AMGEN INC
Form 10-K
February 27, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K
(Mark One)

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

For the fiscal year ended December 31, 2012
OR

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

Commission file number 000-12477
Amgen Inc.
(Exact name of registrant as specified in its charter)

Delaware	95-3540776
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California	91320-1799
(Address of principal executive offices)	(Zip Code)

(805) 447-1000
(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, $0.0001 par value	The 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 ý No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No ý
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 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 ý 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 ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $56,028,159,915 as of June 30, 2012(A)

(A) Excludes 771,532 shares of common stock held by directors and executive officers at June 30, 2012. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

748,430,018

(Number of shares of common stock outstanding as of February 19, 2013)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2013 Annual Meeting of stockholders to be held May 22, 2013, are incorporated by reference into Part III of this annual report.

INDEX

i

PART I

Item 1. BUSINESS

Overview

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. Our medicines help millions of patients in the fight against cancer, kidney disease, rheumatoid arthritis (RA), bone disease, and other serious illnesses. We operate in one business segment: human therapeutics.

We were incorporated in 1980 and organized as a Delaware corporation in 1987. Our public website is www.amgen.com. On our website, investors can find press releases, financial filings and other information about the Company. The U.S. Securities and Exchange Commission (SEC) website, www.sec.gov, also offers access to reports and documents we have electronically filed with or furnished to the SEC. These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.

Our principal products are Neulasta® (pegfilgrastim), a pegylated protein, based on the Filgrastim molecule, and NEUPOGEN® (Filgrastim), a recombinant-methionyl human granulocyte colony-stimulating factor (G-CSF), both of which stimulate the production of neutrophils (a type of white blood cell that helps the body fight infection); Enbrel® (etanercept), an inhibitor of tumor necrosis factor (TNF), a substance that plays a role in inflammatory diseases; Aranesp® (darbepoetin alfa) and EPOGEN® (epoetin alfa), erythropoiesis-stimulating agents (ESAs) that stimulate the production of red blood cells; and XGEVA®/Prolia® (denosumab), two products that contain the same active ingredient but which are approved for different indications, patient populations, doses and frequencies of administration. Denosumab is a human monoclonal antibody that specifically targets RANKL, an essential regulator of osteoclasts (the cells that break down bone). Our principal products represented 89%, 90% and 92% of our sales in 2012, 2011 and 2010, respectively. Our other marketed products include primarily Sensipar®/Mimpara® (cinacalcet), a small molecule calcimimetic that lowers serum calcium levels; Vectibix® (panitumumab), a monoclonal antibody that binds specifically to the epidermal growth factor receptor (EGFr); and Nplate® (romiplostim), a thrombopoietin (TPO) receptor agonist that mimics endogenous TPO, the primary driver of platelet production.

We maintain sales and marketing forces primarily in the United States, Europe and Canada. We have also entered into agreements with third parties to assist in the commercialization and marketing of certain of our products in specified geographic areas. (See Business Relationships.) Together with our partners, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In addition to our marketed products, we have various product candidates in mid- to late-stage development in a variety of therapeutic areas, including oncology, hematology, inflammation, bone health, nephrology, cardiovascular and general medicine, which includes neuroscience. Our research and development (R&D) organization has expertise in multiple treatment modalities, including large molecules (such as proteins, antibodies and peptibodies) and small molecules.

Our manufacturing operations consist of bulk manufacturing, formulation, fill and finish and distribution activities for all of our principal products as well as most of our product candidates. We operate a number of commercial and/or clinical manufacturing facilities, and our primary manufacturing facilities are located in the United States, Puerto Rico and the Netherlands. See Item 2. Properties.

Drug development in our industry is complex, challenging and risky; and failure rates are high. Product development cycles are very long — approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable benefit-risk profile. Biological products, which are produced in living systems, are inherently complex due to naturally occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Upon approval, marketed products in our industry generally face substantial competition.

Our industry is highly regulated, and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business. Government authorities in the United States and other countries regulate the manufacturing and marketing of our products as well as our ongoing R&D activities. In recent years, regulators have placed a greater scrutiny on drug safety. This has led to, and may in the future lead to: fewer products being approved by the U.S. Food and Drug Administration (FDA) or other regulatory bodies; delays in receiving approvals; additional safety-related requirements; restrictions on the use of products, including expanded safety labeling, or required risk management activities.

Significant Developments

Following is a summary of significant developments that occurred in 2012 affecting our business.

Products/Pipeline

AMG 145

- In November 2012, we presented data from four phase 2 studies evaluating AMG 145 as monotherapy, in combination with statin therapy, in heterozygous familial hypercholesterolemia, and in statin-intolerant subjects. In each of these studies, treatment with AMG 145 resulted in statistically significant reductions in low-density lipoprotein cholesterol compared to the control arms at 12 weeks. Based on the study results, phase 3 enrollment is underway in these populations.

Sensipar®/Mimpara®

- In November 2012, we presented at American Society of Nephrology's (ASN) Kidney Week the results of the phase 3 E.V.O.L.V.E.™ (EValuation Of Cinacalcet HCl Therapy to Lower CardioVascular Events) trial. As previously reported, the primary analysis showed that the trial did not reach its primary endpoint (time to composite event comprising all-cause mortality or first non-fatal cardiovascular event, including myocardial infarction, hospitalization for unstable angina, heart failure or peripheral vascular event) in the intent-to-treat analysis. See Significant Developments in our Quarterly Report on Form 10-Q for the period ended June 30, 2012.

Rilotumumab

- In November 2012, we initiated a phase 3 study for the treatment of gastric cancer.

Brodalumab (AMG 827)

- In October 2012, we announced the start of a phase 3 program in moderate-to-severe psoriasis. The program consists of three phase 3 studies, with ustekinumab and/or placebo controls. Brodalumab is one of five inflammation monoclonal antibodies being jointly developed in the collaboration with AstraZeneca Plc. (AstraZeneca).

XGEVA®

- In April 2012, we announced that the FDA issued a Complete Response Letter for the supplemental Biologics License Application (sBLA) for XGEVA® to treat men with castration-resistant prostate cancer at high risk of developing bone metastases. The Complete Response Letter states that the FDA cannot approve the application in its present form. The FDA determined that the effect on bone metastases-free survival was of insufficient magnitude to outweigh the risks (including osteonecrosis of the jaw) of XGEVA® in the intended population.

Romosozumab (AMG 785)

- In April 2012, we along with our partner UCB announced the start of two phase 3 clinical studies in postmenopausal osteoporosis (PMO). The registrational study is a placebo-controlled trial that will evaluate incidence of new vertebral fractures at 12 and 24 months in 6,000 patients. We are also conducting an active-controlled trial versus alendronate that will evaluate the incidence of clinical fracture and new vertebral fracture at 12 and 24 months in 4,000 patients.

Acquisitions/Collaborations

- In June 2012, we acquired substantially all of the outstanding stock of Mustafa Nevzat Pharmaceuticals (MN), a privately held company that is a leading supplier of pharmaceuticals to the hospital sector and a major supplier of injectable medicines in Turkey. The acquisition provides us with the opportunity to expand our presence in Turkey and the surrounding region.
- In March 2012, we entered into a collaboration agreement with AstraZeneca to jointly develop and commercialize certain monoclonal antibodies from Amgen's clinical inflammation portfolio including brodalumab, AMG 139, AMG 157, AMG 181 and AMG 557. The agreement covers the worldwide development and commercialization except for certain Asian countries for brodalumab and Japan for AMG 557, which are licensed to other third parties.
- In March 2012, we acquired Micromet, Inc. (Micromet), a publicly held biotechnology company focused on the discovery, development and commercialization of innovative antibody-based therapies for the treatment of cancer.

Marketed Products

We market our principal products, Neulasta®, NEUPOGEN®, ENBREL, Aranesp®, EPOGEN®, XGEVA® and Prolia®, in supportive cancer care, inflammation, nephrology and bone disease. Certain of our marketed products face — and our product candidates, if approved, are also expected to face — substantial competition. Our products' competitive positions among other biological and pharmaceutical products may be based on, among other things, safety, efficacy, reliability, availability, patient convenience/delivery devices, price, reimbursement, timing of market entry and patent position and expirations.

Over the next several years, certain of the existing patents on our principal products will expire, and we expect to face increasing competition thereafter, including from biosimilars. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "biosimilar" to the original reference product. This demonstration will typically consist of comparative analytical, preclinical and clinical data from the biosimilar to show that it has similar safety and efficacy as the reference product. The 2010 U.S. healthcare reform legislation authorized the FDA to approve biosimilars under a new, abbreviated pathway. In February 2012, the FDA released three draft guidance documents that provide insight into the FDA's current thinking on the development of biosimilars and broad parameters for the scientific assessment of biosimilar applications. The FDA guidance documents leave room for the FDA to consider, on a case-by-case basis, the specifics of what evidence would be required for a biosimilar to gain approval. (See Government Regulation.) In the European Union (EU), there is already an established regulatory pathway for biosimilars and we are facing increasing competition from biosimilars. In the United States after patent expiration, we expect to face greater competition than today, including from manufacturers with biosimilars approved in Europe, that may seek to obtain U.S. approval. In some cases we may experience additional competition prior to the expiration of our patents as a result of agreements we have made in connection with the settlement of patent litigation with companies developing potentially competing products. See the discussions of Neulasta®/NEUPOGEN® and Aranesp® later in this section.

Further, the introduction of new products or the development of new processes or technologies by competitors or new information about existing products may result in increased competition for our marketed products, even for those protected by patents, or in a reduction of price that we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates.

In addition to the challenges presented by competition, our existing products and product candidates are also subject to increasing regulatory compliance requirements that could be imposed as conditions of approval or after a product has been approved. This is increasingly true of new therapies with novel mechanisms of action. While such therapies may offer important benefits and/or better treatment alternatives, they may also involve relatively new or higher levels of scientific complexity and may therefore generate increased safety concerns. We design and implement comprehensive proactive pharmacovigilance programs for all of our products to help ensure the detection, assessment and communication of adverse effects. When deemed necessary and appropriate, additional measures for risk communication and mitigation are designed and implemented in consultation with regulatory agencies. As a condition of approval or due to safety concerns after a product has been approved, we may be required to perform additional clinical trials or studies, including postmarketing requirements (PMRs) and postmarketing commitments (PMCs). A PMR is a trial or study that a sponsor company is required by statute or regulation to conduct. A PMC is a trial or study that a sponsor company agrees to in writing, but is not required by law, to conduct. In addition, we may be required to implement risk management plans for our products in the various regions in which they are approved. The FDA requires risk evaluation and mitigation strategies (REMS) for various approved products to ensure that the benefits of the drugs outweigh the risks. A REMS may also be imposed as a condition of approval or after a product has been on the market. A REMS may include a medication guide or a patient package insert, a healthcare provider communication plan or elements to assure safe use that the FDA deems necessary. While the elements of REMS may vary, all REMS require the sponsor company to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. The FDA evaluates such assessments and may require additional modifications to the REMS elements. REMS may also be modified as the FDA and companies gain more experience with REMS and how they are implemented, operated and monitored. We currently have REMS for a number of our marketed products.

See discussion on PMRs, PMCs and REMS in Government Regulation.

Most patients receiving our principal products for approved indications are covered by either government or private payer healthcare programs, which influence demand. The reimbursement environment continues to evolve with greater emphasis on both cost containment and demonstration of the economic value of products. In addition, the current worldwide economic conditions have also contributed to increasing pressures on cost containment.

Neulasta® (pegfilgrastim)/NEUPOGEN® (Filgrastim)

We were granted an exclusive license to manufacture and market Neulasta® and NEUPOGEN® in the United States, Europe, Canada and Australia under a licensing agreement with Kirin-Amgen, Inc. (K-A), a joint venture between Kirin Holdings Company, Limited (Kirin), and Amgen. See Business Relationships — Kirin-Amgen, Inc.

Neulasta® and NEUPOGEN® stimulate production of neutrophils, a type of white blood cell important in the body's fight against infection. Both the treatments for various diseases and the diseases themselves can result in extremely low numbers of neutrophils, a condition called neutropenia. Myelosuppressive chemotherapy, one treatment option for individuals with certain types of cancers, targets cell types that grow rapidly, such as tumor cells. Normal cells that divide rapidly, such as those in the bone marrow that become neutrophils, are also vulnerable to the cytotoxic effects of myelosuppressive chemotherapy, resulting in neutropenia with an increased risk of severe infection. NEUPOGEN® is our registered trademark for Filgrastim, our recombinant-methionyl human G-CSF. Neulasta® is our registered trademark for pegfilgrastim, a pegylated protein based on the Filgrastim molecule. A polyethylene glycol molecule is added to the Filgrastim molecule to make pegfilgrastim. Because pegfilgrastim is eliminated from the body through binding to its receptor on neutrophils and neutrophil precursor cells, pegfilgrastim remains in circulation in the body until neutrophil recovery has occurred. This neutrophil-mediated clearance allows for administration as a single dose per chemotherapy cycle, compared with NEUPOGEN®, which requires more frequent dosing.

We market Neulasta® and NEUPOGEN® primarily in the United States and Europe. Neulasta® was launched in the United States and Europe in 2002 and is indicated to decrease the incidence of infection associated with chemotherapy-induced febrile neutropenia in cancer patients with non-myeloid malignancies. Administration of Neulasta® in all cycles of chemotherapy is approved for patients receiving myelosuppressive chemotherapy associated with a clinically significant risk of febrile neutropenia. NEUPOGEN® was launched in the United States and Europe in 1991. NEUPOGEN® is indicated for reducing the incidence of infection as manifested by febrile neutropenia for patients with non-myeloid malignancies undergoing myelosuppressive chemotherapy associated with a significant incidence of severe neutropenia with fever; reducing the duration of neutropenia and neutropenia-related consequences for patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; reducing the incidence and duration of neutropenia-related consequences in symptomatic patients with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia (collectively, severe chronic neutropenia); mobilizing peripheral blood progenitor cells (PBPC) in cancer patients who have undergone myeloablative chemotherapy for stem cell transplantation; and reducing the recovery time of neutrophils and the duration of fever following induction or consolidation chemotherapy treatment in adult patients with acute myeloid leukemia (AML).

Total Neulasta®/NEUPOGEN® sales were as follows (in millions):

	2012	2011	2010
Neulasta® — U.S.	$3,207	$3,006	$2,654
Neulasta® — rest-of-the-world (ROW)	885	946	904
Total Neulasta®	4,092	3,952	3,558
NEUPOGEN® — U.S.	1,007	959	932
NEUPOGEN® — ROW	253	301	354
Total NEUPOGEN®	1,260	1,260	1,286
Total Neulasta®/NEUPOGEN®	$5,352	$5,212	$4,844

Our outstanding material patents for pegfilgrastim are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	Pegylated G-CSF	10/20/2015
Europe[1]	Pegylated G-CSF	2/8/2015

(1) This European patent is also entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary by country. For example, supplementary protection certificates covering pegfilgrastim have issued in France, Germany, Italy, Spain, and the United Kingdom, and will expire in 2017.

Our outstanding material patents for Filgrastim are described in the following table.

Territory	General Subject Matter	Expiration
U.S.	G-CSF polypeptides	12/3/2013
U.S.	Methods of treatment using G-CSF polypeptides	12/10/2013

Our principal European patent related to G-CSF expired in August 2006. Upon expiration of that patent, some companies received approval to market products, including biosimilars, that compete with NEUPOGEN® and

Neulasta® in Europe, as further discussed below.

Our outstanding material U.S. patents for Filgrastim (NEUPOGEN®) expire in December 2013. We expect to face competition in the United States beginning in the fourth quarter of 2013, which may have a material adverse impact over time on future sales of NEUPOGEN® and, in turn, Neulasta®. See discussion of Teva below.

Any products or technologies that are directly or indirectly successful in treating neutropenia associated with chemotherapy, for bone marrow and PBPC transplant patients, severe chronic neutropenia and AML could negatively impact Neulasta® and/or NEUPOGEN® sales. Neulasta®