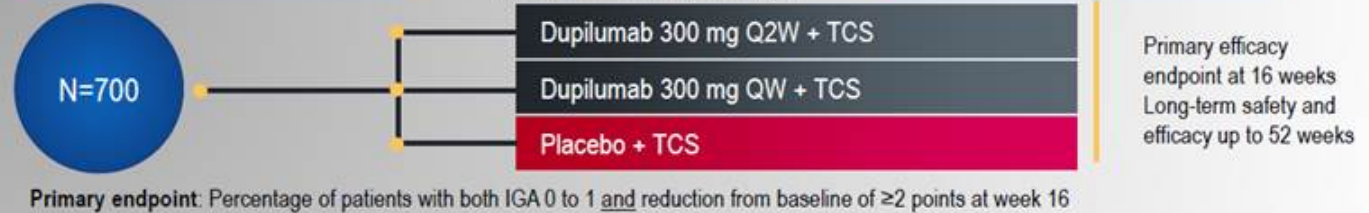


# DUPILUMAB AD: LIBERTY SOLO AND CHRONOS STUDY DESIGN

## SOLO 1 and SOLO 2 Study Design



## CHRONOS Study Design



Data from Phase 3 SOLO studies expected in 1H16

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## DUPILUMAB ASTHMA: UNMET NEED DESPITE EXISTING THERAPIES

- Estimated that approximately 26 million people are affected by asthma in the U.S. Despite therapy with ICS/LABA, asthma is not adequately controlled in 5% to 10% of the patients<sup>1</sup>
- Approximately 1.7 million patients have moderate-to-severe, uncontrolled asthma in the U.S.
- It is estimated that asthma results in
  - 1.9 million visits to the emergency room each year
  - 479,300 hospital admissions each year
  - 9 deaths each day

<sup>1</sup><http://www.cdc.gov/asthma/asthma.htm>

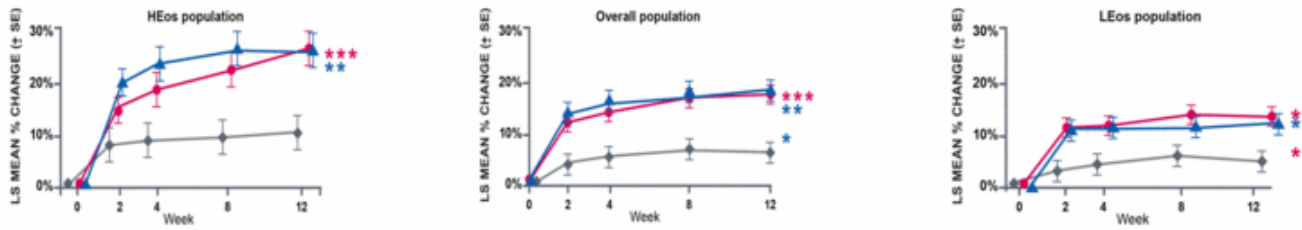
LABA = long acting beta agonist. ICS = inhaled corticosteroid

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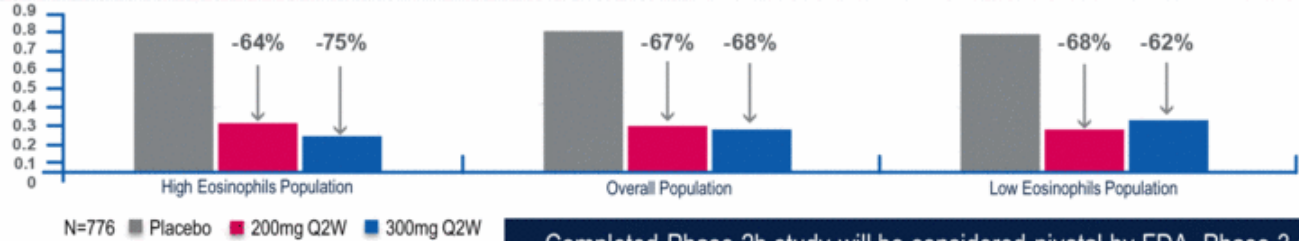
# DUPIUMAB ASTHMA: EFFICACY SEEN IN ALL PATIENT SUBSETS IN PIVOTAL PHASE 2B TRIAL IN UNCONTROLLED PERSISTENT ASTHMA

## PHASE 2b MEAN IMPROVEMENT IN FEV1 (mL and % Change from Baseline)



FEV1=forced expiratory volume over one second | During the treatment period, patients continue their stable medium- or high-dose inhaled corticosteroid and long-acting beta agonist (ICS/LABA) combination product | This result was based on a pre-specified interim analysis, which occurred when all patients had reached Week 12 of the 24-week treatment period | \*\*P < 0.01, \*\*\*P < 0.001 vs placebo

## PHASE 2b REDUCTION IN EXACERBATIONS



Completed Phase 2b study will be considered pivotal by FDA, Phase 3 ongoing

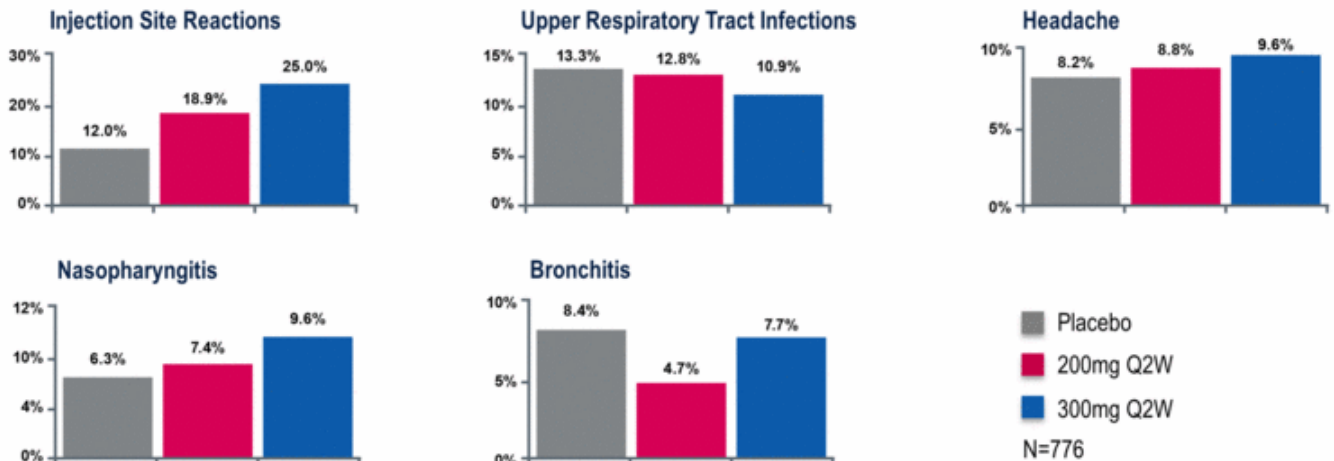
The annualized rate of asthma exacerbation events (e.g. LOAC, severe exacerbation) was analyzed using a negative binomial regression model. The model included the total number of events occurring during the double-blind treatment period as the response variable, with treatment group, pooled countries/regions, and number of asthma events prior to the study as covariates. Arrows represent percent change compared to placebo; \*P < 0.05, \*\*P < 0.01, \*\*\*P < 0.001 vs placebo.

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# DUPIUMAB: SAFETY PROFILE IN UNCONTROLLED PERSISTENT ASTHMA

## Phase 2b Study in Uncontrolled Persistent Asthma – Common AEs\*

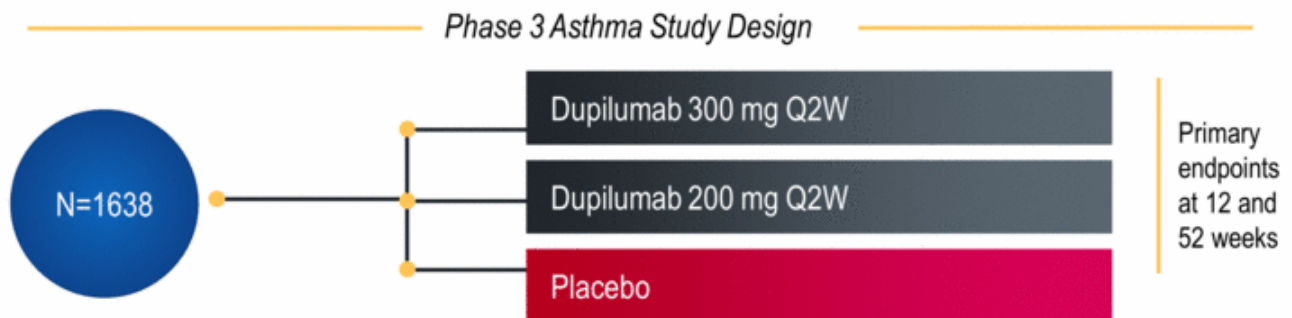


\*More than 5% of patients in any treatment group by Preferred Term (included also: back pain, cough, influenza, sinusitis, and oropharyngeal pain)

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## DUPILUMAB: PHASE 3 IN ASTHMA



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

## FASINUMAB: PHASE 3 STUDY IN OSTEOARTHRITIS PAIN

- Fasinumab (NGF mAb) presents a novel, non-opioid approach to addressing chronic pain
- Osteoarthritis (OA) estimated to affect about 25 million adults in the U.S., with many inadequately served by current therapies\*
- Based on discussions with the FDA, Phase 3 trials (>16 weeks) expected to begin in 1H16
- Data from 16 week Phase 2/3 in OA pain anticipated in 1H16
- Partnered with Mitsubishi Tanabe Pharma (MTPC) in Japan, Korea, and nine other Asian countries, excluding China



\* <http://www.cdc.gov/arthritis/basics/osteoarthritis.htm>



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

- 1 in 5 infants <6 months will require medical attention for RSV infection
  - Hospitalization, emergency room or clinic visits
- Current guidelines restrict use of only approved prophylactic to infants born before 29 weeks gestation, infants with bronchopulmonary dysplasia, or congenital heart disease
- First Phase 3 study, NURSERY-Pre-term underway in infants  $\leq 35$  weeks gestation\*
  - Enrollment expected to be completed in 2017



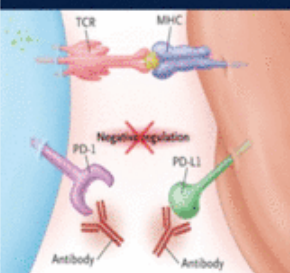
\* Patients must be 6-months or less in age

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## BUILDING A STRONG IMMUNO-ONCOLOGY PIPELINE

### CHECKPOINT INHIBITORS

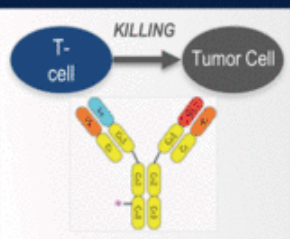


Adapted from NEJM 2012.

**Regeneron and Sanofi collaboration is committed to becoming a major player in immuno-oncology**

- Collaboration is devoting significant resources to advance programs
  - Sanofi has committed to an initial investment of up to \$2.17B, including \$640M in upfront payments to Regeneron and a potential sales milestone of \$375M
- PD-1 antibody to be the foundation for future combination therapies
  - Initial data expected in 1H16
- Multiple additional immune therapy agents to enter the clinic over the next 12-24 months (e.g. LAG-3, GITR)

### BI-SPECIFICS



**Bispecific platform has potential to have significant impact**

- CD20xCD3\* enrollment continues with preliminary evidence of activity at very low doses (<1/100 dose of approved CD20 antibody), initial data expected in 2016
- Multiple additional bispecific antibodies expected to enter the clinic over the next 12-24 months

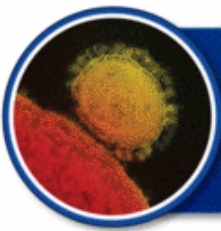
\*Not included in Sanofi collaboration

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## REGENERON RAPID RESPONSE: LEVERAGING CORE VELOCISUITE® TECHNOLOGIES

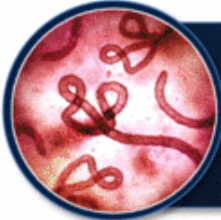
Rapid Response enables Regeneron to compress time for discovery and preclinical validation from years to months



### MERS

- Identification and validation of Spike-protein blocking antibodies
- Phase 1 studies planned for 2H16

PNAS



### EBOLA

- Identification and validation of a novel therapeutic cocktail of three antibodies
- Phase 1 study in healthy volunteers planned for 1H16



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## REGENERON GENETICS CENTER: UNPRECEDENTED SPEED, SCALE & INTEGRATION



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ACTIVITY	GUIDANCE
Non-GAAP Unreimbursed R&D	\$875MM - \$950MM
Non-GAAP SG&A <i>This includes REGN incurred commercial-related expenses for Sanofi collaboration antibodies</i>	\$925MM - \$1000MM
Cash Tax <sup>2</sup> as a % of Non-GAAP Pre-tax Income <i>Includes one-time ~\$222 million tax payment related to the 3Q15 immuno-oncology upfront payment from Sanofi</i>	35% to 45%
Capital Expenditures <i>Expanding manufacturing facilities in Rensselaer, NY and Raheen, Ireland, as well as the continued expansion of the Tarrytown, NY campus</i>	\$580MM - \$680MM

<sup>1</sup>This financial guidance does not assume the completion of any significant business development transactions not completed as of January 12<sup>th</sup>, 2016

<sup>2</sup>Represents estimated income taxes that are payable in cash for the relevant period.

## UPCOMING MILESTONES IN 2016



- EYLEA + PDGF: Readout from Phase 2 study
- EYLEA + ANG2: Initiation of Phase 2 study
- EYLEA: Initiation of Phase 3 study in diabetic retinopathy
- Praluent®: Ongoing launches worldwide
- Praluent®: Interim analyses from ODYSSEY OUTCOMES study
- Sarilumab: Regulatory review and potential launch in the U.S.
- Dupilumab: Phase 3 readouts in atopic dermatitis and rolling BLA submission
- Dupilumab: Initiation of Phase 3 pediatric study in atopic dermatitis
- Fasinumab: Readout from Phase 2/3 clinical study, initiation of Phase 3 studies >16 weeks duration
- Immuno-oncology: Data from Phase 1 PD-1 and CD20xCD3 programs
- Regeneron Rapid Response: MERS and Ebola antibodies to enter clinical development





# ***REGENERON***

J.P. MORGAN 34<sup>TH</sup> ANNUAL  
HEALTHCARE CONFERENCE

JANUARY 2016



# REGENERON

## 2016 FINANCIAL OVERVIEW

ROBERT LANDRY, SVP OF FINANCE - CFO  
JANUARY 2016

### 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"), 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 Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, REGN 2222, and the immuno-oncology program; 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 Regeneron's product candidates in clinical trials; the likelihood and 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, sarilumab, dupilumab, fasinumab, and REGN 2222; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA and Praluent), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron 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; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance, including without limitation those relating to EYLEA U.S. net sales and the Company's expectations regarding non-GAAP unreimbursed R&D, non-GAAP SG&A, cash tax payments, non-GAAP pre-tax income, and capital expenditures; the potential for any license or collaboration agreement, including Regeneron's 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. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2014 and its Form 10-Q for the quarterly period ended September 30, 2015, in each case including in the sections thereof captioned "Item 1A. Risk Factors." Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

This presentation uses non-GAAP unreimbursed R&D, non-GAAP SG&A, and cash tax as a percentage of non-GAAP pre-tax income, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). Regeneron believes that the presentation of these non-GAAP measures is useful 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, such as the Company's stock price on the dates share-based grants are issued, (ii) non-cash interest expense related to the Company's convertible senior notes, since this is not deemed useful in evaluating the Company's operating performance, (iii) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control, and (iv) estimate of income tax expense that is not payable in cash, as there is a significant difference between the Company's effective tax rate and actual cash income taxes paid or payable. Non-GAAP unreimbursed R&D represents non-GAAP R&D expenses reduced by R&D expense reimbursements from the Company's collaboration partners. Non-GAAP pre-tax income represents GAAP pre-tax income less non-GAAP adjustments. Management uses 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. However, there are limitations in the use of these and other non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP.

## 2016 FINANCIAL OVERVIEW



- Committing investments to drive long-term shareholder value
- Significant expenses associated with Praluent®, sarilumab, dupilumab, fasinumab and REGN2222 are incurred offshore

## 2016 FINANCIAL GUIDANCE<sup>1</sup>

**Non-GAAP Unreimbursed R&D:**

**\$875MM - \$950MM**

**Non-GAAP SG&A:**

**\$925MM - \$1,000MM**

*This includes REGN incurred commercial-related expenses for Sanofi collaboration antibodies*

**Cash Tax<sup>2</sup> as a % of Non-GAAP Pre-tax Income:**

**35% - 45%**

*Includes one-time ~\$222 million tax payment related to the 3Q15 immuno-oncology upfront payment from Sanofi*

**Capital Expenditures:**

**\$580MM - \$680MM**

*Expanding manufacturing facilities in Rensselaer, NY and Raheen, Ireland, as well as the continued expansion of the Tarrytown, NY campus*

1) The 2016 guidance, provided on January 12<sup>th</sup>, 2016, does not assume the completion of any significant business development transactions not completed as of January 12, 2016.

2) Represents estimated income taxes that are payable in cash for the relevant period.



## 2016 FINANCIAL OVERVIEW

### LATE-STAGE ANTIBODIES



PRODUCT LAUNCHES

EARLY PROGRAMS

CAPITAL EXPENDITURES

#### Sanofi collaboration antibodies:

Regeneron funds 20% of an antibody's Phase 3 costs after the first positive results in a Phase 3 study for that antibody:

- Praluent®: OUTCOMES study
- Sarilumab: MONARCH and EXTEND studies
- Dupilumab: Atopic Dermatitis and Asthma Phase 3 programs

#### Unpartnered antibodies:

Regeneron incurs 100% of the costs for unpartnered antibodies:

- Fasinumab\* and REGN2222

*\*Partnered with MTPC in Japan and certain other Asian countries*

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## 2016 FINANCIAL OVERVIEW

LATE-STAGE ANTIBODIES

### PRODUCT LAUNCHES



EARLY PROGRAMS

CAPITAL EXPENDITURES

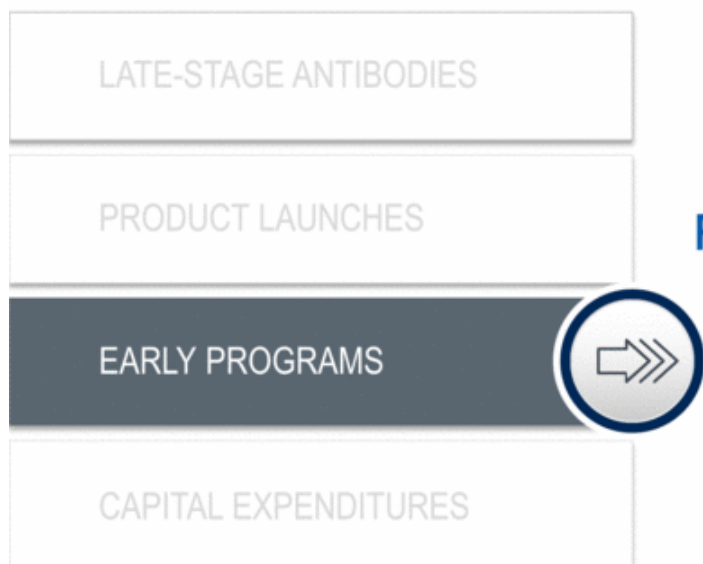
#### Regeneron's ~50% share of commercialization expenses for partnered antibodies:

- Praluent®
  - Our share of 3Q15 loss was ~\$75M
  - First full year launch for Praluent® in 2016 will include additional country launches
- Sarilumab
  - Anticipated 4Q16 launch requires investment
- Dupilumab
  - Ready for launch in atopic dermatitis

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# 2016 FINANCIAL OVERVIEW



**EYLEA + ANG2**  
**EARLY PROGRAMS / TECHNOLOGIES**  
**REGN1979 IMMUNO-ONCOLOGY**  
**REGENERON GENETICS CENTER**  
**EYLEA + PDGFR REGN1500**  
**REGN1908-1909**  
**REGN1033**

## OVERVIEW OF SANOFI I/O COLLABORATION MODELING

### IMMUNO-ONCOLOGY COLLABORATION

#### SANOFI WILL PROVIDE UP TO \$2.17 BILLION INVESTMENT

- \$640 million in upfront payments to be amortized, currently, over eight years
- \$1 billion of funding from discovery through proof of concept, to be split 75/25 between Sanofi and Regeneron
- \$650 million to fund development of PD-1, to be split 50/50
- Additional \$75M transferred from antibody collaboration discovery funding to immuno-oncology collaboration

### 3Q15 EARNINGS

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

# 2016 FINANCIAL OVERVIEW

## 2016 TAX COMMENTARY

- Intellectual property associated with our late stage antibody pipeline (e.g., Praluent<sup>®</sup>, sarilumab, dupilumab, etc.) has been migrated outside the U.S.
- When we recognize losses in lower tax jurisdictions, we experience a higher tax rate because these offshore expenses cannot be used to reduce U.S. taxable income
- If and when these late-stage assets become profitable, our tax rate will be lowered as a result
- In 2016, we expect our late-stage antibodies to operate at a loss, resulting in a higher tax rate