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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

(X) ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**NASDAQ Global Select Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ✓ No _

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes _ No ✓

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ✓ No _

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ✓ No _

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§232.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this form 10-K. ✓

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

Large accelerated filer ✓	Accelerated filer _	Non-accelerated filer _	Smaller reporting company _

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes _ No ✓

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $50,626,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2015, the last trading day of the registrant's most recently completed second fiscal quarter. For purposes of this calculation only, the registrant has assumed that all of its directors and executive officers, and no other persons, are its affiliates. This determination of affiliate status is not necessarily a determination for other purposes.

The number of shares outstanding of each of the registrant's classes of common stock as of February 4, 2016:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,913,776
Common Stock, $.001 par value	102,874,369

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2016 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 91 to 97 of this filing.

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"ARCALYST®", "EYLEA®", "ZALTRAP®", "*VelocImmune*®", "*VelociGene*®", "*VelociMouse*®", "*VelociMab*®", and "*VelociSuite*®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

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PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned, including without limitation sarilumab, dupilumab, fasinumab, and REGN2222; the likelihood and timing of achieving any of our anticipated clinical development milestones; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA® (aflibercept) Injection and Praluent), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our sales or other financial projections or guidance, including without limitation capital expenditures and income tax obligations, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part I, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

General

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

Our significant 2015 business highlights include:

- EYLEA (aflibercept) Injection, which is approved by the U.S. Food and Drug Administration (FDA) for use in retinal indications, delivered net sales growth of 54% over 2014, and is now the market-leading, branded anti-VEGF therapy in the United States.
- We, along with our partner Sanofi, received regulatory approval in the United States and Europe for Praluent (alirocumab) Injection for the treatment of uncontrolled LDL-cholesterol in certain patients. Praluent has been launched in the United States and certain European countries.
- We reported positive data from three Phase 3 studies of sarilumab in rheumatoid arthritis and submitted a regulatory application to the FDA.
- We reported positive, pivotal, Phase 2b data for dupilumab in the asthma indication and completed enrollment of three Phase 3 studies of dupilumab in atopic dermatitis.
- Two of our antibodies advanced to Phase 3 studies: REGN 2222 for the prevention of Respiratory Syncytial Virus (RSV) infection in infants; and fasinumab, an antibody against nerve growth factor (NGF), for osteoarthritis pain.
- We entered into significant new research and development collaborations: a collaboration with Mitsubishi Tanabe Pharma Corporation for fasinumab in certain Asian countries and a broad immuno-oncology collaboration with Sanofi.
- Our initiatives in genomics also advanced, enabling us to sequence exomes at the rate of 100,000 per year.

- From a company growth perspective, we hired our 4,000th employee, expanded into two new buildings on our Tarrytown, New York campus, continued to expand our bulk drug product manufacturing operations in Rensselaer, New York, and continued building out and hiring people for our new Limerick, Ireland commercial manufacturing facility.
- We were named one of the two top employers in the global biopharmaceutical industry by *Science*, for the fifth consecutive year.

Our total revenues were $4,103.7 million in 2015, compared to $2,819.6 million in 2014 and $2,104.7 million in 2013. Our net income was $636.1 million, or $5.52 per diluted share, in 2015, compared to $338.1 million, or $2.98 per diluted share, in 2014, and $413.7 million, or $3.72 per diluted share, in 2013. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations" below for further details of our financial results.

We currently have three marketed products:

- **EYLEA (aflibercept) Injection**, known in the scientific literature as VEGF Trap-Eye, is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD), diabetic macular edema (DME), macular edema following retinal vein occlusion (RVO), which includes macular edema following central retinal vein occlusion (CRVO) and macular edema following branch retinal vein occlusion (BRVO). EYLEA is also available in Japan and the EU for the treatment of myopic choroidal neovascularization (mCNV) and in the United States for the treatment of diabetic retinopathy in patients with DME. Bayer HealthCare has additional regulatory applications for EYLEA for various indications pending in other countries. We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States.
- **Praluent (alirocumab) Injection**, which is available in the United States where it is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol. In September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (heterozygous familial hypercholesterolemia (HeFH) and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent.
- **ARCALYST® (rilonacept) Injection for Subcutaneous Use**, which is available in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children 12 years and older.

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

We have 13 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 12 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our *VelocImmune*® technology.

Trap-based Clinical Programs
EYLEA
In Phase 3 clinical development for the treatment of Neovascular Glaucoma (NVG) (in Japan) in collaboration with Bayer HealthCare. As described below, aflibercept is also being studied in combination with (i) an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), and (ii) an antibody to angiopoietin-2 (Ang2).
Antibody-based Clinical Programs in Collaboration with Sanofi
Praluent
Antibody to PCSK9. In Phase 3 clinical development for LDL cholesterol reduction and for the prevention of cardiovascular events. In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In September 2015, the European Commission granted marketing authorization for Praluent for the treatment of LDL cholesterol in certain adult patients with hypercholesterolemia. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.
Sarilumab (REGN88)
Antibody to the interleukin-6 receptor (IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).
Dupilumab (REGN668)
Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis in adults (Phase 3), atopic dermatitis in pediatric patients (Phase 2), asthma (Phase 3), nasal polyps in patients who also have chronic sinusitis (NPwCS) (Phase 2), and eosinophilic esophagitis (EoE) (Phase 2).
REGN2810
Antibody to programmed cell death protein 1 (PD-1). Phase 1 clinical study in advanced malignancies initiated in the first quarter of 2015.
Antibody-based Clinical Program in Collaboration with Bayer HealthCare
REGN2176-3*
Combination product comprised of an antibody to PDGFR-beta co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 2 clinical study for the treatment of wet AMD initiated in the second quarter of 2015. Fast Track designation received from the FDA for the treatment of patients with wet AMD.
Antibody-based Clinical Program in Collaboration with Mitsubishi Tanabe Pharma
Fasinumab (REGN475)*
Antibody to Nerve Growth Factor (NGF). Phase 2b/3 study (16-weeks) in pain due to osteoarthritis initiated in the second quarter of 2015.
Antibody-based Clinical Programs Developing Independently
REGN2222*
Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. Phase 3 clinical study in RSV initiated in the second quarter of 2015.
Evinacumab (REGN1500)*
Antibody to Angptl-3. Phase 2 clinical study for the treatment of dyslipidemia in homozygous familial hypercholesterolemia initiated in the first quarter of 2015. Partial clinical hold that excluded women of childbearing potential was lifted by the FDA in the third quarter of 2015.
REGN1033*
Antibody to myostatin (GDF8). Phase 2 monotherapy clinical development in skeletal muscle disorders completed. Combination therapy plans are in development. In the second quarter of 2015, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN1033.
REGN1908-1909*
Antibody to Feld1 in Phase 1/Phase 2 clinical development against allergic disease.
REGN1979
Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia.
Nesvacumab/aflibercept (REGN910-3)*
Combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 1 clinical development for the treatment of wet AMD and DME completed.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

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Sync your system to PACER to automate legal marketing.