CELGENE CORP /DE/
Form 10-K
February 20, 2015
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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, 2014
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 (State or other jurisdiction of incorporation or organization)	22-2711928 (I.R.S. Employer Identification No.)
86 Morris Avenue Summit, New Jersey (Address of principal executive offices)	07901 (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 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 x 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 x
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 x 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 x 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. x
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 x Accelerated filer o Non-accelerated filer o

		Smaller reporting company o
	(Do not check if a smaller reporting company)	

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2014, the last business day of the registrant's most recently completed second quarter, was $68,638,903,046 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

There were 800,590,656 shares of Common Stock outstanding as of February 12, 2015.

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, 2014. The proxy statement is incorporated herein by reference into the following parts of the Form 10-K:

Part II, Item 5.(d)	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.

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CELGENE CORPORATION
ANNUAL REPORT ON FORM 10-K
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PART I

ITEM 1. BUSINESS

Celgene Corporation, together with its subsidiaries (collectively "we," "our," "us," "Celgene" or the "Company"), is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation. We are dedicated to innovative research and development designed to bring new therapies to market and we are involved in research in several scientific areas designed to deliver proprietary next-generation therapies, targeting areas including intracellular signaling pathways, protein homeostasis and epigenetics in cancer and immune cells, immunomodulation in cancer and autoimmune diseases and therapeutic application of cell therapies. Celgene Corporation was incorporated in the State of Delaware in 1986.

Our primary commercial stage products include REVLIMID®, ABRAXANE®, POMALYST®/IMNOVID®, VIDAZA®, azacitidine for injection (generic version of VIDAZA®), THALOMID® (sold as THALOMID® or Thalidomide Celgene™ outside of the U.S.), OTEZLA® and ISTODAX®. OTEZLA® was approved by the U.S. Food and Drug Administration (FDA) in March 2014 for the treatment of adult patients with active psoriatic arthritis and in September 2014 for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. In January 2015, OTEZLA® was approved by the European Commission (EC) for the treatment of both psoriasis and psoriatic arthritis in certain adult patients. We began recognizing revenue related to OTEZLA® during the second quarter of 2014. Additional sources of revenue include royalties from Novartis Pharma AG (Novartis) on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, the sale of products and services through our Celgene Cellular Therapeutics (CCT) subsidiary and other licensing arrangements.

We continue to invest substantially in research and development in support of multiple ongoing proprietary clinical development programs which support our existing products and pipeline of new drug candidates. REVLIMID® is in several phase III trials across a range of hematological malignancies that include multiple myeloma, lymphomas, chronic lymphocytic leukemia (CLL) and myelodysplastic syndromes (MDS). POMALYST®/IMNOVID® was approved in the United States and the European Union for indications in multiple myeloma based on phase II and phase III trial results, respectively, and an additional phase III trial is underway with POMALYST®/IMNOVID® in relapsed and refractory multiple myeloma. Phase III trials are also underway for CC-486 in MDS and acute myeloid leukemia (AML) and ISTODAX® in first-line peripheral T-cell lymphoma (PTCL). In solid tumors, ABRAXANE® is currently in various stages of investigation for breast, pancreatic and non-small cell lung cancers. In inflammation and immunology, OTEZLA® is being evaluated in phase III trials for Behçet's disease and expanded indications in psoriatic arthritis and psoriasis. Also in the inflammation and immunology therapeutic area, we have acquired a global development and commercialization license to GED-0301 from Nogra Pharma Limited and have initiated a multi-trial clinical program that is designed to support global registrations of GED-0301 in Crohn's disease. For more information see Note 2 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Beyond our phase III programs, we have access to a growing early-to-mid-stage pipeline of novel potential therapies to address significant unmet medical needs that consists of new drug candidates and cell therapies developed in-house, licensed from other companies or able to be optioned from collaboration partners.

We believe that continued use 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.

The diseases that our primary commercial stage products are approved to treat are described below for the major markets of the United States, the European Union and Japan. Approvals in other international markets are indicated in the aggregate for the disease indication that most closely represents the majority of the other international approvals.

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REVLIMID® (lenalidomide): REVLIMID® is an oral immunomodulatory drug marketed in the United States and many international markets for the treatment of patients as indicated below:

Disease	Geographic Approvals
Multiple myeloma (MM) Multiple myeloma in combination with dexamethasone, in patients who have received at least one prior therapy	- United States - European Union - Japan - Other international markets
Multiple myeloma in combination with dexamethasone for newly diagnosed patients	- United States (Approved February 2015)
Adult patients with previously untreated multiple myeloma who are not eligible for transplant	- European Union (Approved February 2015)
Myelodysplastic syndromes (MDS) Transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities	- United States - Other international markets
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS in patients with isolated deletion 5q cytogenetic abnormality when other options are insufficient or inadequate	- European Union
MDS with a deletion 5q cytogenetic abnormality. The efficacy or safety of REVLIMID for International Prognostic Scoring System (IPSS) intermediate-2 or high risk MDS has not been established.	- Japan
Mantle cell lymphoma (MCL) in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib	- United States

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, and CLL. In December 2014, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for continuous oral treatment with REVLIMID® in adult patients with previously untreated multiple myeloma who are not eligible for stem cell transplantation. In February 2015, the indication for REVLIMID® in combination with dexamethasone was expanded by the FDA to include the treatment of newly diagnosed multiple myeloma (NDMM) in the United States and REVLIMID® was approved in the EU for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.

REVLIMID® is distributed in the United States through contracted pharmacies under the REVLIMID® Risk Evaluation and Mitigation Strategy (REMS) program, which is a proprietary risk-management distribution program tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID®. Internationally, REVLIMID® is distributed under mandatory risk-management distribution programs tailored to meet local authorities' specifications to provide for the safe and 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.

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ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension): ABRAXANE® is a solvent-free chemotherapy product which was developed using our proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. ABRAXANE® is approved for the treatment of patients as indicated below:

Disease	Geographic Approvals
Breast Cancer	
Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.	- United States - Other international markets
Metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease for whom standard, anthracycline containing therapy is not indicated	- European Union
Breast cancer	- Japan
Non-Small Cell Lung Cancer (NSCLC)	
Locally advanced or metastatic NSCLC, as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy	- United States - Other international markets
NSCLC	- Japan
Pancreatic Cancer	
Metastatic adenocarcinoma of the pancreas, a form of pancreatic cancer, as first line treatment in combination with gemcitabine	- United States - European Union - Other international markets
Unresectable pancreatic cancer	- Japan (Approved December 2014)
Gastric cancer	- Japan

ABRAXANE® is currently in various stages of investigation for breast cancer, pancreatic cancer and non-small cell lung cancer (NSCLC) and is currently under review by the EMA for first-line treatment of NSCLC in adult patients who are not candidates for potentially curative surgery.

POMALYST®/IMNOVID®-(pomalidomide)[1]: POMALYST®/IMNOVID® is a proprietary, distinct, small molecule that is administered orally and modulates the immune system and other biologically important targets. POMALYST®/IMNOVID® received its first approvals from the FDA and the EC during 2013 for the treatment of patients as indicated below:

Disease	Geographic Approvals
Multiple myeloma for patients who have received at least two prior therapies, including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy	- United States
Relapsed and refractory multiple myeloma, in combination with dexamethasone, for adult patients who have received at least two prior therapies including both lenalidomide and bortezomib and have demonstrated disease progression on the last therapy	- European Union

[1] We received FDA approval for pomalidomide under the trade name POMALYST®. We received EC approval for pomalidomide under the trade name IMNOVID®.

POMALYST®/IMNOVID® is also being evaluated in multiple trials in various phases for expanded usage in multiple myeloma and in a phase II trial for systemic sclerosis. POMALYST® is distributed in the United States through contracted pharmacies under the POMALYST REMS™ program, which is a proprietary risk-management

distribution program tailored specifically to provide for the safe and appropriate distribution and use of POMALYST®. Internationally, IMNOVID® is distributed under mandatory risk-management distribution programs tailored to meet local authorities' specifications to provide for the safe and appropriate distribution and use of IMNOVID®. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product is sold through hospitals or retail pharmacies.

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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. The U.S. regulatory exclusivity for VIDAZA® expired in May 2011. After the launch of a generic version of VIDAZA® in the United States by a competitor in September 2013, we experienced a significant reduction in our U.S. sales of VIDAZA®. In 2013, we also contracted with Sandoz AG to sell a generic version of VIDAZA® in the United States, which we supply. Regulatory exclusivity for VIDAZA® is expected to continue in Europe through 2018. VIDAZA® is marketed in the United States and many international markets for the treatment of patients as indicated below:

Disease	Geographic Approvals
Myelodysplastic syndromes (MDS)	
All French-American-British (FAB) subtypes	- United States
Intermediate-2 and high-risk MDS	- European Union - Other international markets
MDS	- Japan
Chronic myelomonocytic leukemia with 10% to 29% marrow blasts without myeloproliferative disorder	- European Union - Other international markets
Acute myeloid leukemia (AML) with 20% to 30% blasts and multi-lineage dysplasia	- European Union - Other international markets

azacitidine for injection (generic version of VIDAZA®): We contracted with Sandoz AG to sell azacitidine for injection, which they launched after the introduction of a generic version of VIDAZA® in the United States by a competitor in September 2013. We recognize net product sales from our sales of azacitidine for injection to Sandoz AG.

THALOMID® (thalidomide): THALOMID®, sold as THALOMID® or Thalidomide Celgene™ outside of the United States, is administered orally for the treatment of diseases as indicated below:

Disease	Geographic Approvals
Multiple myeloma	
Newly diagnosed multiple myeloma, in combination with dexamethasone	- United States
Thalomid in combination with dexamethasone is indicated for induction therapy prior to high dose chemotherapy with autologous stem cell rescue, for the treatment of patients with untreated multiple myeloma	- Other international markets
Multiple myeloma after failure of standard therapies (relapsed or refractory)	- Other international markets
Thalidomide Celgene™ in combination with melphalan and prednisone as a first line treatment for patients with untreated multiple myeloma who are aged sixty-five years of age or older or ineligible for high dose chemotherapy	- European Union - Other international markets
Erythema nodosum leprosum	
Cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL), an inflammatory complication of leprosy	- United States - Other international markets
Maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence	- United States - Other international markets

THALOMID® is distributed in the United States under our THALOMID REMS™ program, which is a proprietary risk-management distribution program tailored specifically to provide for the safe and appropriate distribution and use of THALOMID®. Internationally, THALOMID® and Thalidomide Celgene™ are also distributed under mandatory risk-management distribution programs tailored to meet local authorities' specifications to provide for the safe and

appropriate distribution and use of THALOMID® and Thalidomide Celgene™. These programs may vary by country and, depending upon the country and the design of the risk-management program, the products are sold through hospitals or retail pharmacies.

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OTEZLA® (apremilast): OTEZLA® is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels. During 2014 and January 2015, OTEZLA® received initial approvals in the U.S. and EU as indicated below:

Disease	Geographic Approvals
Psoriatic arthritis	
Adult patients with active psoriatic arthritis	- United States (Approved March 2014)
Adult patients with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior DMARD therapy	- European Union (Approved January 2015)
Psoriasis	
Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	- United States (Approved September 2014) - Other international markets (Approvals beginning November 2014)
Adult patients with moderate to severe chronic plaque psoriasis who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light	- European Union (Approved January 2015)

ISTODAX® (romidepsin): ISTODAX® is administered by intravenous infusion for the treatment of diseases as indicated below and has received orphan drug designation for the treatment of non-Hodgkin's T-cell lymphomas, including CTCL and PTCL.

Disease	Geographic Approvals
Cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy	- United States - Other international markets
Peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy	- United States - Other international markets

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®. We receive royalties from Novartis on their sales of these products.

PRECLINICAL AND CLINICAL-STAGE PIPELINE

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

Oral anti-inflammatory agents: We are developing novel, orally administered 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- , leukotrienes and nitric oxide synthase.

Next generation of Cereblon Modulatory drugs: CC-122 (a PPM™ Pleiotropic Pathway Modifier) and CC-220 represent novel compounds that are in phase I clinical trials for hematological and solid tumor cancers and inflammation and immunology diseases. They have been differentiated from previous compounds (such as Thalidomide, Lenalidomide and Pomalidomide) and have been developed based on our scientific understanding of Cereblon-mediated protein homeostasis.

Cellular therapies: At CCT we are conducting research with stem cells derived from the human placenta as well as from the umbilical cord. CCT is our research and development division dedicated to fulfilling the promise of cellular technologies by developing 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 that 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, and other inflammatory diseases.

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We are developing our cellular therapies, PDA-001 (IV formulation) and PDA-002 (IM/SC injectable formulation), with the initiation of a PDA-001 phase I safety and dose finding study for Crohn's disease and a PDA-002 phase II study in peripheral arterial diseases. We are also continuing research to define the potential of placental-derived stem cells and to characterize other placental-derived products.

CC-486: We have initiated two phase III trials of CC-486 that are currently enrolling to evaluate CC-486 in the treatment of MDS and AML. In addition, a phase I trial of CC-486 for the treatment of solid tumors is currently in progress.

Sotatercept (ACE-011) and luspatercept (ACE-536): We have collaborated with Acceleron Pharma, Inc. (Acceleron) to develop sotatercept and luspatercept to treat anemia in patients with rare blood disorders. Several phase II trials are in progress to evaluate the use of sotatercept or luspatercept in the treatment of anemia in patients with rare blood disorders and chronic kidney disease, beta-thalassemia and MDS.

mTOR pathway inhibitors: CC-223 and CC-115 target the important cancer pathway that is dysregulated in a large proportion of cancers. In particular, activity is being investigated in lymphomas, hepatocellular and prostate cancers in phase I/II trials.

Epigenetics: The current insights into molecular regulation of genetic information (Epigenetics) has the potential to transform human diseases. Celgene has two epigenetic modifiers on the market, VIDAZA® and ISTODAX®. In addition, we are collaborating with Epizyme Inc. (Epizyme) to develop EPZ-5676 for AML.

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 $2.431 billion in 2014, $2.226 billion in 2013 and $1.724 billion in 2012. The product candidates in our pipeline are at various stages of preclinical and clinical development. The path to regulatory approval ordinarily 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. There are many difficulties and uncertainties inherent in research and development of new products, resulting in 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-marketing events or developments. 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 of manufacture, alternative therapies or infringement of the patents or intellectual property rights of others. Uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunities. Consequently, it is very difficult to predict which products will ultimately be submitted for approval, which will obtain approval and which will be commercially viable and generate profits. Successful results in preclinical or 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 initiation of clinical investigation of a new drug or product candidate and usually involve up to 80 healthy volunteers or subjects. These trials 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 trial 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 trials generally take from one to three years to complete.

Phase II Clinical Trials

Phase II clinical trials are conducted on a limited number of subjects with the targeted disease. An initial evaluation of the drug's effectiveness on subjects is performed and additional information on the drug's safety and dosage range is obtained. Phase II clinical trials normally include up to several hundred subjects and may take as many as two to three years to complete.

Phase III Clinical Trials

Phase III clinical trials are typically controlled multi-center trials that involve a larger target patient population that normally consists of from several hundred to several thousand subjects to ensure that study results are statistically

significant. During phase III clinical trials, physicians monitor subjects to determine efficacy and to gather further information on safety. These trials are generally global in nature and are designed to generate the clinical data necessary to submit an application for marketing approval to regulatory agencies. Phase III testing varies by disease state, but can often last from two to seven years.

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Regulatory Review

If a product candidate successfully completes clinical trials and is submitted to governmental regulators, such as the FDA in the United States or the EC 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 to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval, or that decisions on marketing approvals or treatment indications will be consistent across geographic areas.

The current stage of development of our commercial stage products and new drug candidates in various areas of research are outlined in the following table:

Area of Research		Status	Entered Current Status
Multiple Myeloma (MM)			
REVLIMID®	Relapsed/refractory	Post-approval research[1]	2006
	Newly diagnosed	Post-approval research[1]	February 2015
	Maintenance	Phase III	2004
POMALYST®/IMNOVID®	Relapsed/refractory[2]	Post-approval research[1]	2013
THALOMID®/Thalidomide Celgene™	Newly diagnosed	Post-approval research[1]	2006
Anti-CD38 Antibody: MOR202[3]	Relapsed/refractory	Phase I	2011
Myelodysplastic Syndromes (MDS)			
VIDAZA®	.	Post-approval research[1]	2004
REVLIMID®	Deletion 5q	Post-approval research[1]	2005
	Non-deletion 5q	Phase III	2010
CC-486	Lower-risk	Phase III	2013
sotatercept (ACE-011)[4]	MDS	Phase II	2012
luspatercept (ACE-536)[4]	MDS	Phase II	2013
Acute Myeloid Leukemia (AML)			
VIDAZA®	AML (20%-30% blasts) (EU)	Post-approval research[1]	2008
	AML (>30% blasts) (EU)	Regulatory filing and approval	December 2014
CC-486	Post-induction AML maintenance	Phase III	2013
IDH2 Inhibitor: AG-221[5]	.	Phase I	2013
DOT 1L Inhibitor: EPZ-5676[6]	.	Phase I	2012

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Area of Research		Status	Entered Current Status
Lymphoma			
REVLIMID®	Mantle cell lymphoma: Relapsed/refractory (US)	Post-approval research[1]	2013
	Mantle cell lymphoma: Relapsed/refractory (EU)	Regulatory filing and approval	November 2014
	Diffuse large B-cell: Maintenance	Phase III	2009
	Diffuse large B-cell (ABC-subtype): First line	Phase III opened for enrollment	January 2015
	Relapsed/refractory indolent lymphoma	Phase III	2013
	Follicular lymphoma: First-line	Phase III	2011
	Adult T-cell leukemia-lymphoma (Japan)	Phase II	2012
ISTODAX®	Cutaneous T-cell lymphoma (US)[7]	Post-approval research[1]	2009
	Peripheral T-cell lymphoma: Relapsed/refractory (US)[7]	Post-approval research[1]	2011
	Peripheral T-cell lymphoma: Relapsed/refractory (Japan)	Phase II	2013
	Peripheral T-cell lymphoma: First-line	Phase III	2013
PPM™ Pleiotropic Pathway Modifier: CC-122	Diffuse large B-cell lymphoma	Phase Ib	January 2014
Chronic Lymphocytic Leukemia (CLL)			
REVLIMID®	Maintenance: Second-line	Phase III	2009
Anemias			
sotatercept (ACE-011)[4]	Renal anemia with metabolic bone disease	Phase II	2010
	Beta-thalassemia	Phase II	2012
	MDS	Phase II	2012
luspatercept (ACE-536)[4]	Beta-thalassemia	Phase II	2013
	MDS	Phase II	2013
Solid Tumors			
ABRAXANE®	Breast: Metastatic	Post-approval research[1]	2005
	Breast: Metastatic (first-line, triple negative)	Phase II/III	2013
	Non-small cell lung: Advanced (first-line) (US, Japan)	Post-approval research[1]	2012
	Non-small cell lung: Advanced (first-line) (EU)	Regulatory filing and approval	June 2014
	Pancreatic: Advanced (first-line)	Post-approval research[1]	2013
	Pancreatic: Adjuvant	Phase III	April 2014
	Gastric: Metastatic (Japan)[8]	Post-approval research[1]	2013
Dual TORK Inhibitor: CC-223	.	Phase I	2012
Dual TORK/DNA PK Inhibitor: CC-115	.	Phase I	2011
	.	Phase I	2011

PPM™ Pleiotropic Pathway Modifier: CC-122			
CC-486	.	Phase I	2011

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Area of Research		Status	Entered Current Status
Anti-Inflammatory			
OTEZLA® (apremilast)	Psoriatic arthritis (US)	Post-approval research[1]	March 2014
	Psoriatic arthritis (EU)	Post-approval research[1]	January 2015
	Psoriasis (US)		