#### 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 (Date of earliest event reported): January 14, 2014 (January 14, 2014)

### **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))

D 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 14, 2014, at the 32<sup>nd</sup> Annual J.P. Morgan Healthcare Conference in San Francisco, California, Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., is providing a corporate update. Dr. Schleifer's presentation includes information regarding the Company's preliminary U.S. net sales of EYLEA® (aflibercept) Injection for the fourth quarter and full year 2013. 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 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 32<sup>nd</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 14, 2014

#### EXHIBIT INDEX

#### Description

#### Number 99.1

Presentation by Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., at the 32<sup>nd</sup> Annual J.P. Morgan Healthcare Conference.

## **REGENERON** science to medicine®

### **J.P. Morgan Healthcare Conference** January 2014

**Leonard S. Schleifer, M.D., Ph.D.** Chief Executive Officer

### **Safe Harbor Statement**

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 clinica programs now underway or planned; 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 EYLEAP, Alirocumab, Sarilumab, and Dupilumab; ongoing regulatory obligations and oversight and 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 non-GAAP unreimbursed R&D, non-GAAP SG&A and capital expenditures, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, 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, 2012 and its Form 10-Q for the quarterly period ended September 30, 2013, 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 net income, non-GAAP unreimbursed R&D, and non-GAAP SG&A, which are financial measures that are not calculated in accordance with the 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) non-cash income tax expense, since the Company does not currently pay, or expect to pay in the near future, significant cash income taxes due primarily to the utilization of net operating loss and tax credit carry-forwards; therefore, non-cash income tax expense is not deemed useful in evaluating the Company's operating performance, and (iv) a noncash tax benefit as a result of releasing substantially all of the valuation allowance associated with the Company's deferred tax assets. Non-GAAP unreimbursed R&D represents non-GAAP R&D expenses reduced by R&D expense reimbursements from the Company's collaboration partners. 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. A reconciliation of the Company's GAAP to non-GAAP results is included at the end of this presentation.

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### **Products**



Three approved products with sales in 50+ countries around the world\*

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\*EYLEA <sup>®</sup>ex-U.S is partnered with Bayer HealthCare. ZALTRAP <sup>®</sup>is partnered with Sanofi

## Products

## Pipeline



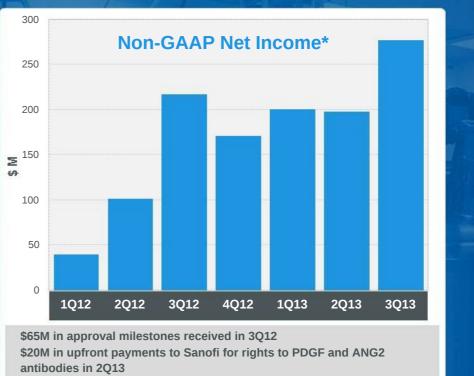
	Phase 1	Phase 2	Phase 3
Alirocumab (REGN727) PSCK9 Antibody for LDL cholesterol reduction			
Sarilumab (REGN88) IL-6R Antibody for Rheumatoid arthritis			
Dupilumab (REGN668) IL-4R Antibody for asthma, atopic dermatitis, nasal polyposis			
Sarilumab (REGN88) IL-6R Antibody for Non-infectious Uveitis			
REGN1033 (GDF8) Antibody for Metabolic disorders			
Fasinumab (NGF antibody) on clinical hold			
Enoticumab (REGN421) DII4 Antibody for Advanced malignancies			
Nesvacumab (REGN910) Ang2 Antibody for Advanced malignancies			
REGN1400 (ErbB3) Antibody for Advanced malignancies			
REGN1154 (undisclosed target)			
REGN1500 (undisclosed target)			
REGN1193 (undisclosed target)			
REGN1908-1909 (undisclosed target)			
REGN2009 (undisclosed target)			

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### **Products**

Pipeline

**Profits** 



 $45 \mathrm{M}$  in milestone payments from Bayer for ex-U.S. EYLEA  $^{\mathrm{\otimes}}$  in 3Q13

Non-GAAP net income excludes non-cash share-based compensation expense, non-cash interest and non-cash income tax expense See page 38 for GAAP to non-GAAP reconciliation

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### Products

Pipeline

**Profits** 

Awards



Regeneron named top employer in global biopharmaceutical industry by *Science Magazine* for second year in a row

Named the best place to work by *The Scientist* in 2013

CEO and CSO named "Management Team of the Year" by Scrip Intelligence Dupilumab named "Clinical Advance of the Year" by Scrip Intelligence

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### Products

Pipeline

**Profits** 

Awards

People



Regeneron named top employer in global biopharmaceutical industry by *Science Magazine* for second year in a row Number of employees grew by 20 percent in 2013 to 2,340

In four locations: Tarrytown, NY; Basking Ridge, NJ; Rensselaer, NY; and Limerick, Ireland

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Continuing Top Line Growth Investment in R&D and Technology



## **Organic Growth**

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Significant News January 2014

What's New for Regeneron			
EYLEA <sup>®</sup> & Ophthalmology Franchise	4Q13 and full year 2013 U.S. net sales PDGFR- $\beta$ clinical and business update		
Alirocumab Sarilumab Dupilumab	Update on data and filing timelines		
Sanofi Collaboration	Amended investor agreement		
Early R&D	Regeneron Genetics Center Immuno-Oncology		
2014 Financial Guidance	Non-GAAP SG&A, unreimbursed R&D, and capital expenditures		

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Continuing Top Line Growth



Investment in R&D and Technology



## **Organic Growth**

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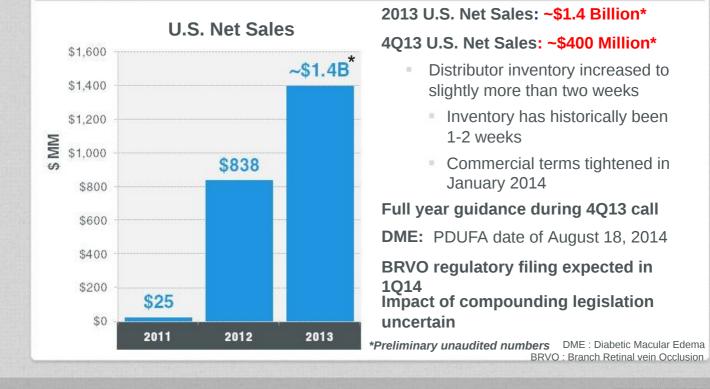
## EYLEA<sup>®</sup> Franchise

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U.S. EYLEA : Demographics, Market Share, New Indications to Drive Growth



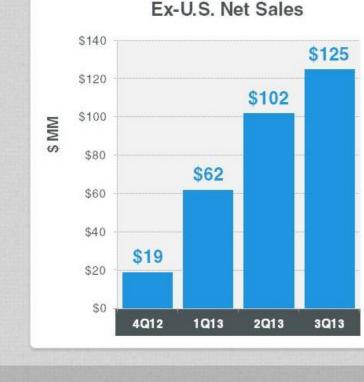


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## **Regeneron** — **Optimize and Extend EYLEA**® Ex-U.S. EYLEA: Launch is Still in Early Innings

(aflibercept) Injection For Intravitreal Injection



#### Ex-U.S. launch by partner, Bayer HealthCare, continues to do well

- In wet-AMD, 40%-50% market share in Australia, Japan and Germany
- Approved for macular edema following CRVO in EU and Japan

#### Ex-U.S. sales contributing to bottom line

DME submitted in EU

Myopic CNV filed in Japan

Global macular edema following BRVO submission expected in 2014

DME : Diabetic Macular Edema AMD: Age-related macular degeneration CRVO : Central Retinal Vein Occlusion BRVO : Branch Retinal vein Occlusion CNV : Choroidal Neovascularization

REGENERON

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## **Regeneron** — Optimize and Extend EYLEA

Protecting the Long Term Value of The Retina Franchise

#### **PDGFR-**β

PDGFR-β/EYLEA<sup>®</sup> co-formulation IND submitted in December 2013

First patient enrolled in Phase 1 expected in 1Q14

Regeneron owns 100% commercial rights in U.S.

Bayer collaborating outside the U.S.

- \$25.5M upfront
- \$40M in option and milestone payments
- Bayer/REGN share global development expenses
- Bayer responsible for certain third party royalties and share of milestones
- Companies share profits equally

#### ANG2

Intravitreal co-formulation with EYLEA<sup>®</sup> : IND expected to be submitted in 2014

### **Ophthalmology Research**

Commitment to remain a leader in retinal diseases

Investment in internal research and external collaborations

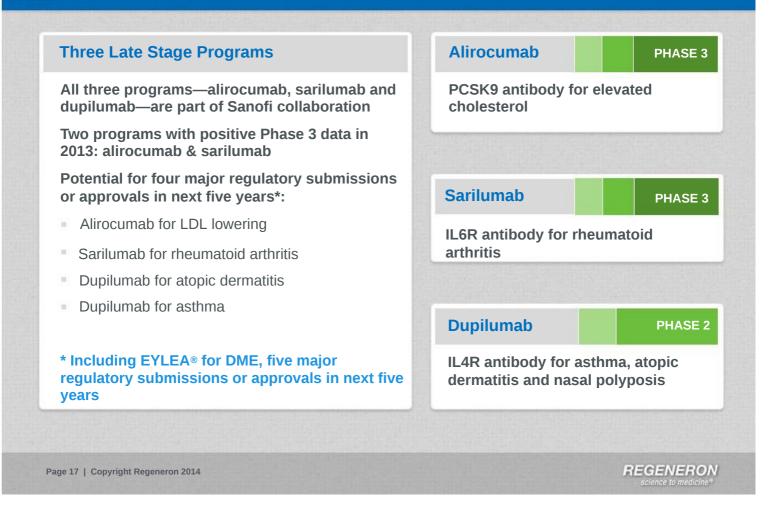
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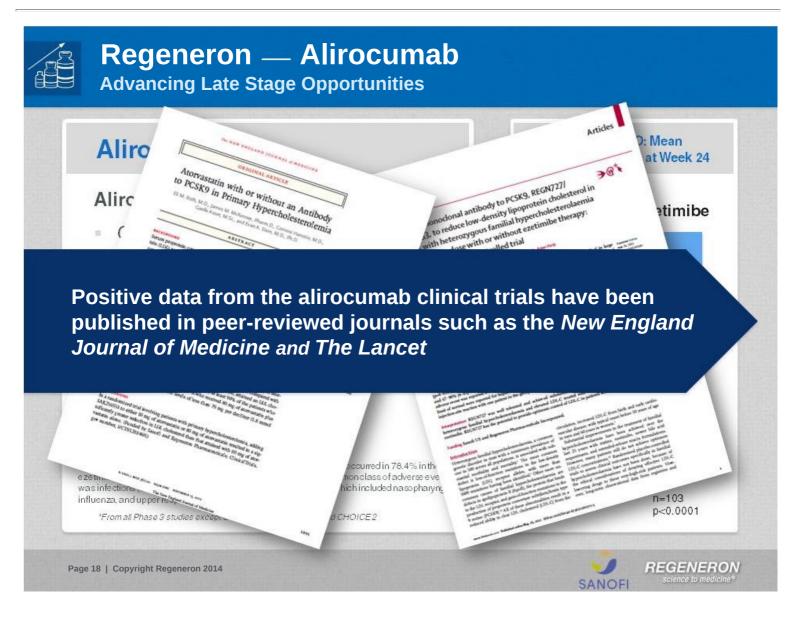
## Late Stage Pipeline

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### **Regeneron** — **Advance Late Stage Pipeline** Late Stage Pipeline Expected to Drive Continued Top-Line Growth







#### **Regeneron** — **Sarilumab** Advancing Late Stage Opportunities

Sarilumab for Rheumatoid Arthritis

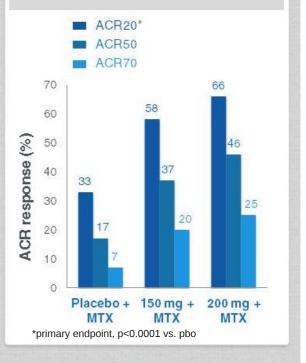
- Positive Phase 3 data from MOBILITY (N=1,200) reported 4Q13
  - Both sarilumab dose groups—150 mg and 200 mg—given subcutaneously, every other week, in combination with methotrexate (MTX) achieved all three co-primary endpoints
  - Patients receiving 200 mg + MTX showed a 90% reduction in radiographic progression (mTSS) at week 52
  - Data to be presented at a medical conference
- Additional Phase 3 data expected in 2015
  - Ongoing Phase 3 studies are: COMPARE, TARGET, ASCERTAIN, EXTEND
- Regulatory submission expected in 2015

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.

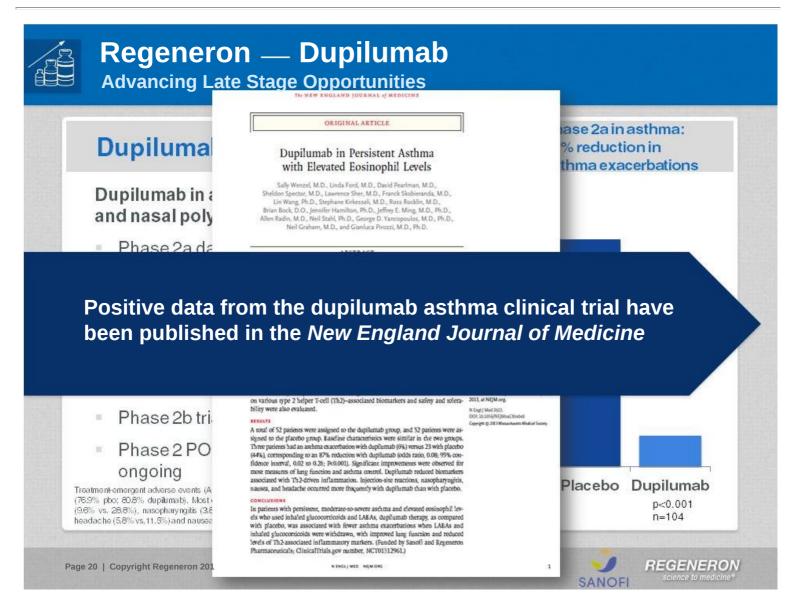
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## MOBILITY: ACR responses at 24 weeks



SANOFI







Continuing Top Line Growth Investment in R&D and Technology



**Organic Growth** 

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#### Sanofi Collaboration



Wholly-Owned Pipeline of Products

Fasinumab*		Phase 2
REGN1400	Phase 1	
REGN1154	Phase 1	
REGN1500	Phase 1	
REGN1193	Phase 1	-
REGN1908-1909	Phase 1	-

Investment in R&D and Technology

Innovative Research & Technologies





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## Sanofi Collaboration

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### **Sanofi Collaboration**



#### **Discovery**

#### **Development**

\$160 million of annual funding<br/>through 2017 (plus possibleSanofi funds approximately 100%<br/>of clinical development cost

#### Commercialization

Regeneron retains 50% of profits in US\*



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### **Sanofi Collaboration**



	Phase 1	Phase 2 Ph	ase 3
Alirocumab (REGN727) PSCK9 Antibody for LDL cholesterol reduction			
Sarilumab (REGN88) IL-6R Antibody for Rheumatoid arthritis			
Dupilumab (REGN668) IL-4R Antibody for Asthma, Atopic dermatitis, nasal polyposis			
Sarilumab (REGN88) IL-6R Antibody for Non-infectious Uveitis			
REGN1033 GDF8 Antibody for Metabolic disorders			
Enoticumab (REGN421) DII4 Antibody for Advanced malignancies			
Nesvacumab (REGN910) Ang2 Antibody for Advanced malignancies			
REGN2009 (undisclosed target)		SANO	FI

## Sanofi collaboration a major contributor to Regeneron R&D

 Sanofi is estimated to spend more than \$1 Billion on collaboration programs in 2014\*

## Regeneron contribution to collaboration R&D funding increasing in 2014

- 20% funding of alirocumab and sarilumab Phase 3 trials
  - Estimated to be ~\$115 MM in 2014

\*Regeneron to repay 50% of collaboration clinical development spending out of antibody profits

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## **Pipeline of Wholly-Owned Antibodies**

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**Wholly-Owned Clinical Stage Antibodies** 

#### Advancing early stage pipeline of Regeneron-owned antibodies

- Pipeline compounds address six distinct therapeutic areas
- Committed to advance through POC to maximize value
  - Fasinumab\* (Phase 2, NGF antibody)
  - REGN1400 (Phase 1, ErbB3, advanced malignancies)
  - REGN1154 (Phase 1, undisclosed target)
  - REGN1500 (Phase 1, undisclosed target)
  - REGN1193 (Phase 1, undisclosed target)
  - REGN1908-1909 (Phase 1, undisclosed target)

As pipeline advances, R&D expense will increase

\*Currently on clinical hold by the FDA

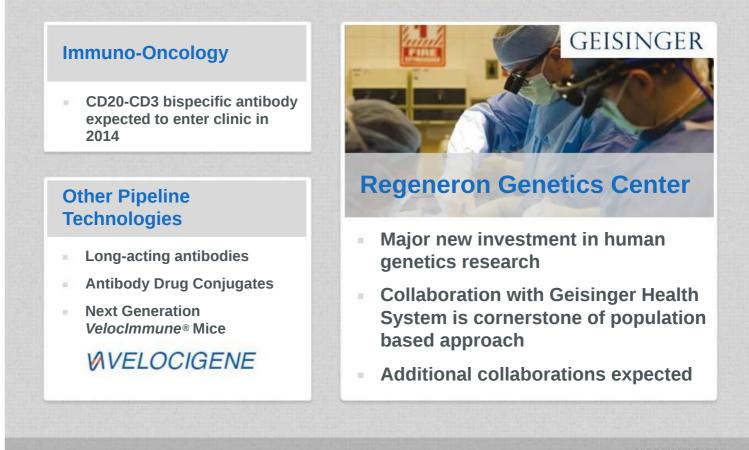
## Innovative Research and Novel Technologies

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## Regeneron — Innovating for the Future

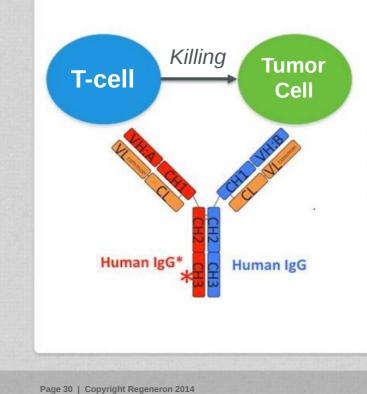
Investment in Research & Development and Technology



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#### Immuno-Oncology Approach: CD20-CD3 Bispecific Antibody



Bispecific antibody bind T Cells (via CD3) and tumor (via specific surface marker)

Use of modified *VelocImmune* <sup>®</sup> mice to generate fully human bispecific antibodies provides benefits

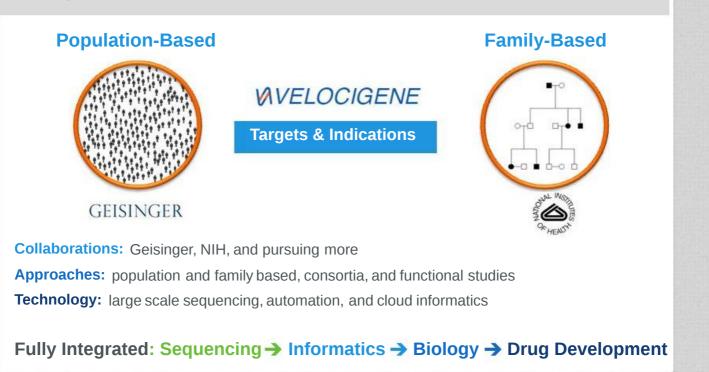
- High affinity to target
- Ease of manufacturing
- Typical antibody pharmacodynamics

Initial CD20-CD3 antibody expected to enter the clinic in 2014

Additional immuno-oncology approaches in preclinical development



### **Regeneron Genetics Center**



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Continuing Top Line Growth Investment in R&D and Technology



## **Organic Growth**

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## **Regeneron** — **Organic Growth**

Growth in Manufacturing and at Corporate Headquarters

#### **Expansion in** Tarrytown, NY

Two new buildings to support additional research and development

#### **New Manufacturing Facilities**

Expansion in Rensselaer, NY and new facility in Limerick, Ireland

#### People

Expect to increase headcount to >4,000 by 2018



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Limerick, Ireland



## **Regeneron** — **Financial Guidance**

#### **Financial Guidance**

### **2014 Financial Guidance**

#### Non-GAAP SG&A: \$330MM - \$380MM

 Increase in prelaunch commercial expenses, contribution to patient assistance programs, pharma fee and headcount

#### Non-GAAP Unreimbursed R&D: \$425MM - \$475MM

- ~\$115 M in expenses related to alirocumab and sarilumab Phase 3 trials
- Investment in PDGFR  $\beta$  and Ang2 programs
- Growing wholly-owned antibody pipeline
- Early technologies, such as Regeneron Genetics Center

#### Capital Expenditures: \$350MM - \$425MM

- Manufacturing expansions in Rensselaer and Ireland
- R&D and corporate headquarters expansion in Tarrytown

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Continuing Top Line Growth



Investment in R&D and Technology



## **Organic Growth**

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## **Regeneron** — **2014** Milestones

**Upcoming Milestones** 

#### Regulatory

EYLEA for DME PDUFA date of August 18, 2014

Filing of EYLEA for BRVO indication expected in 1Q14

EYLEA for DME regulatory applications submitted outside the U.S.

#### Clinical

Phase 2 data for dupilumab in atopic dermatitis in 1H14

Phase 3 trial to start with dupilumab in AD in 2014

Phase 3 data from alirocumab ODYSSEY program in mid-2014 through 3Q14

PDGFRβ/EYLEA coformulation to enter clinic in 1Q14

CD20-CD3 bispecific antibody to enter clinic

#### Commercial

EYLEA U.S. net sales guidance to be provided on 4Q13 conference call

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Significant News Flow at J.P. Morgan

### What's News for Regeneron at J.P. Morgan 2014

EYLEA®	Full year 2013 U.S. Net Sales: ~\$1.4 <sup>#</sup> Billion 4Q13 U.S. Net Sales: ~\$400 Million* <sup>#</sup>
PDGFR-β	<b>Clinical trial to start in 1Q14</b> Signed a collaboration with <b>Bayer HealthCare</b> for commercial rights outside the U.S.
Alirocumab	Phase 3 data from ODYSSEY program expected mid-year** Initial regulatory submission ex-US in early 2015, U.S. in 2015
Dupilumab	Phase 2a atopic dermatitis data to be presented at AAAAI in March Top-line Phase 2b atopic dermatitis data expected in 2Q14 Plan to initiate Phase 3 trial in atopic dermatitis in 2014
Sanofi	Amended investor agreement to allow for Sanofi to nominate a single director to Regeneron BOD; amended voting rights, lock-up, and stand still agreement
Human Genetics	Announced major effort in human genetics: <b>The Regeneron Genetics Center</b> Entered into first significant genetics collaboration with Geisinger Health System
Immuno-Oncology	CD20-CD3 bispecific antibody to enter clinic in 2014
2014 Financial Guidance	Non-GAAP SG&A: \$330MM - \$380MM Non-GAAP unreimbursed R&D: \$425MM - \$475MM Capital expenditures: \$350MM - \$425MM

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\*Includes increase in distributor inventory
 \*Includes increase in distributor inventory
 \*\*From all Phase 3 studies except OUTCOMES, CHOICE 1, and CHOICE 2

## **GAAP to Non-GAAP Reconciliation**

	A Share and the second second		North Contraction	A STATE OF THE OWNER AND A STATE OF	a second s	Sector and particularly	<b>Service - Alberta</b> tion
	1Q'12	2Q'12	3Q'12	4Q'12	1Q'13	2Q'13	3Q'13
GAAP net income	11,651	76,743	191,468	470,407	98,874	87,376	141,306
Adjustments	Adjustments						
R&D: Non-cash share-based compensation expense <sup>(1)</sup>	10,556	11,442	13,337	18,498	26,761	27,722	28,258
SG&A: Non-cash share-based compensation expense <sup>(1)</sup>	12,578	7,790	7,030	11,851	25,787	16,344	17,114
COGS: Non-cash share-based compensation expense <sup>(1)</sup>	111	391	150	422	483	376	373
Interest expense: Non-cash interest related to convertible senior notes <sup>(2)</sup>	5,218	5,316	5,499	5,591	5,781	5,535	5,823
Income taxes: Non-cash income tax expense <sup>(7)</sup>				4,308(	42,957	60,316	84,378
Income taxes: Release of valuation allowance				(340,156)(8)			
Non-GAAP net income	40,114	101,682	217,484	170,921	200,643	197,669	277,252
Non-GAAP net income per share – basic	0.43	1.07	2.29	1.79	2.07	2.02	2.82
Non-GAAP net income per share – diluted	0.37(3)	0.90(5)	1.89(6)	1.47(9)	1.78(10)	1.73(11)	2.40(12)
Shares used in calculating Non-GAAP net income per share - basic	93,446	94,589	95,012	95,691	96,878	97,700	98,226
Shares used in calculating Non-GAAP net income per share – diluted <sup>(4)</sup>	112,495	114,928	115,830	117,237	113,730	115,261	116,068

1) 2)

To exclude non-cash compensation expense related to employee stock option and restricted stock award To exclude non-cash interest expense related to the amortization of the debt discount and debt issuance costs on the Company's 1875% convertible senior notes For diluted non-GAAP per share calculations, excludes \$1.9 million of interest expense related to the 3)

contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive

4) 5)

dilutive Weighted average shares outstanding includes the dilutive effect, if any, of employee stock options, restricted stock awards, convertible senior notes, and warrants For diluted non-GAAP per share calculations, excludes \$1.9 million of interest expense for the three months ended June 30, 2012 related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive For diluted non-GAAP per share calculations, excludes \$1.9 million of interest expense for the three months ended Spetember 30, 2012 related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive To exclude GAAP income tax expense as this amount is not payable in cash To exclude dAAP income tax expense as this amount is not payable in cash To exclude non-cash tax benefit related to releasing substantially all of the valuation allowance associated with the Company's deferred tax assets 6)

7) 8)

1.875% convertible

 9)
 For diluted non-GAAP per share calculations, excludes \$1.9 million of interest expense for the three months ended December 31, 2012 related to the contractual coupon interest rate on the Company's senior notes, since these securities were dilutive 10)
 1.875% converting for diluted non-GAAP per share calculations, excludes \$1.9 million of interest expense for the three month ended March 31, 2013 related to the contractual coupon interest senior notes, since these securities were dilutive

senior notes, since these securities were dilutive
For diluted non-GAAP per share calculations, excludes \$1.8 million of interest expense for the three month periods ended June 30, 2013 related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive
For diluted non-GAAP per share calculations, excludes \$1.8 million of interest expense for the three months ended September 30, 2013, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive

**REGENERON** science to medicine®

# Thank you!