CELGENE CORP /DE/
Form 10-K
February 22, 2012

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, 2011

or

o **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 001-34912

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**22-2711928**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
86 Morris Avenue Summit, New Jersey	**07901**
(Address of principal executive offices)	(Zip Code)

(908) 673-9000
(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 $.01 per share	NASDAQ Global Select Market
Contingent Value Rights	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 o

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 o No ý

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 ý No o

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 o

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. o

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 ý	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes o No ý

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2011, the last business day of the registrant's most recently completed second quarter, was $27,747,802,356 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

There were 438,810,304 shares of Common Stock outstanding as of February 16, 2012.

Documents Incorporated by Reference

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2011. The proxy statement is incorporated herein by reference into the following parts of the Form 10-K:

Part II, Item 5.	Equity Compensation Plan Information.
Part III, Item 10.	Directors, Executive Officers and Corporate Governance.
Part III, Item 11.	Executive Compensation.
Part III, Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.
Part III, Item 13.	Certain Relationships and Related Transactions, and Director Independence.
Part III, Item 14.	Principal Accountant Fees and Services.

CELGENE CORPORATION
ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

Table of Contents

PART I

ITEM 1. ***BUSINESS***

Celgene Corporation and its subsidiaries (collectively "we," "our," "us" or the "Company") is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. We are dedicated to innovative research and development which is designed to bring new therapies to market, and we are involved in research in several scientific areas that may deliver proprietary next-generation therapies, targeting areas such as intracellular signaling pathways in cancer and immune cells, immunomodulation in cancer and autoimmune diseases, and therapeutic application of cell therapies.

Our primary commercial stage products include REVLIMID®, VIDAZA®, THALOMID®, ABRAXANE® and ISTODAX®. Additional sources of revenue include a licensing agreement with Novartis, which entitles us to royalties on FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through our Cellular Therapeutics subsidiary and other miscellaneous licensing agreements.

We continue to invest substantially in research and development, and the drug candidates in our pipeline are at various stages of preclinical and clinical development. These candidates include pomalidomide and apremilast, our leading oral anti-cancer and anti-inflammatory agents, PDA-001, our leading cellular therapy, oral azacitidine, CC-223 and CC-115 for hematological and solid tumor malignancies, CC-122, our anti-cancer pleiotropic pathway modifier, and ACE-011 and ACE-536 biological products for anemia in several clinical settings of unmet need. We believe that continued acceptance of our primary commercial stage products, participation in research and development collaboration arrangements, depth of our product pipeline, regulatory approvals of new products and expanded use of existing products will provide the catalysts for future growth.

In 1986, we were spun off from Celanese Corporation and, in July 1987, completed an initial public offering. Our initial operations focused on the research and development of chemical and biotreatment processes for the chemical and pharmaceutical industries. In the intervening years, we invested significantly in developing additional internal pharmaceutical programs and have completed a number of strategic acquisitions that strengthened our research and manufacturing capabilities in addition to enhancing our commercial product portfolio. Our most recent strategic acquisitions included:

In January 2012, we and Avila Therapeutics, Inc., or Avila, a privately-held biotechnology company, announced a definitive merger agreement under which we will acquire Avila for $350.0 million in cash plus up to $575.0 million in contingent development and regulatory approval milestones. The acquisition is expected to expand our leading role in the future treatment of hematologic cancers with Avila's AVL-292, a highly-selective Bruton's tyrosine kinase (Btk) inhibitor, currently in phase I clinical development. In addition, Avila's proprietary Avilomics platform will augment our investment in the discovery and development of novel therapeutics. The transaction is subject to customary closing conditions, including the expiration or termination of the applicable waiting period under

Table of Contents

the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and will be accounted for as an acquisition of a business.

In October 2010, we acquired Abraxis Bioscience Inc., or Abraxis, a fully integrated global biotechnology company dedicated to the discovery, development and delivery of next-generation therapeutics and core technologies that offer patients treatments for cancer and other critical illnesses. The acquisition of Abraxis accelerates our strategy to become a global leader in oncology and added ABRAXANE®, which is based on Abraxis' proprietary tumor-targeting platform known as nab® technology, to our portfolio of leading cancer products.

In January 2010, we acquired Gloucester Pharmaceuticals, Inc., or Gloucester, a privately held pharmaceutical company which developed new therapies that address unmet medical needs in the treatment of hematological cancers, including cutaneous T-cell lymphoma, or CTCL, peripheral T-cell lymphoma, or PTCL, and other hematological malignancies. Gloucester added ISTODAX® to our product portfolio and advanced our leadership position in the development of disease-altering therapies through innovative approaches for patients with rare and debilitating blood cancers.

For the year ended December 31, 2011, we reported revenue of $4.842 billion, net income of $1.318 billion and diluted earnings per share of $2.85. Revenue increased by $1.216 billion in 2011 compared to the year ended December 31, 2010 primarily due to our continuing expansion into international markets, growth of REVLIMID® and VIDAZA® in both U.S. and international markets and the inclusion of a full year's sales of ABRAXANE® in 2011. Net income and earnings per share increases in 2011 reflect the earnings contributions from a higher sales level, partly offset by increased spending for new product launches, research and development, and expansion of our international operations.

Our future growth and operating results will depend on the continued acceptance of our marketed products, future regulatory approvals and successful commercialization of new products and new product indications, depth of our product pipeline, competition with our marketed products and protection of our intellectual property. See also, Forward-Looking Statements and Risk Factors contained in Part I, Item 1A of this Annual Report on Form 10-K.

COMMERCIAL STAGE PRODUCTS

REVLIMID® (lenalidomide): REVLIMID® is an oral immunomodulatory drug marketed in the United States and many international markets, in combination with dexamethasone, for treatment of patients with multiple myeloma who have received at least one prior therapy. It is also marketed in the United States and certain international markets for the treatment of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes, or MDS, associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID® is distributed in the United States through contracted pharmacies under the RevAssist® program, which is a proprietary risk-management distribution program tailored specifically to help ensure the safe and appropriate distribution and use of REVLIMID®. Internationally, REVLIMID® is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities' specifications to help ensure the safe and

Table of Contents

appropriate distribution and use of REVLIMID®. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies.

REVLIMID® continues to be evaluated in numerous clinical trials worldwide either alone or in combination with one or more other therapies in the treatment of a broad range of hematological malignancies, including multiple myeloma, MDS, various lymphomas, chronic lymphocytic leukemia, or CLL, other cancers and other diseases.

VIDAZA® (azacitidine for injection): VIDAZA® is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA® is a Category 1 recommended treatment for patients with intermediate-2 and high-risk MDS according to the National Comprehensive Cancer Network and is marketed in the United States for the treatment of all subtypes of MDS. The U.S. regulatory exclusivity for VIDAZA® expired in May 2011. If a generic version of VIDAZA® is successfully launched, we may quickly lose a significant portion of our sales for this product in the United States. In Europe, VIDAZA® is marketed for the treatment of intermediate-2 and high-risk MDS as well as acute myeloid leukemia, or AML, with 30% blasts and has been granted orphan drug designation for the treatment of MDS and AML.

THALOMID® (thalidomide): THALOMID® is marketed for patients with newly diagnosed multiple myeloma and for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum, or ENL, an inflammatory complication of leprosy and as maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence.

THALOMID® is distributed in the United States under our "*System for Thalidomide Education and Prescribing Safety*," or *S.T.E.P.S.*®, program, which we developed and is a proprietary comprehensive education and risk-management distribution program with the objective of providing for the safe and appropriate distribution and use of THALOMID®. Internationally, THALOMID® is also distributed under mandatory risk-management distribution programs tailored to meet local competent authorities' specifications to help ensure the safe and appropriate distribution and use of THALOMID®. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies.

ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension): ABRAXANE®, which was obtained in the 2010 acquisition of Abraxis, is a solvent-free chemotherapy treatment option for metastatic breast cancer which was developed using our proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. It is approved for the treatment of metastatic breast cancer in the United States and specific international markets. ABRAXANE® is currently in various stages of investigation for the treatment of the following cancers: expanded applications for metastatic breast; non-small cell lung; malignant melanoma; pancreatic; bladder and ovarian.

ISTODAX® (romidepsin): ISTODAX®, which was obtained in the 2010 acquisition of Gloucester, is approved in the United States for the treatment of CTCL in patients who have received at least one prior systemic therapy. Additionally, in June 2011, ISTODAX® received approval for the treatment of PTCL in patients who have received at least one prior therapy. ISTODAX® has received orphan drug designation for the treatment of non-Hodgkin's T-cell

Table of Contents

lymphomas, which includes CTCL and PTCL. The European Agency for the Evaluation of Medicinal Products, or EMA, has granted orphan drug designation for ISTODAX® for the treatment of both CTCL and PTCL.

FOCALIN®, FOCALIN XR® and RITALIN LA®: We licensed the worldwide rights (excluding Canada) regarding certain chirally pure forms of methylphenidate for FOCALIN® and FOCALIN XR® to Novartis. We also licensed to Novartis the rights related to long-acting formulations of methylphenidate and dex-methylphenidate products which are used in FOCALIN XR® and RITALIN LA®. As a result of the grant of these licenses we receive royalties on sales of these products.

Product Development: We devote significant resources to research and development programs in an effort to discover and develop potential future product candidates. Research and development expenses amounted to $1.600 billion in 2011, $1.128 billion in 2010, and $0.795 billion in 2009. The product candidates in our pipeline are at various stages of preclinical and clinical development. The path to regulatory approval includes three phases of clinical trials in which we collect data to support an application to regulatory authorities to allow us to market a product for treatment of a specified disease indication. There are many difficulties and uncertainties inherent in research and development and the introduction of new products, including a high rate of failure. To bring a drug from the discovery phase to regulatory approval, and ultimately to market, takes many years and significant cost. Failure can occur at any point in the process, including after the product is approved based on post-market factors. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, reimbursement challenges, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Delays and uncertainties in the Food and Drug Administration, or FDA, approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. Consequently, it is very difficult to predict which products will ultimately be submitted for approval, which have the highest likelihood of obtaining approval, and which will be commercially viable and generate profits. Successful results in preclinical or phase I/II clinical studies may not be an accurate predictor of the ultimate safety or effectiveness of a drug or product candidate.

Phase I Clinical Trials

Phase I clinical trials begin when regulatory agencies allow a request to initiate clinical investigations of a new drug or product candidate and usually involve up to 50 healthy volunteers or patients. The tests study a drug's safety profile, and may include a preliminary determination of a drug or product candidate's safe dosage range. The phase I clinical study also determines how a drug is absorbed, distributed, metabolized and excreted by the body, and therefore the potential duration of its action. Phase I clinical studies generally take from one to three years to complete.

Phase II Clinical Trials

Phase II clinical trials are conducted on a limited number of patients with the targeted disease. An initial evaluation of the drug's effectiveness on patients is performed and additional information on the drug's safety and dosage range is obtained. Our phase II

Table of Contents

clinical trials normally include up to 200 patients and may take as much as two to three years to complete.

Phase III Clinical Trials

Phase III clinical trials typically include controlled multi-center trials and involve a larger target patient population that normally includes from 500 to 1,500 patients to ensure that study results are statistically significant. During phase III clinical trials, physicians monitor patients to determine efficacy and to gather further information on safety. These trials are generally global in nature and are designed to generate all of the data necessary to submit the product to regulatory agencies for marketing approval. Phase III testing varies by disease state, but can often last from two to seven years.

Regulatory Review

If a product successfully completes phase III clinical trials and is submitted to governmental regulators, such as the FDA in the United States or the EMA in the European Union, the time to final marketing approval can vary from six months (for a U.S. filing that is designated for priority review by the FDA) to several years, depending on a number of variables, such as the disease state, the strength and complexity of the data presented, the novelty of the target or compound, risk-management approval and whether multiple rounds of review are required for the agency(ies) to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

Current pivotal or phase III trials of our commercial stage products and their targeted disease indications are outlined in the following table:

Product	Disease Indication	Status	Current Trial Beginning Date
REVLIMID	Newly Diagnosed Multiple Myeloma	Phase III ongoing; Submitted EU regulatory filing; US regulatory filing pending	August 2008
	Maintenance Therapy for Multiple Myeloma	Phase III trials ongoing	December 2004
	MDS del 5q	Submitted EU regulatory filing	N/A
	MDS non-del 5q	Phase III trial ongoing	February 2010
	Mantle Cell Lymphoma for U.S. filing	Phase II ongoing	January 2009
	Mantle Cell Lymphoma for EU filing	Phase II ongoing	April 2009
	Diffuse Large B Cell Lymphoma	Phase II/III enrolling	July 2010
	Diffuse Large B Cell Lymphoma Maintenance	Phase III enrolling	May 2009
	Follicular Lymphoma Consolidation & Maintenance	Phase III enrolling	December 2011
	CLL First Line	Phase III ongoing	November 2009
	CLL Maintenance	Phase III ongoing	February 2009
VIDAZA	AML	Phase III trial enrolling	October 2010
ISTODAX	PTCL	Submitted EU regulatory filing	N/A
ABRAXANE	Non-small cell lung cancer	Submitted U.S. regulatory filing	N/A
	Pancreatic Cancer	Phase III trial ongoing	May 2009
	Melanoma	Phase III trial ongoing	April 2009

Table of Contents

PRECLINICAL AND CLINICAL STAGE PIPELINE

Our preclinical and clinical-stage pipeline of new drug candidates and cell therapies is highlighted by multiple classes of small molecule, orally administered therapeutic agents designed to selectively regulate disease-associated genes and proteins. The product candidates in our pipeline are at various stages of preclinical and clinical development.

Pomalidomide: Pomalidomide is a proprietary, distinct, small molecule that is orally available and modulates the immune system and other biologically important targets. Pomalidomide is being evaluated in a phase III clinical trial for the treatment of myelofibrosis and a phase III clinical trial evaluating pomalidomide as a treatment for patients with relapsed/refractory multiple myeloma is currently accruing patients. Regulatory filings for relapsed/refractory multiple myeloma are targeted for submission in the U.S. and Europe in first half of 2012.

ORAL ANTI-INFLAMMATORY AGENTS: We are developing novel, orally available small molecules that specifically target PDE4, an intracellular enzyme that modulates the production of multiple pro-inflammatory and anti-inflammatory mediators including interleukin-2 (IL-2), IL-10, IL-12, IL-23, INF-gamma, TNF-α, leukotrienes, and nitric oxide synthase. Our lead investigational drug, apremilast (CC-10004), has shown efficacy in phase II studies for the treatment of moderate to severe psoriasis and active psoriatic arthritis and is currently being evaluated in a phase II trial for rheumatoid arthritis and six phase III multi-center international clinical trials. A phase III clinical trial is planned to evaluate apremilast's efficacy in ankylosing spondylitis. In addition, we are investigating our next generation oral PDE4 inhibitor, CC-11050, a unique anti-inflammatory compound with the potential to treat a variety of chronic inflammatory conditions such as Cutaneous Lupus Erythematosus, or CLE.

KINASE INHIBITORS: We have generated valuable intellectual property in the identification of multiple kinases that regulate pathways critical in inflammation and oncology. Our oral kinase inhibitor platform includes inhibitors of the c-Jun N-terminal kinase, or JNK, mTOR kinase, spleen tyrosine kinase, or Syk, c-fms tyrosine kinase, or c-FMS, and DNA-dependent protein kinase, or DNAPK. Our oral Syk, c-FMS and DNAPK kinase inhibitors are being investigated in pre-clinical studies and we are targeting human trials in 2012. Our new second generation JNK inhibitor, tanzisertib (CC-930), is currently being evaluated in a phase II trial for the treatment of idiopathic pulmonary fibrosis and a phase II trial for the treatment of discoid lupus is currently accruing patients.

Amrubicin: Amrubicin is a third-generation fully synthetic anthracycline molecule with potent topoisomerase II inhibition. The regulatory strategy for international markets is being evaluated.

CELLULAR THERAPIES: At Celgene Cellular Therapeutics, or CCT, we are researching stem cells derived from the human placenta as well as from the umbilical cord. CCT is our state-of-the-art research and development division dedicated to fulfilling the promise of cellular technologies by developing cutting-edge products and therapies to significantly benefit patients. Our goal is to develop proprietary cell therapy products for the treatment of unmet medical needs.

Stem cell based therapies offer the potential to provide disease-modifying outcomes for serious diseases which lack adequate therapy. We have developed proprietary technology for collecting, processing and storing placental stem cells with potentially broad therapeutic applications in cancer, auto-immune diseases including Crohn's disease, multiple sclerosis, neurological

Table of Contents

disorders including stroke and amyotrophic lateral sclerosis, or ALS, graft-versus-host disease, and other immunological / anti-inflammatory, rheumatologic and bone disorders. We have initiated phase II studies for our human placenta derived cell product, PDA-001, to evaluate it as a potential treatment for patients with moderate-to-severe Crohn's disease refractory to oral corticosteroids and immune suppressants, patients with rheumatoid arthritis, and patients with sarcoidosis. A phase Ib study is also underway to evaluate PDA-001 as a potential treatment for patients with multiple sclerosis.

We also maintain investigational new drug applications, or INDs, with the FDA for a trial with human umbilical cord blood in sickle cell anemia, and to support a study to assess the safety of the transplantation of human placental-derived stem cells with umbilical cord blood stem cells in subjects with certain malignant hematological diseases and non-malignant disorders. We are continuing additional preclinical and clinical research to define further the potential of placental-derived stem cells and to characterize other placental-derived products.

SOTATERCEPT (ACE-011): We have collaborated with Acceleron Pharma, Inc., or Acceleron, to develop sotatercept. Sotatercept acts as a decoy receptor for members of the growth and differentiation factor, or GDF, family of ligands that bind the ACTIIRA receptor, with highest affinity for Activin A, Activin B and GDF-11. Two phase I clinical studies have been completed and two phase II studies are closed and awaiting completion of the clinical study report. An additional phase II clinical study has been initiated and is currently ongoing related to treatments for end-stage renal anemia and to evaluate effects on red blood cell mass and plasma volume.

Table of Contents

CELGENE LEADING PRODUCT CANDIDATES

The development of our leading new drug candidates and their targeted disease indications are outlined in the following table:

Product	Disease Indication	Status	Current Trial Beginning Date
Pomalidomide (CC-4047)	Myelofibrosis	Phase III trial ongoing	September 2010
	Multiple myeloma	Phase II trial completed U.S. and EU regulatory filings pending	N/A
	Multiple myeloma	Phase III trial enrolling	April 2011
Oral Anti-Inflammatory:			
Apremilast (CC-10004)	Psoriasis	Phase III trials ongoing	September 2010
	Psoriatic arthritis	Phase III trials ongoing	June 2010
	Rheumatoid arthritis	Phase II trial ongoing	December 2010
	Ankylosing Spondylitis	Phase III trial planned	June 2012
CC-11050	Cutaneous lupus	Phase II trial enrolling	February 2011
Kinase Inhibitors:			
Tanzisertib (CC-930)	Idiopathic pulmonary fibrosis	Phase II trial ongoing	January 2011
	Discoid Lupus	Phase II trial enrolling	November 2011
Cellular Therapies:			
PDA-001	Crohn's disease	Phase II trial ongoing	August 2010
	Multiple sclerosis	Phase Ib trial ongoing	December 2010
	Rheumatoid arthritis	Phase II trial ongoing	December 2010
	Sarcoidosis	Phase II trial ongoing	September 2011
Activin Biology:			
Sotatercept (ACE-011)	Renal anemia	Phase II trial ongoing	June 2010
ACE-536	Anemia in MDS	Phase I trial ongoing	September 2011
Novel Anti-tumor Agents:			
CC-223	Solid Tumors, Non-Hodgkin Lymphoma, Multiple Myeloma	Phase I trial ongoing	July 2010
CC-115	Solid Tumors, Non-Hodgkin Lymphoma, Multiple Myeloma	Phase I trial ongoing	April 2011
CC-122	Solid Tumors, Non-Hodgkin Lymphoma, Multiple Myeloma	Phase I trial ongoing	September 2011
Oral Azacitidine	Solid Tumors	Phase II trial ongoing	November 2011
	MDS	Phase II trial ongoing	September 2010

PATENTS AND PROPRIETARY TECHNOLOGY

We consider intellectual property protection (including, but not limited to, patents and regulatory exclusivities) relative to certain products, particularly those products discussed below, to be critical to our operations. For many of our products, in addition to compound patents, we hold other patents on manufacturing processes, formulations, or uses that may extend exclusivity beyond the expiration of the product patent.

Table of Contents

KEY PRODUCTS: TABLE OF EXCLUSIVITIES

The following table shows the expected expiration dates in the United States and in Europe of the last-to-expire period of exclusivity (regulatory or patent) related to the following approved drugs and are subject to challenges and risk factors as described herein:

	U.S.	Europe
REVLIMID® brand drug (U.S. and European Patent Office, or EPO, drug substance patents)	2027	2024
THALOMID® brand drug (Use and/or drug product patents)	2023	2019
VIDAZA® brand drug (U.S. and EMA regulatory exclusivities only)	2011	2018
ABRAXANE® brand drug (U.S. and EPO use/drug product patents)	2024	2022
ISTODAX® brand drug (U.S. drug substance patents) (EMA regulatory exclusivity upon approval)	2021	(10 years regulatory exclusivity upon approval)
FOCALIN® brand drug (U.S. use patents)	2015	N/A
FOCALIN XR® brand drug (U.S. use patents) (EPO drug product patent)	2015	2018

In the United States, the patents covering the REVLIMID® brand drug include 14 patents that are listed in the U.S. Orange Book, all of which are assigned to us. The last-to-expire patent (2027), U.S. Patent No. 7,465,800, covers certain polymorphic forms of the pharmaceutically active ingredient of REVLIMID® brand drug.

REVLIMID® brand drug is also covered in foreign countries by certain patents and patent applications that are equivalent to those listed in the U.S. Orange Book. For example, patents related to the active pharmaceutical ingredient, uses and pharmaceutical compositions are granted in Europe. The patents are currently scheduled to expire in 2017 or 2018, except that patents granted in certain European countries such as, for example, Spain, France, Italy, Germany and the United Kingdom will not expire until 2022 due to the Supplementary Protection Certificates, or SPCs, granted in these countries. In addition, patents in Europe that relate to certain polymorphic forms of the pharmaceutically active ingredient of REVLIMID® brand drug will not expire until 2024.

The patents covering THALOMID® brand drug in the United States include 15 patents that are listed in the U.S. Orange Book. The last-to-expire patent that is assigned to us (2023), U.S. Patent No. 7,230,012, covers marketed THALOMID® formulations.

Table of Contents

In foreign countries, THALOMID® brand drug is also covered by certain patents and patent applications that are equivalent to those listed in the U.S. Orange Book. Patents related to the approved uses of thalidomide are granted in Europe. The patents are currently scheduled to expire in 2014 or 2017, except that patents granted in certain European countries, such as for example, Spain, France and Italy, will not expire until 2019 due to the SPCs granted in these countries.

Exclusivity with respect to the currently approved formulation for VIDAZA® brand drug stems from regulatory mechanisms. In the United States, orphan drug exclusivity with respect to VIDAZA® brand drug expired in May 2011. In Europe, new drug and orphan exclusivities relative to VIDAZA® brand drug will expire in December 2018.

The patents covering ABRAXANE® brand drug in the United States include ten patents that are listed in the U.S. Orange Book. The last-to-expire patent (2024), U.S. Patent No. 7,820,788, covers marketed ABRAXANE® formulations. In Europe, new drug exclusivity relative to ABRAXANE® brand drug expires in 2018. We have applied for and received in certain European countries SPCs relative to EP 0 961 612 B1 that extend exclusivity for ABRAXANE® brand drug to 2022. EP 0 961 612 B1, which was under opposition at the European Patent Office by Teva Pharmaceutical Industries Ltd., was confirmed at a hearing in November 2011 in all relevant respects. There is a possibility that Teva will appeal this decision in February 2012.

Our acquisition of Gloucester included the acquisition of certain intellectual properties relative to ISTODAX® brand drug. These patents, listed in the U.S. Orange Book, expire in August 2021.

In the United States, the patents covering FOCALIN® brand drug include three patents that are listed in the U.S. Orange Book. All of these patents are assigned to us. These patents all expire in December 2015.

In the United States, the patents covering FOCALIN XR® brand drug comprise six patents that are listed in the U.S. Orange Book. All of these patents are assigned to us. These patents all expire in December 2015. A relevant European patent, owned by us, expires in June 2018.

In the United States, the patents covering RITALIN LA® brand drug comprise three patents that are listed in the U.S. Orange Book. All of these patents are assigned to us. These patents all expire in December 2015. A relevant European patent, owned by us, expires in June 2018. Actavis Group, a generic manufacturer, has announced that they have launched a generic version of RITALIN LA® in January 2012.

With respect to our U.S. patents for FOCALIN®, FOCALIN XR® and RITALIN LA® brand drugs litigations with generic drug companies (e.g. TEVA Pharmaceuticals USA, Inc., IntelliPharmaCeutics Corp., Actavis South Atlantic LLC, Abrika Pharmaceuticals, Inc., Barr Pharmaceutical, Inc. and KV Pharmaceutical Company), were resolved pursuant to confidential settlements which allow for the entrance of their respective generic products in the United States prior to the 2015 patent expirations in the event their respective abbreviated new drug applications, or ANDA, receive FDA approval.

As noted above, patent protection is very important to us and our business and, therefore, we have applied for and received SPCs in Europe relative to certain in-licensed thalidomide patents.

Table of Contents

These SPCs, reflected in the chart above, extend the terms of these patents relative to certain uses of thalidomide to 2019. In addition, we have applied for and received SPCs to 2022 in Europe relative to both REVLIMID® and ABRAXANE® brand drug. In the United States, we have been granted a patent term extension of a REVLIMID® composition of matter patent to 2019. By way of further example, in the United States, and as reflected in the chart above, we have been granted patent term adjustment with respect to a REVLIMID® polymorph patent; this patent is presently scheduled to expire in 2027.

Patent term extensions have been granted in other markets as well, including Australia and Korea, relative to certain of our patents covering lenalidomide. Patent term extension applications relative to lenalidomide also are pending in Japan. Further, patent term extensions relative to ABRAXANE® brand drug have been secured and/or are actively being sought in Australia, Japan, Russia and Korea. In addition, we have actively considered and may pursue alternate exclusivity strategies, mostly related to international treaties, in a variety of countries throughout Latin America.

Trade secret strategies also are integral to our success. There exist certain trade secrets related to many of our key products.

Our brand names, logos and trademarks are also important to us and in the aggregate important to our success. We maintain both registered and common law trademarks. Common law trademark protection typically continues where and for as long as the mark is used. Registered trademarks continue in each country for as long as the trademark is registered.

In total, we own or have exclusively licensed over 290 issued U.S. patents. In addition, approximately 400 additional pending patent applications are owned by or exclusively licensed to us. We have a policy to seek worldwide patent protection for our inventions and have foreign patent rights corresponding to most of our U.S. patents.

In August 2001, we entered into an agreement, termed the "New Thalidomide Agreement," with EntreMed, Inc., or EntreMed, Children's Medical Center Corporation, or CMCC, and Bioventure Investments kft, relating to patents and patent applications owned by CMCC, which agreement superseded several agreements already in place between CMCC, EntreMed and us. Pursuant to the New Thalidomide Agreement, CMCC directly granted to us an exclusive worldwide license under the relevant patents and patent applications relating to thalidomide. Several U.S. and European patents have been issued to CMCC in this patent family and certain of these patents expire in 2014 and 2017. We have applied for and received SPCs in Europe relative to certain of these issued CMCC thalidomide patents. These SPCs extend the terms of these patents relative to uses of thalidomide to 2019. Corresponding foreign patent applications and additional U.S. patent applications are still pending.

In addition to the New Thalidomide Agreement, we entered into an agreement, entitled the "New Analog Agreement," with CMCC and EntreMed in December 2002, pursuant to which we have been granted an exclusive worldwide license to certain CMCC patents and patent applications relating to thalidomide analogs. Under the New Analog Agreement, CMCC exclusively licensed to us these patents and patent applications, which relate to analogs, metabolites, precursors and hydrolysis products of thalidomide, and stereoisomers thereof. Under the New Analog Agreement, we are obligated to comply with certain milestones and other

Table of Contents

obligations, including those relating to REVLIMID® brand drug sales. The New Analog Agreement grants us control over the prosecution and maintenance of the licensed thalidomide analog patent rights.

Our research leads us to seek patent protection for molecular targets and drug discovery technologies, as well as therapeutic and diagnostic products and processes. More specifically, proprietary technology has been developed for use in molecular target discovery, the identification of regulatory pathways in cells, assay design and the discovery and development of pharmaceutical product candidates. An increasing percentage of our recent patent applications have been related to potential product candidates or compounds.

CCT, our cellular therapeutics subsidiary, seeks patent protection for the collection, processing, composition, formulation and uses of mammalian placental and umbilical cord tissue and placental and umbilical cord stem cells, as well as cells and biomaterials derived from the placenta. As of December 2011, CCT owned, in whole or in part, 18 U.S. patents, including claims to novel cells and cellular compositions. In addition, CCT has approximately 75 U.S. patent applications, including pending provisional applications.

Our patents are regularly subject to challenge by generic drug companies and manufacturers. See Part I, Item 3, "Legal Proceedings." We rely on several different types of patents to protect our products, including, without limitation, compound, polymorph, formulation and method of use patents. We do not know whether any of these patents will be circumvented, invalidated or found unenforceable as a result of challenge by generic companies or manufacturers. For a more detailed discussion of risks related to our patent portfolio, see Part I, Item 1A. "Risk Factors."

GOVERNMENTAL REGULATION/EXCLUSIVITIES AFFORDED BY REGULATORY AUTHORITIES

Governmental Regulation: Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. Most, if not all, of our therapeutic products require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal and, in some cases, state statutes and regulations also govern or impact upon the manufacturing, testing for safety and effectiveness, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals, and the continuing need for compliance with applicable statutes and regulations, requires the expenditure of substantial resources. Regulatory approval, if and when obtained, may be limited in scope which may significantly limit the indicated uses for which a product may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing post-marketing review, inspection and discovery of previously unknown problems with such products or the manufacturing or quality control procedures used in their production, which may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Any failure by us, our suppliers of manufactured drug product, collaborators or licensees to obtain or maintain, or any delay in obtaining, regulatory approvals could adversely affect the marketing of our products and our ability to receive product revenue, license revenue or profit sharing payments.