CELGENE CORP /DE/
Form 10-K
February 10, 2017

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, 2016
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. 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 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, 2016, the last business day of the registrant's most recently completed second quarter, was $76,439,256,026 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

There were 777,966,471 shares of Common Stock outstanding as of February 3, 2017.

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, 2016. 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.

CELGENE CORPORATION
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

Item No.		Page
Part I		
1.	Business	1
1A.	Risk Factors	16
1B.	Unresolved Staff Comments	28
2.	Properties	29
3.	Legal Proceedings	29
4.	Mine Safety Disclosures	29
Part II		
5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	30
6.	Selected Financial Data	32
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	33
7A.	Quantitative and Qualitative Disclosures About Market Risk	52
8.	Financial Statements and Supplementary Data	57
9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	117
9A.	Controls and Procedures	117
9B.	Other Information	119
Part III		
10.	Directors, Executive Officers and Corporate Governance	119
11.	Executive Compensation	119
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	119
13.	Certain Relationships and Related Transactions, and Director Independence	119
14.	Principal Accountant Fees and Services	119
Part IV		
15.	Exhibits, Financial Statement Schedules	120
16.	Form 10-K Summary	123
	Signatures	124

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 next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. Celgene Corporation was incorporated in the State of Delaware in 1986.

Our primary commercial stage products include REVLIMID®, POMALYST®/IMNOVID®, OTEZLA®, ABRAXANE®, VIDAZA®, azacitidine for injection (generic version of VIDAZA®) and THALOMID® (sold as THALOMID® or Thalidomide Celgene® outside of the U.S.). In addition, we earn revenue from other product sales and 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. Our clinical trial activity includes trials across the disease areas of hematology, solid tumors, and inflammation and immunology. REVLIMID® is in several phase III trials covering a range of hematological malignancies that include multiple myeloma, lymphomas and myelodysplastic syndromes (MDS). 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, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. We also have a growing number of potential products in phase III trials across multiple diseases. In the inflammation and immunology therapeutic area, we have phase III trials underway for ozanimod in relapsing multiple sclerosis (RMS) and ulcerative colitis (UC) and for GED-0301 (mongersen) in Crohn’s disease. In hematology, phase III trials are underway for CC-486 and luspatercept in MDS, for CC-486 and AG-221 (enasidenib) in acute myeloid leukemia (AML) and for luspatercept in beta-thalassemia. In the fourth quarter of 2016, we submitted a new drug application (NDA) for enasidenib for the treatment of patients with relapsed or refractory AML with isocitrate dehydrogenase-2 (IDH2) mutation.

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, potential regulatory approvals of new products and new indications for 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.

REVLIMID® (lenalidomide): REVLIMID® is an oral immunomodulatory drug approved in the United States and many international markets for the following uses:

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 - Japan - Other international markets
Adult patients with previously untreated multiple myeloma who are not eligible for transplant	- European Union
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 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.	- European Union - Japan
Mantle cell lymphoma (MCL) in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib	- United States - European Union (July 2016) - Other international markets

In January 2017, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for treatment with REVLIMID® in patients with newly diagnosed multiple myeloma (NDMM) after autologous stem cell transplantation (ASCT).

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® is approved for the following uses:

Disease	Geographic Approvals
Multiple myeloma, in combination with dexamethasone, for patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor 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

Relapsed and refractory multiple myeloma for patients who have received REVLIMID or bortezomib - Japan

[1] We received regulatory approval for pomalidomide under the trade name POMALYST® in the United States and Japan and under the trade name IMNOVID® in the European Union.

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. OTEZLA® is approved for the following uses:

Disease	Geographic Approvals
Psoriatic arthritis	
Adult patients with active psoriatic arthritis	- United States - Japan (December 2016)
Adult patients with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior DMARD therapy	- European Union
Psoriasis	
Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	- United States - Other international markets
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
Adult patients with plaque psoriasis with inadequate response to topical therapies	- Japan (December 2016)

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 following uses:

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 - European Union - 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
Gastric Cancer	- Japan

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 contracted with Sandoz AG (Sandoz) to sell a generic version of VIDAZA® in the United States, which we supply, and we recognize net product sales from our sales to Sandoz. Regulatory exclusivity for VIDAZA® is expected to continue in Europe through 2019. VIDAZA® is approved in the United States and many international markets for the following uses:

Disease	Geographic Approvals
Myelodysplastic syndromes (MDS)	
All French-American-British (FAB) subtypes	- United States - European Union - Other international markets
Intermediate-2 and high-risk MDS	- Japan - European Union - Other international markets
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
Acute myeloid leukemia with >30% bone marrow blasts according to the WHO classification in patients aged 65 years or older who are not eligible for haematopoietic stem cell transplantation	

THALOMID® (thalidomide): THALOMID®, sold as THALOMID® or Thalidomide Celgene® outside of the United States, is administered orally for the following uses:

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

Maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence	markets - United States - Other international markets

REVLIMID®, POMALYST® and THALOMID® are distributed in the United States primarily through contracted pharmacies under the REVLIMID® Risk Evaluation and Mitigation Strategy (REMS), POMALYST REMS® and THALOMID REMS® programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID®, POMALYST® and THALOMID®. Internationally, REVLIMID®, THALOMID®/Thalidomide Celgene® and IMNOVID® are distributed under mandatory risk-management distribution programs tailored to meet local authorities' specifications to provide for the product's safe and appropriate distribution and use. 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. VIDAZA®, ABRAXANE®, and OTEZLA® are distributed through the more

traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID®, POMALYST®/IMNOVID® and THALOMID®/Thalidomide Celgene®.

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.

Immune-Inflammatory Diseases: OTEZLA® (apremilast) a novel PDE4 inhibitor, is being studied in clinical trials in ankylosing spondylitis, Behçet's disease, atopic dermatitis, and ulcerative colitis, and is approved in psoriasis and psoriatic arthritis. Differentiated oral therapies are advancing through mid- to late-stage trials in inflammatory diseases, including GED-0301, a potential first-in-class smad7 anti-sense treatment, with a phase III program in Crohn’s Disease (CD) recruiting subjects, and a phase II trial in UC fully enrolled. In addition, ozanimod is a potential best-in-class S1P receptor modulator, with a phase III trial fully enrolled in RMS, a phase III trial in UC underway, and a phase II trial in CD fully enrolled. Other potential oral therapies include, CC-220 for systemic lupus erythematosus (SLE), CC-90001 for Fibrosis and ABX-1431 for multiple sclerosis spasticity. In addition, a phase I trial in healthy volunteers is in progress for CC-90006, an injectable PD-1 agonist antibody for autoimmune disorders.

Other Myeloid Diseases: We have collaborated with Acceleron Pharma, Inc. (Acceleron) to develop luspatercept (ACE-536).
We are evaluating luspatercept for the treatment of patients with beta-thalassemia and MDS in phase III trials.

Epigenetics: The current insights into molecular regulation of genetic information (Epigenetics) have the potential to transform human diseases. We currently market two epigenetic modifiers, VIDAZA® and ISTODAX®. We have two phase III trials of CC-486 (oral 5-azacitidine) currently enrolling to evaluate its efficacy in the treatment of MDS and AML and two on-going phase II trials of CC-486 in solid tumors. We acquired the IDH2 inhibitor enasidenib from Agios Pharmaceuticals, Inc. (Agios) and have submitted a NDA to the U.S. Food and Drug Administration (FDA) for relapsed/refractory AML with IDH2 mutations. We are currently evaluating enasidenib in combination with VIDAZA® in newly diagnosed AML with IDH2 mutations. We are also evaluating AG-881 (IDH1 and IDH2 inhibitor) in glioma with IDH mutations, in collaboration with Agios. Additionally, a phase I trial of LSD1 inhibitor (CC-90011) is underway in Non-Hodgkin lymphoma (NHL) and solid tumors.

Protein Homeostasis: CC-122 (Cereblon Modulator, or CELMoD®) and CC-220 represent novel compounds that are in phase I and phase II clinical trials, both as single agents and in combination, 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. CC-90009 is a unique cereblon targeted molecule, currently in phase I, whose activity is related to the depletion of a novel substrate and which has been identified active in AML models.

Immuno-Oncology: The strategic collaboration with Astra Zeneca/Medimmune evaluating durvalumab, an anti-PDL-1 antibody, in multiple hematological cancers in combination with REVLIMID®, POMALYST®, VIDAZA® and CC-486 is underway with phase III enabling data expected in 2017. JCAR17, the CD19 CAR-T program under collaboration with Juno Therapeutics, Inc. (Juno), has been granted Breakthrough Therapy designation by the FDA and has been given access to the Priority Medicines scheme by the EMA CHMP. Interim data for JCAR17 shows high complete response rates in NHL, with manageable safety profiles. A pivotal program in NHL will be initiated in 2017. BCMA is emerging as a compelling target in multiple myeloma (MM) and in this regard, we have invested in some critical assets. The bluebird bb2121 BCMA CAR-T early phase I data has shown impressive efficacy with a good safety profile. With the acquisition of EngMab AG (EngMab) in 2016, we also will develop a

BCMA targeted T cell engager program in MM with an Investigational New Drug (IND) expected by end of 2017. Our anti-CD47 antibody targeting macrophage activity, CC-90002, is currently in phase I trials, being evaluated for the treatment of multiple cancers, including NHL and AML. Three additional programs from our collaboration partners Lycera Corp. (Lycera) (RORg agonist), Jounce Therapeutics, Inc. (Jounce) (anti-ICOS-agonist) and OncoMed Pharmaceuticals, Inc. (OncoMed) (anti-TIGIT antibody) are progressing into clinical testing in multiple solid tumor indications.

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 $4.470 billion in 2016, $3.697 billion in 2015, and $2.431 billion in 2014. 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 U.S. 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 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 clinical trial testing varies by disease state, but can often last from two to seven years.

Regulatory Review
If a product candidate successfully completes clinical trials and trial data is submitted to governmental regulators, such as the FDA in the United States or the European Commission (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 regulatory 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	2006
	Newly diagnosed transplant ineligible	Post-approval research	2015
	NDMM post-ASCT maintenance	Regulatory submission[1]	Q3 2016
POMALYST®/IMNOVID®	Relapsed/refractory	Post-approval research	2013
THALOMID®/Thalidomide Celgene®	Newly diagnosed	Post-approval research	2006
PD-L1 Inhibitor: durvalumab[2]	MM	Phase I	2015
Cereblon Modulator: avadomide (CC-122)	MM	Phase I	2015

Area of Research		Status	Entered Current Status
BCMA CAR-T (bb2121)[3]	MM	Phase I	Q1 2016
Cereblon Modulator: CC-220	MM	Phase I	Q3 2016
Marizomib	MM	Phase I	2014
citarinostat (ACY-241)	Relapsed/refractory	Phase I	2015
Myelodysplastic Syndromes (MDS)			
VIDAZA®	MDS	Post-approval research	2004
REVLIMID®	Deletion 5q	Post-approval research	2005
CC-486	Lower-risk	Phase III	2013
	Post hypomethylating agent (HMA) failure	Phase II	2015
luspatercept (ACE-536)[4]	MDS	Phase III	Q1 2016
PD-L1 Inhibitor: durvalumab[2]	MDS	Phase II	2015
Anti-CD47 Antibody: CC-90002	MDS	Phase I	Q1 2016
Acute Myeloid Leukemia (AML)			
VIDAZA®	AML (20%-30% blasts) (EU)	Post-approval research	2008
	AML (>30% blasts) (EU)	Post-approval research	2015
CC-486	Post-induction AML maintenance	Phase III	2013
IDH2 Inhibitor: enasidenib (AG-221)[5]	AML	Regulatory submission[1]	Q4 2016
PAN-IDH Inhibitor: AG-881[5]	AML	Phase I	2015
PD-L1 Inhibitor: durvalumab[2]	AML	Phase II	2015
Anti-CD47 Antibody: CC-90002	AML	Phase I	Q1 2016
Cereblon Modulator: CC-90009	AML	Phase I	Q4 2016
Lymphoma			
REVLIMID®	Mantle cell lymphoma: Relapsed/refractory (US)	Post-approval research	2013
	Mantle cell lymphoma: Relapsed/refractory (EU)	Post-approval research	Q3 2016
	Diffuse large B-cell (ABC-subtype): First line	Phase III	2015
	Indolent lymphoma: Relapsed/refractory	Phase III	2013
	Follicular lymphoma: First-line	Phase III	2011
	Adult T-cell leukemia-lymphoma (Japan)	Regulatory submission[1]	Q2 2016
ISTODAX®	Cutaneous T-cell lymphoma (US)[6]	Post-approval research	2009
	Peripheral T-cell lymphoma: Relapsed/refractory (US)[6]	Post-approval research	2011
			Q3 2016

	Peripheral T-cell lymphoma: Relapsed/refractory (Japan)	Regulatory submission[1]	
	Peripheral T-cell lymphoma: First-line	Phase III	2013
Cereblon Modulator: avadomide (CC-122)	Diffuse large B-cell lymphoma	Phase Ib	2014
	Indolent lymphoma: Relapsed/refractory	Phase I	2014

Area of Research		Status	Entered Current Status
CC-486	Lymphoma	Phase I	2015
PD-L1 Inhibitor: durvalumab[2]	Non-Hodgkin lymphoma (NHL)	Phase I	Q1 2016
CD19 CAR-T (JCAR017)[7]	Aggressive large B-cell lymphoma: Relapsed/refractory	Phase I	2015
Acute Lymphocytic Leukemia (ALL)			
CD19 CAR-T (JCAR015)[7]	ALL	Phase II	2015
Chronic Lymphocytic Leukemia (CLL)			
Cereblon Modulator: avadomide (CC-122)	CLL	Phase I	2015
PD-L1 Inhibitor: durvalumab[2]	CLL	Phase I	2015
Beta Thalassemia			
luspatercept (ACE-536)[4]	Beta-thalassemia	Phase III	Q2 2016
Solid Tumors			
ABRAXANE®	Breast: Metastatic	Post-approval research	2005
	Non-small cell lung: Advanced (first-line)	Post-approval research	2012
	Pancreatic: Metastatic (first-line)	Post-approval research	2013
	Pancreatic: Adjuvant	Phase III	2014
	Gastric: Metastatic (Japan)[8]	Post-approval research	2013
CC-486	Breast: Metastatic	Phase II	2015
	Non-small cell lung: Advanced	Phase II	2015
Marizomib	Glioblastoma	Phase II	Q4 2016
Cereblon Modulator: avadomide (CC-122)	Hepatocellular carcinoma	Phase I	2015
Anti-CD47 Antibody: CC-90002	Solid tumors	Phase I	2015
PAN-IDH Inhibitor: AG-881[5]	Glioma	Phase I	2015
LSD1 Inhibitor: CC-90011	Solid tumors	Phase I	Q2 2016
Inflammation and Immunology			
OTEZLA® (apremilast)	Psoriatic arthritis	Post-approval research	2014
	Psoriasis	Post-approval research	2014
	Ankylosing spondylitis	Phase III	2012
	Behçet's disease	Phase III	2014
	Atopic dermatitis	Phase II	2014
	Ulcerative colitis	Phase II	2014
GED-0301	Crohn's disease	Phase III	2015
	Ulcerative colitis	Phase II	2015
ozanimod	Relapsing multiple sclerosis	Phase III	2013

	Ulcerative colitis	Phase III	2015
	Crohn's disease	Phase II	2015
RPC-4046	Eosinophilic esophagitis	Phase II	2014

Area of Research		Status	Entered Current Status
Cereblon Modulator: CC-220	Systemic lupus erythematosus (SLE)	Phase II	2014
CC-90001	Fibrosis	Phase I	2014
ABX-1431[9]	Functional dyspepsia	Phase I	Q4 2016
CC-90006	Autoimmune disorders	Phase I	Q4 2016
Cellular Therapies			
PDA-002	Diabetic foot ulcers	Phase II	2013
	Peripheral artery disease	Phase II	2015
PNK-007	AML	Phase I	Q2 2016
	MM	Phase I	Q3 2016

[1] "Regulatory submission" indicates US and/or EU submission unless another country or region is indicated under Area of Research.
[2] In collaboration with MedImmune Limited, a wholly owned subsidiary of AstraZeneca PLC.
[3] In collaboration with bluebird bio, Inc.
[4] In collaboration with Acceleron Pharma, Inc.
[5] In collaboration with Agios Pharmaceuticals, Inc.
[6] Regulatory approval based on pivotal phase II data.
[7] In collaboration with Juno.
[8] Trial conducted by licensee partner, Taiho Pharmaceuticals Co. Ltd.
[9] In collaboration with Abide Therapeutics, Inc.

PATENTS AND PROPRIETARY TECHNOLOGY

We consider intellectual property protection to be critical to our operations. For many of our products, in addition to compound (e.g., drug substance) and composition (e.g., drug product) patents, we hold polymorph, formulation, methods of treatment or use, delivery mechanism and methods of manufacture patents, as well as manufacturing trade secrets, that may extend exclusivity beyond the expiration of the compound patent or composition patent.

Key patent expirations and exclusivities:

The following table shows the expected expiration dates in the United States and Europe of the last-to-expire period of exclusivity (primary patent or regulatory approval) related to our primary marketed drug products. In some instances, there are later-expiring patents relating to particular forms or compositions, methods of manufacturing, or use of the drug in the treatment of particular diseases or conditions. However, such additional patents may not protect our drug products from generic competition after the expiration of the primary patent.

	U.S.[1]	Europe
REVLIMID® brand drug (U.S. and European use patents)	2027[2]	2024[3]
THALOMID® brand drug (U.S. formulation/ European use patents)	2023	2019
VIDAZA® brand drug (U.S. use patent and EMA regulatory exclusivities only)	2011[4]	2019
ABRAXANE® brand drug (U.S. use patent and European use/formulation patents)	2026	2022[5]
POMALYST®/IMNOVID® brand drug (U.S. drug substance/use patent)	2024[6]	2023[7]
OTEZLA® brand drug (U.S./European drug substance patent)	2024[8]	2028[3]

9

[1] The patents covering these drugs include patents listed in the U.S. Orange Book. The date provided reflects the last-to-expire key patent as listed in the U.S. Orange Book, which may not be the last date on which all relevant patents (e.g., polymorph and manufacturing patents) expire.

[2] In December 2015, we announced the settlement of litigations with Natco Pharma Ltd. and its partners and affiliates, relating to certain patents for REVLIMID®. As part of the settlement, we agreed to provide Natco with a volume-limited license to sell generic lenalidomide in the U.S. commencing in March 2022, which is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the U.S. during the first year and is expected to increase gradually each twelve months until March 2025, and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license. Natco's ability to market generic lenalidomide in the U.S. will be contingent on its obtaining approval of an Abbreviated New Drug Application.

[3] Subject of ongoing EPO opposition proceedings. See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for more information.

[4] We contracted with Sandoz 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.

[5] Subject of ongoing supplementary protection certificate (SPC) appeal proceedings in the UK and the Court of Justice for the European Union that may result in patent extension until 2022. See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for more information.

[6] Application for Patent Term Extension pending, receipt of which would extend exclusivity through 2025.

[7] Based on ten years regulatory exclusivity. Subject of ongoing EPO opposition proceedings. See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for more information.

[8] Application for Patent Term Extension pending, receipt of which would extend exclusivity through 2028.

The term of individual patents and patent applications will depend upon the legal term of the patents in the countries in which they are obtained. In the United States, the patent term is 20 years from the date of filing of the patent application although term extensions are available. We may obtain patents for certain products many years before marketing approval is obtained for those products. Because of the limited life of patents, which ordinarily commences prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to obtain patent term extensions upon marketing approval. For example, SPCs on some of our products have been granted in a number of European countries, compensating in part for delays in obtaining marketing approval. Also, under the Hatch-Waxman Act, the term of a patent that covers an FDA-approved drug may also be eligible for patent term extension (for up to five years, but not beyond a total of 14 years from the date of product approval) as compensation for patent term lost during the FDA regulatory review process. When possible, depending upon the length of clinical trials and other factors involved in the filing of a NDA with the FDA, we expect to apply for patent term extensions for patents covering our drug products and their use in treating various diseases.

In most cases, our drugs are also covered in foreign countries by patents and patent applications that correspond to certain of those listed in the U.S. Orange Book. For example, patents related to the active pharmaceutical ingredient, uses and pharmaceutical compositions for most of our drugs have been granted in Europe. Although certain of the patents granted by the regulatory authorities of the European Union may expire at specific dates, patents granted in certain European countries, such as Spain, France, Italy, Germany and the United Kingdom, will extend beyond such European Union patent expiration date due to the SPCs granted in these countries for many of our drugs. The table above may also reflect patents in Europe that relate to certain polymorphic forms of the active pharmaceutical ingredient of our drugs.

Patent term extensions have been granted in other markets for certain of our patents related to REVLIMID®. Patent term extensions for certain of our patents related to lenalidomide have been granted in Europe, Australia, Korea, Japan and Russia. Further, patent term extensions for certain of our patents related to ABRAXANE® have been secured and/or are actively being sought in Europe, Australia, Japan, Russia and Korea. We are also considering alternative

exclusivity strategies, mostly through international treaties, in a variety of countries throughout Latin America.

The existence of issued patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents which could be used to prevent or attempt to prevent us from commercializing the patented product candidates. Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes, such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or re-examination proceedings (including oppositions and invalidity proceedings such as interparty reviews) regarding the enforcement or validity of our existing patents or any future patents could invalidate such patents or substantially reduce their protection.

Our patents are subject to challenge by generic drug companies and others for a variety of reasons. For more information regarding challenges to certain of our patents, see Item 1A. "Risk Factors" and Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

As of December 31, 2016, we owned or had exclusively licensed 730 issued U.S. patents and 593 additional pending U.S. patent applications. We have a policy to seek broad global patent protection for our inventions and have foreign patent rights corresponding to most of our U.S. patents.

Trade secret strategies and intellectual property rights in our brand names, logos and trademarks are also important to our business. 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.

GOVERNMENTAL REGULATION

General: 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. Our therapeutic products require regulatory approval by governmental agencies. Human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing and post-marketing approval requirements of 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 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, require the expenditure of substantial resources. Regulatory approval, if and when obtained, may be limited in scope, which may significantly limit the uses for which a product may be promoted. 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 or delay by us, our suppliers of manufactured drug product, collaborators or licensees, 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. For more information, see Item 1A. “Risk Factors.”

Clinical Development: Before a product may be administered to human subjects, it must undergo preclinical testing. Preclinical tests include laboratory evaluation of a product candidate's chemistry and biological activities and animal studies to assess potential safety and efficacy. The results of these studies must be submitted to the FDA as part of an IND application which must be reviewed by the FDA primarily for safety considerations before clinical trials in humans can begin.

Typically, clinical trials in humans involve a three-phase process as previously described under “- Product Development.”

In some cases, further studies beyond the three-phase clinical trial process described above are required as a condition for an NDA or biologics license application (BLA) approval. The FDA requires monitoring of all aspects of clinical trials and reports of all adverse events must be made to the FDA. The FDA may also require the conduct of pediatric studies for the drug and indication either before or after submission of an NDA.

FDA Review and Approval: The results of the preclinical testing and clinical trials are submitted to the FDA as part of an NDA or BLA for evaluation to determine if there is substantial evidence that the product is sufficiently safe and effective to warrant approval. In responding to an NDA or BLA, the FDA may grant marketing approval, deny approval, or request additional information, including data from new clinical trials. Modifications to an approved drug or biologic, including new indication or changes to labeling or manufacturing processes or facilities, may require the submission and approval of a supplemental NDA or BLA before modifications can be implemented, which may

require that we develop additional data or conduct additional preclinical and clinical trials.

Expedited Programs for Serious Conditions: The FDA has developed four distinct approaches to make new drugs available as rapidly as possible in cases where there is no available treatment or there are advantages over existing treatments.

The FDA may grant “accelerated approval” to products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments. For accelerated approval, the product must have an effect on a surrogate endpoint or an intermediate clinical endpoint that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe clinical benefit. These studies are known as "confirmatory trials." Approval of a drug may be withdrawn or the labeled indication of the drug changed if these trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug.

The FDA may grant “fast track” status to products that treat serious diseases or conditions and demonstrate the potential to address an unmet medical need. Fast track is a process designed to facilitate the development and expedite the review of such products by providing, among other things, more frequent meetings with the FDA to discuss the product's development plan, more frequent written correspondence from the FDA about trial design, eligibility for accelerated approval if relevant criteria are met, and rolling review, which allows submission of individually completed sections of an NDA or BLA for FDA review before the entire submission is completed. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval.

“Breakthrough Therapy” designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. For drugs and biologics that have been designated as Breakthrough Therapies, robust FDA-sponsor interaction and communication can help to identify the most efficient and expeditious path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may grant “priority review” status to products that, if approved, would provide significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Priority review is intended to reduce the time it takes for the FDA to review an NDA or BLA, with the goal to take action on the application within six months, compared to ten months for a standard review.

Orphan Drug Act: Under the United States Orphan Drug Act, a sponsor may request that the FDA designate a drug intended to treat a “rare disease or condition” as an “orphan drug.” A “rare disease or condition” is one which affects less than 200,000 people in the United States, or which affects more than 200,000 people, but for which the cost of developing and making available the product is not expected to be recovered from sales of the product in the United States. Upon the approval of the first NDA or BLA for a drug designated as an orphan drug for a specified indication, the sponsor of that NDA or BLA is entitled to seven years of exclusive marketing rights in the United States unless the sponsor cannot assure the availability of sufficient quantities to meet the needs of persons with the disease. However, orphan drug status is particular to the approved indication and does not prevent another company from seeking approval of an off-patent drug that has other labeled indications that are not under orphan or other exclusivities. Orphan drugs may also be eligible for federal income tax credits for costs associated with the drugs' development. In order to increase the development and marketing of drugs for rare disorders, regulatory bodies outside the United States have enacted regulations similar to the Orphan Drug Act.

Review and Approval Outside of the United States: Approval procedures must be undertaken in virtually every other country comprising the market for our products. The approval procedure and the time required for approval vary from country to country and may involve additional testing. In certain countries such as the EU countries, Switzerland, Canada and Australia, regulatory requirements and approval processes are similar to those in the United States, where approval decisions by regulators are based on the regulators’ review of the results of clinical trials performed for specific indications. Other countries may have a less comprehensive review process in terms of data requirements and may rely on prior marketing approval from a foreign regulatory authority in other countries such as the United States or the EU.

Manufacturing Quality Control: Among the conditions for NDA or BLA approval is the requirement that the prospective manufacturer’s quality control and manufacturing procedures continually conform with the FDA’s current Good Manufacturing Practice (cGMP) regulations (which are regulations established by the FDA governing the manufacture, processing, packing, storage and testing of drugs and biologics intended for human use). In complying with cGMP, manufacturers must devote substantial time, money and effort in the areas of production, quality control and quality assurance to maintain compliance. Material changes in manufacturing equipment, location or process, may result in additional regulatory review and approval. The FDA, the EC and other regulatory agencies conduct periodic

visits to inspect equipment, facilities, and processes following the initial approval of a product. If a manufacturing facility is not in substantial compliance with the applicable regulations and requirements imposed when the product was approved, regulatory enforcement action may be taken, which may include a warning letter or an injunction against shipment of products from the facility and/or recall of products previously shipped.

Post-approval Review and Enforcement: Regulatory authorities closely review and regulate the marketing and promotion of drug and biologic products. In most countries, regulatory approval is granted for a specified indication and is required before marketing or promoting a product for that indication. Regulatory authorities may take enforcement action against a company for promoting unapproved uses of a product (off-label promotion) or for other violations of advertising and labeling laws and regulations.

When an NDA or BLA is approved, the NDA or BLA holder must, among other things, (a) employ a system for obtaining reports of adverse events and side effects associated with the drug and make appropriate submissions to the FDA and (b) timely advise the FDA if any approved product fails to adhere to specifications established by the NDA or BLA. If the FDA concludes that a drug previously shown to be effective can be safely used only if distribution or use is restricted, the FDA will require post-marketing restrictions as necessary to assure safe use. The sponsor may be required to establish systems to assure use of the

product under safe conditions. The FDA may require the drug sponsor to implement programs similar to our REMS programs to ensure that benefits of a drug outweigh risks and that safety protocols are adhered to.

In addition, a sponsor of a drug product has an ongoing obligation to update product labels with new information and to report to regulatory authorities concerning assessment of serious risks associated with the drug. Following assessment of these reports, regulatory authorities can require product label updates to reflect new safety data or warnings. If the FDA or other regulatory authorities become aware of new safety information, they can also require us to conduct studies or clinical trials to assess the potential for a serious risk. The FDA and other regulatory authorities can also impose marketing restrictions, including the suspension of marketing or complete withdrawal of a product from the market.

The FDA may issue publicly available warning letters and non-compliance letters, which may require corrective actions, including modification of advertising or other corrective communications to consumers or healthcare professionals.

Failure to comply with applicable FDA or other regulatory agency requirements can result in enforcement actions, such as license revocation or suspension; orders for retention, recall, seizure or destruction of product; cessation of manufacturing; injunctions; inspection warrants; search warrants; civil penalties, including fines based on disgorgement; restitution; and criminal prosecution.

Other Regulations: We are also subject to various federal and state laws, as well as foreign laws, pertaining to healthcare “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescription of a particular drug that is reimbursed by a state or federal program. False claims laws generally prohibit knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid) any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities related to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

We are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local laws, rules and regulations. Our research and development activities may involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. We believe our procedures comply with the standards prescribed by federal, state or local laws, rules and regulations; however, the risk of injury or accidental contamination cannot be completely eliminated.

Additionally, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments or providing anything of value to any foreign government official, government staff member, political party or political candidate, with corrupt intent for the purpose of obtaining or retaining an improper business advantage. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and regulations to which our activities are subject.

COMPETITION

Our current products and products under development face competition from other innovative drugs and, in some cases, generic drugs. The relative speed with which we develop new products, complete clinical trials, obtain

regulatory approvals, receive pricing and reimbursement approvals, and finalize manufacturing and distribution arrangements, and market our products are critical factors in gaining a competitive advantage. Competition among approved products depends, among other things, on product efficacy, safety, convenience, reliability, availability, price, third-party reimbursement, sales and promotional activities, product liability issues and patent and non-patent exclusivity. For additional information, see Item 1A. "Risk Factors."

SIGNIFICANT ALLIANCES

We have entered into a variety of alliances in the ordinary course of our business. Although we do not consider any individual alliance to be material, a brief description of certain of the more notable alliances are identified in Note 17 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

MANUFACTURING

We own and operate a manufacturing facility in Zofingen, Switzerland which produces the active pharmaceutical ingredient (API) for REVLIMID® and THALOMID® and have contracted with third-party contract manufacturers to provide backup API manufacturing services for these products. Manufacturing services for REVLIMID® and THALOMID®, which consist of formulation, encapsulation, packaging, warehousing and distribution, are performed at our drug product manufacturing facility in Boudry, Switzerland. We have contracted with a number of third-party drug product manufacturing service providers and packaging service providers to provide backup manufacturing and packaging services. All of our facilities are approved by the regulatory authorities for the geographies that they serve and we require that our contract manufacturers and other third-party service providers are similarly approved.

The API for ABRAXANE® is generally available from two sources in quantities adequate to meet market demands. Manufacturing services for ABRAXANE® are performed at our manufacturing facility in Arizona, U.S.A. and by a third party contract manufacturing facility.

The API for POMALYST®/IMNOVID® is supplied from two sources with primary manufacturing services being performed at our Boudry, Switzerland manufacturing facility. We have contracted with a number of third-party drug product manufacturing service providers and packaging service providers to provide backup manufacturing and packaging services for this product.

The API for VIDAZA® and azacitidine for injection (generic version of VIDAZA®) is supplied by two suppliers. Manufacturing and packaging services are provided by a number of third-party service providers.

The API for OTEZLA® is supplied by two suppliers with primary API production being performed at our Zofingen, Switzerland facility. Manufacturing services are performed at our Boudry, Switzerland facility and at a contract manufacturing site. Packaging services are provided by a number of third-party service providers.

The API for ISTODAX® and manufacturing services are supplied by a single-source. Packaging services are provided by a number of third-party service providers.

We have established, or are in the process of establishing, primary and back up suppliers and/or manufacturing sites for late phase development programs, enasidenib, ozanimod, and GED-0301. Luspatercept is currently manufactured at contract manufacturing sites.

INTERNATIONAL OPERATIONS

We have significant operations outside the United States conducted both through our subsidiaries and through distributors. For a geographic breakdown of total revenues see Note 19 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K and for further discussion of our total revenues by geographic area see Item 7. "Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations."

Our international headquarters and a drug product manufacturing facility which performs formulation, encapsulation, packaging, warehousing and distribution are located in Boudry, Switzerland.

Our international operations are subject to risks associated with operating on an international basis, including currency fluctuations, price and exchange controls and other restrictive governmental actions. Our international operations are also subject to government-imposed constraints, including laws on pricing, reimbursement and patient access to our products. Depending on the direction of change relative to the U.S. dollar, foreign currency values can increase or

decrease the reported dollar value of our net assets and results of operations. While we cannot predict with certainty future changes in foreign exchange rates or the effect they will have, we attempt to mitigate their impact through operational means and by using foreign currency derivative instruments. For more information, see Item 7A. "Quantitative and Qualitative Disclosures About Market Risk."

SALES AND COMMERCIALIZATION

We promote our brands globally through our hematology, oncology, and inflammation and immunology commercial organizations which support our currently marketed brands and prepare for the launches of new products, as well as new indications for existing products. For OTEZLA®, we also provide information about the appropriate use of our products to consumers in the U.S. through direct-to-consumer print and television advertising. We have a team of dedicated market access professionals to help physicians, patients and payers understand the value our products deliver. Given our goal to ensure that patients who might benefit from our therapies have the opportunity to do so and given the complex reimbursement environment in the United States, we offer the

services of Celgene Patient Support® and Otezla SupportPlus® to serve as dedicated, central points of contact for patients and healthcare professionals who use or prescribe our products. Celgene Patient Support® and Otezla SupportPlus® are free services that help patients and healthcare professionals navigate the challenges of reimbursement by providing information regarding insurance coverage, prior authorization requirements, appeals processes and financial assistance programs.

In most countries, we promote our products through our own sales organizations. In some countries, particularly in Latin America, we partner with third-party distributors. Generally, we distribute our products through commonly used channels in local markets. However, REVLIMID®, POMALYST®/IMNOVID® and THALOMID®/Thalidomide Celgene® are distributed under mandatory risk-management distribution programs (such as REMS) tailored to meet local authorities' specifications to provide for their safe and appropriate distribution and use.

EMPLOYEES

As of December 31, 2016, we had 7,132 full-time employees, of whom 2,570 were engaged primarily in research and development activities, 2,459 were engaged primarily in sales and commercialization activities, 654 were engaged primarily in manufacturing, and the remaining 1,449 were engaged primarily in management and general and administrative activities. The number of full-time employees in our international operations has grown from 2,869 at the end of 2015 to 3,039 at the end of 2016. We also employ a number of part-time employees and maintain consulting arrangements with a number of researchers at various universities and other research institutions around the world.

SEASONALITY

Our worldwide product sales do not reflect any significant degree of seasonality in end-user demand. Several other factors, including government rebates, distributor buying patterns and government tender timing impact the dollar value of product sales recorded in any particular quarter. In the United States, manufacturers of pharmaceutical products are responsible for 50 percent of the patient’s cost of branded prescription drugs related to the Medicare Part D Coverage Gap. We fulfill this obligation by providing rebates to the government, resulting in a reduction in the dollar value of U.S. net product sales in the quarter in which the rebates are provided. Historically, these rebates are higher during the first quarter primarily due to the larger volume of patient deductibles at the beginning of a calendar year. In addition, in the U.S., the timing of net product sales may be affected by fluctuations in wholesaler inventory levels. Outside of the U.S., the timing of governmental tenders for product may also impact net product sales in a particular quarter.

AVAILABLE INFORMATION

Our Current Reports on Form 8-K, Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K are electronically filed with or furnished to the Securities and Exchange Commission (SEC), and all such reports and amendments to such reports have been and will be made available, free of charge, through our website (http://www.celgene.com) as soon as reasonably practicable after submission to the SEC. Such reports will remain available on our website for at least 12 months. The contents of our website or any other website are not incorporated by reference into this Annual Report on Form 10-K. The public may read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, NW, Washington, D.C. 20549.

The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

DISCLOSURE PURSUANT TO SECTION 219 OF THE IRAN THREAT REDUCTION AND SYRIA HUMAN RIGHTS ACT OF 2012

Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 (ITRSHRA) added Section 13(r) to the Securities Exchange Act of 1934, as amended, which requires, among other things, disclosure by an issuer, in its annual or quarterly reports, as applicable, whether it or any of its affiliates knowingly conducted, without specific authority from a U.S. federal department or agency, any transaction or dealing with the Government of Iran, which includes, without limitation, any person or entity owned or controlled, directly or indirectly, by the Government of Iran or any of its political subdivisions, agencies or instrumentalities. Neither Celgene nor, to its knowledge, any of its affiliates engaged in activities during 2016 that are required to be disclosed pursuant to ITRSHRA.

FORWARD-LOOKING STATEMENTS

Certain statements contained or incorporated by reference in this Annual Report on Form 10-K are considered forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended) concerning our business, results of operations, economic performance and/or financial condition, based on management's current expectations, plans, estimates, assumptions and projections. Forward-looking statements are included, for example, in the discussions about:

- strategy;
- new product discovery and development;
- current or pending clinical trials;
- our products' ability to demonstrate efficacy or an acceptable safety profile;
- actions by the FDA and other regulatory authorities;
- product manufacturing, including our arrangements with third-party suppliers;
- product introduction and sales;
- royalties and contract revenues;
- expenses and net income;
- credit and foreign exchange risk management;
- liquidity;
- asset and liability risk management;
- the outcome of litigation and other proceedings;
- intellectual property rights and protections;
- economic factors;
- competition; and
- operational and legal risks.

Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words "expects," "anticipates," "believes," "intends," "estimates," "aims," "plans," "may," "could," "will," "will continue," "seeks," "should," "predict," "potential," "outlook," "guidance," "target," "forecast," "probable," "possible" or the negative of such terms and similar expressions. Forward-looking statements are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws.

We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements, and therefore you should not place too much reliance on them. These factors include, among others, those described herein, under "Risk Factors" and elsewhere in this Annual Report on Form 10-K and in our other public reports filed with the SEC. It is not possible to predict or identify all such factors, and therefore the factors that are noted are not intended to be a complete discussion of all potential risks or uncertainties that may affect forward-looking statements. If these or other risks and uncertainties materialize, or if the assumptions underlying any of the forward-looking statements prove incorrect, our actual performance and future actions may be materially different from those expressed in, or implied by, such forward-looking statements. We can offer no assurance that our estimates or expectations will prove accurate or that we will be able to achieve our strategic and operational goals.

ITEM 1A. RISK FACTORS

The following describes major risks to our business and should be considered carefully. Any of these factors could significantly and negatively affect our business, prospects, financial condition, operating results or credit ratings, which could cause the trading prices of our equity securities to decline. The risks described below are not the only risks we may face. Additional risks and uncertainties not presently known to us, or risks that we currently consider immaterial, could also negatively affect us.

Our operating results may be subject to significant fluctuations.

Our operating results may fluctuate from quarter to quarter and year to year for a number of reasons, including the risks discussed elsewhere in this “Risk Factors” section. Events such as a delay in product development or a revenue shortfall may cause financial results for a particular period to be below our expectations. In addition, we have experienced and may continue to experience fluctuations in our quarterly operating results due to the timing of charges that we may take. We have recorded, or may be required to record, charges that include development milestone and license payments under collaboration and license agreements, amortization of acquired intangibles and other acquisition related charges, and impairment charges. Several other factors, including

government rebates, distributor buying patterns and government tender timing, impact the dollar value of product sales recorded in any particular quarter.

Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations. We recognize foreign currency gains or losses arising from our operation in the period in which we incur those gains or losses. Although we utilize foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased put options to manage foreign currency risk, our efforts to reduce currency exchange losses may not be successful. As a result, currency fluctuation among our reporting currency, the U.S. Dollar, and the currencies in which we do business will affect our operating results. Our net income may also fluctuate due to the impact of charges we may be required to take with respect to foreign currency and other hedge transactions. In particular, we may incur higher than expected charges from hedge ineffectiveness or from the termination of a hedge arrangement. For more information, see Item 7A. "Quantitative and Qualitative Disclosures About Market Risk."

We are dependent on the continued commercial success of our primary products, REVLIMID®, POMALYST®/IMNOVID®, ABRAXANE®, OTEZLA®, VIDAZA® and THALOMID®.

Our business is largely dependent on the commercial success of REVLIMID®, POMALYST®/IMNOVID®, ABRAXANE®, OTEZLA®, VIDAZA® and THALOMID®. REVLIMID® currently accounts for over half of our total revenue. As new products, such as POMALYST®/IMNOVID® and OTEZLA®, have obtained regulatory approval and gained market acceptance, our dependence on REVLIMID® has decreased, a trend that we expect to continue. A significant decline in REVLIMID® net revenue, in the absence of offsetting increases in revenue from our other marketed products, would have a material adverse effect on our results of operations, cash flows and financial condition. The success of these products depends on acceptance by regulators, key opinion leaders, physicians, and patients as effective drugs with certain advantages over other therapies. A number of factors, as discussed in greater detail below, may adversely impact the degree of acceptance of these products, including their efficacy, safety, price and benefits over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans.

If unexpected adverse events are reported in connection with the use of any of these products, physician and patient acceptance of the product could deteriorate and the commercial success of such product could be adversely affected. We are required to report to the FDA or similar bodies in other countries events associated with our products relating to death or serious injury. Adverse events could result in additional regulatory controls, such as the imposition of costly post-approval clinical studies or revisions to our approved labeling which could limit the indications or patient population for a product or could even lead to the withdrawal of a product from the market. THALOMID® is known to be toxic to the human fetus and exposure to the drug during pregnancy could result in significant deformities. REVLIMID® and POMALYST®/IMNOVID® are also considered toxic to the human fetus and their respective labels contain warnings against use which could result in embryo-fetal exposure. While we have restricted distribution systems for THALOMID®, REVLIMID®, and POMALYST®/IMNOVID®, and endeavor to educate patients regarding the potential known adverse events, including pregnancy risks, we cannot ensure that all such warnings and recommendations will be complied with or that adverse events resulting from non-compliance will not occur.

Our future commercial success depends on gaining regulatory approval for products in development, and obtaining approvals for our current products for additional indications.

The testing, manufacturing and marketing of our products require regulatory approvals, including approval from the FDA and similar bodies in other countries. Our future growth would be negatively impacted if we fail to obtain timely, or at all, requisite regulatory approvals in the United States and internationally for products in development and approvals for our existing products for additional indications.

The principal risks to obtaining and maintaining regulatory approvals are as follows:

- In general, preclinical tests and clinical trials can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials may not lead to regulatory approval;
- Delays or rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality;
- Requirements for approval may become more stringent due to changes in regulatory agency policy or the adoption of new regulations or legislation;

- Even if a product is approved, the scope of the approval may significantly limit the indicated uses or the patient population for which the product may be marketed and may impose significant limitations in the nature of warnings, precautions and contra-indications that could materially affect the sales and profitability of the product;
- After a product is approved, the FDA or similar bodies in other countries may withdraw or modify an approval in a significant manner or request that we perform additional clinical trials or change the labeling of the product due to a number of reasons, including safety concerns, adverse events and side effects;
- Products, such as REVLIMID® and POMALYST®/IMNOVID®, that receive accelerated approval can be subject to an expedited withdrawal if post-marketing restrictions are not adhered to or are shown to be inadequate to assure safe use, or if the drug is shown to be unsafe or ineffective under its conditions of use;
- Guidelines and recommendations published by various governmental and non-governmental organizations can reduce the use of our approved products;
- Approved products, as well as their manufacturers, are subject to continuing and ongoing review by regulatory agencies, and the discovery of previously unknown problems with these products or the failure to comply with manufacturing or quality control requirements may result in restrictions on the manufacture, sale or use of a product or its withdrawal from the market; and
- Changes in regulatory agency policy or the adoption of new regulations or legislation could impose restrictions on the sale or marketing of our approved products.

If we fail to comply with laws or government regulations or policies our business could be adversely affected.

The discovery, preclinical development, clinical trials, manufacturing, risk evaluation and mitigation strategies (such as our REMS program), marketing and labeling of pharmaceuticals and biologics are all subject to extensive laws and government regulations and policies. In addition, individual states, acting through their attorneys general, are increasingly seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. If we fail to comply with the laws and regulations regarding the promotion and sale of our products, appropriate distribution of our products under our restricted distribution systems, off-label promotion and the promotion of unapproved products, government agencies may bring enforcement actions against us or private litigants may assert claims on behalf of the government against us that could inhibit our commercial capabilities and/or result in significant damage awards and penalties.

Other matters that may be the subject of governmental or regulatory action which could adversely affect our business include laws, regulations and policies governing:

- protection of the environment, privacy, healthcare reimbursement programs, and competition;
- parallel importation of prescription drugs from outside the United States at prices that are regulated by the governments of various foreign countries; and
- mandated disclosures of clinical trial or other data, such as the EMA’s policy on publication of clinical data.

Sales of our products will be significantly reduced if access to and reimbursement for our products by governmental and other third-party payers are reduced or terminated.

Sales of our current and future products depend, in large part, on the conditions under which our products are paid for by health maintenance, managed care, pharmacy benefit and similar health care management organizations (HCMOs), or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers.

The influence of HCMOs has increased in recent years due to the growing number of patients receiving coverage through a few large HCMOs as a result of industry consolidation. One objective of HCMOs is to contain and, where possible, reduce healthcare expenditures. HCMOs typically use formularies (lists of approved medicines available to members of a particular HCMO), clinical protocols, volume purchasing, long-term contracts and other methods to negotiate prices with pharmaceutical providers. Due to their lower cost generally, generic medicines are typically

placed in preferred tiers of HCMO formularies. Additionally, many formularies include alternative and competitive products for treatment of particular medical problems. Exclusion of our products from a formulary or HCMO-implemented restrictions on the use of our products can significantly impact drug usage in the HCMO patient population, and consequently our revenues.

Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payer of patients' healthcare costs. These health care management organizations and third-party payers are increasingly challenging the prices charged for medical products and services, seeking to implement cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Our products continue to be subject to increasing price and reimbursement pressure due to price controls imposed by governments in many countries; increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates; and the tendency of governments and private health care providers to favor generic pharmaceuticals. In addition, governmental and private third-party payers and purchasers of our products may restrict access to formularies or otherwise discourage use of our products. Limitations on patient access to our drugs, adoption of price controls and cost-containment measures could adversely affect our business. In addition, our operating results may also be affected by distributors seeking to take advantage of price differences among various markets by buying our products in low cost markets for resale in higher cost markets.

The Affordable Care Act and other legislation may affect our pricing policies and government reimbursement of our products which may adversely impact our revenues and profitability.

In the U.S. there have been and are likely to continue to be a number of legislative and regulatory proposals and enactments related to drug pricing and reimbursement that could impact our profitability. The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law in March 2010, and are referred to collectively as the Healthcare Reform Acts. These reforms have significantly impacted the pharmaceutical industry and, in the coming years, it is likely that additional changes, including the repeal of all or certain aspects of these reforms, will be made. Moreover, changes could be made to governmental healthcare and insurance reimbursement programs that could significantly impact the profitability of our products. Additionally, the pricing and reimbursement of pharmaceutical products, in general and specialty drugs in particular, have recently received the attention of U.S. policymakers and others. At this time, we cannot predict the impact of this increased scrutiny on the pricing or reimbursement of our products or pharmaceutical products generally.

The Healthcare Reform Acts, among other things, made significant changes to the Medicaid rebate program by increasing the minimum rebates that manufacturers like us are required to pay. These changes also expanded the government's 340B drug discount program by expanding the category of entities qualified to participate in the program and benefit from its deeply discounted drug pricing. The Healthcare Reform Acts also obligate the Health Resources and Services Administration (HRSA), which administers the 340B program, to update the agreement that each manufacturer must sign to participate in the 340B program to require each manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug product available to any other purchaser at any price, and to report the ceiling prices for its drugs to the government. HRSA issued this update in late 2016 and we signed an amendment to our agreement on December 29, 2016. In addition, HRSA recently finalized regulations that, among other things, implement rules regarding civil monetary penalties for knowing and intentional overcharges of 340B covered entities by pharmaceutical manufacturers.

HRSA also issued proposed regulations to implement an administrative dispute resolution (ADR) process for certain disputes arising under the 340B program, including (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers; and (2) claims by manufacturers, after a manufacturer has conducted an audit, that a covered entity has violated the prohibition on diversion to ineligible patients or duplicate discounts. The exact timing and content of final action on these matters is uncertain at this time. Depending on their final form, these actions could affect our obligations under the 340B program in ways that may have an adverse impact on our business.

We have received inquiries from HRSA regarding our compliance with the 340B program. We have cooperated fully in responding to these inquiries and believe that we have complied with applicable legal requirements. If, however, we

are ultimately required to change our sales or pricing practices, there would be an adverse effect on our revenues and profitability.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations.

Many existing and potential customers for our products become members of group purchasing organizations (GPOs). GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of that contractual arrangement. Our failure to enter into or renew contracts with GPOs may cause us to lose market share and could adversely affect our sales.

Our long-term success depends, in part, on intellectual property protection.

Our success depends, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties and to conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biopharmaceutical companies, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that if claims of any of our owned or licensed patents are challenged by one or more third parties (through, for example, litigation or post grant review in the United States Patent and Trademark Office (USPTO) or European Patent Office (EPO)), a court or patent authority ruling on such challenge will ultimately determine, after all opportunities for appeal have been exhausted, that our patent claims are valid and enforceable. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using such products or processes, be subject to significant liabilities to such third party and/or be required to obtain license rights from such third party. Lawsuits involving patent claims are costly and could affect our results of operations, result in significant expense and divert the attention of managerial and scientific personnel. For more information on challenges to certain of our patents and settlement of certain of these challenges, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

In addition, we do not know whether any of our owned or licensed pending patent applications will result in the issuance of patents or, if patents are issued, whether they will be dominated by third-party patent rights, provide significant proprietary protection or commercial advantage or be circumvented, opposed, invalidated, rendered unenforceable or infringed by others.

Our intellectual property rights may be affected in ways that are difficult to anticipate at this time under the provisions of the America Invents Act enacted in 2011. This law represents a significant change to the US patent system. Uncertainty exists in the application and interpretation of various aspects of the America Invents Act. For example, post grant review procedures have been implemented that potentially represent a significant threat to a company’s patent portfolio. Members of the public may seek to challenge an issued patent by petitioning the USPTO to institute a post grant review. Once instituted, the USPTO may find grounds to revoke the challenged patent or specific claims therein. For example, on April 23, 2015, a party filed a petition to institute an Inter Partes Review (IPR) challenging the validity of our patent US 6,045,501 and three petitions challenging patent US 6,315,720. On October 27, 2015, the USPTO granted all four petitions. In addition, on May 7, 2015 another IPR was filed against our compound patent US 5,635,517 for lenalidomide, set to expire in 2019. On November 15, 2015, the USPTO rejected this challenge by denying the institution of the IPR procedure. For more information with respect to IPRs, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K. A procedure similar to the IPR has existed in Europe for many years and we have defended our European patents in certain of those proceedings. For example, the validity of our patent EP 1 667 682 is currently the subject of an opposition proceeding before the EPO. We cannot predict whether any other Celgene patents will ever become the subject of a post grant review. If a significant product patent is successfully challenged in a post grant review proceeding it may be revoked, which would have a serious negative impact on our ability to maintain exclusivity in the market-place for our commercial products affected by such revocation and could adversely affect our future revenues and profitability.

On October 2, 2014, the EMA adopted its clinical transparency policy, "Policy on Publication of Clinical Data for Medicinal Products for Human Use" (Clinical Data Policy), which became effective on January 1, 2015. In general, under the Clinical Data Policy, clinical data is not deemed to be commercially confidential data. Therefore, there is a risk that unpublished proprietary information, including trade secrets that are incorporated into a marketing application before the EMA may be made publicly available. It is difficult to predict how any public disclosure of our trade secrets or other confidential and proprietary information made available under the Clinical Data Policy may adversely impact our patent rights and our competitive advantage in the marketplace.

Also, procedures for obtaining patents and the degree of protection against the use of a patented invention by others vary from country to country. There can be no assurance that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention or that any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country will be similar to or recognized by the judicial interpretation given to a corresponding patent issued in another country.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

We also rely upon unpatented, proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. Despite precautions taken by us, there can be no assurance that these agreements provide meaningful protection, that they will

not be breached, that we would have adequate remedies for any such breach or that our proprietary and trade secret technologies will not otherwise become known to others or found to be non-proprietary.

We receive confidential and proprietary information from collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims, which can result in significant costs if we are found to have improperly used the confidential or proprietary information of others. Even if we are successful in defending against these claims, litigation could result in substantial costs and diversion of personnel and resources.

Our products may face competition from lower cost generic or follow-on products.

Manufacturers of generic drugs are seeking to compete with our drugs and present a significant challenge to us. Those manufacturers may challenge the scope, validity or enforceability of our patents in court, requiring us to engage in complex, lengthy and costly litigation. If any of our owned or licensed patents are infringed or challenged, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on our sales of that product. In addition, manufacturers of innovative drugs as well as generic drug manufacturers may be able to design their products around our owned or licensed patents and compete with us using the resulting alternative technology. For more information concerning certain pending proceedings relating to our intellectual property rights and settlements of certain challenges, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Upon the expiration or loss of patent protection for a product, or upon the "at-risk" launch (despite pending patent infringement litigation against the generic product) by a manufacturer of a generic version of one of our products, we can quickly lose a significant portion of our sales of that product. In addition, if generic versions of our competitors' branded products lose their market exclusivity, our patented products may face increased competition or pricing pressure.

Our business operates in an extremely competitive environment.

The pharmaceutical and biotechnology industries in which we operate are highly competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms, including, but not limited to:

- Hematology and Oncology: AbbVie, Amgen, AstraZeneca, Bristol-Myers-Squibb, Eisai, Gilead, Johnson & Johnson, Merck, Novartis, Roche/Genentech, Sanofi and Takeda; and
- Inflammation and Immunology: AbbVie, Amgen, Biogen, Eisai, Eli Lilly, Johnson & Johnson, Merck, Novartis, Pfizer and UCB S.A.

Some of these companies have considerably greater financial, technical and marketing resources than we have, enabling them, among other things, to make greater research and development investments. We also experience competition in drug development from universities and other research institutions, and we compete with others in acquiring technology from these sources. The pharmaceutical industry has undergone, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances are made and become more widely known. The development of products or processes by our competitors with significant advantages over those that we are developing could adversely affect our future revenues and profitability.

A decline in general economic conditions would adversely affect our results of operations.

Sales of our products are dependent, in large part, on third-party payers. As a result of global credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. For information about amounts receivable from the government-owned or -controlled hospitals in European countries, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

In addition, due to tightened global credit, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including portions of our product manufacturing, clinical development of future collaboration products, conduct of clinical trials and supply of raw materials. If such third parties are unable to satisfy their commitments to us, our business could be adversely affected.

We may be required to modify our business practices, pay fines and significant expenses or experience other losses due to governmental investigations or other enforcement activities.

We may become subject to litigation or governmental investigations in the United States and foreign jurisdictions that may arise from the conduct of our business. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities and we have been subject to claims and other actions related to our business activities.

While the ultimate outcomes of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters could result in, among other things:

- significant damage awards, fines, penalties or other payments, and administrative remedies, such as exclusion and/or debarment from government programs, or other rulings that preclude us from operating our business in a certain manner;
- changes and additional costs to our business operations to avoid risks associated with such litigation or investigations;
- product recalls;
- reputational damage and decreased demand for our products; and
- expenditure of significant time and resources that would otherwise be available for operating our business.

For more information relating to governmental investigations and other legal proceedings and recent settlements of legal proceedings, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

The development of new biopharmaceutical products involves a lengthy and complex process and we may be unable to commercialize any of the products we are currently developing.

Many of our drug candidates are in the early or mid-stages of research and development and will require the commitment of substantial financial resources, extensive research, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. This process takes many years of effort without any assurance of ultimate success. Our product development efforts with respect to a product candidate may fail for many reasons, including:

- the failure of the product candidate in preclinical or clinical studies;
- adverse patient reactions to the product candidate or indications of other safety concerns;
- insufficient clinical trial data to support the effectiveness or superiority of the product candidate;
- our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner;
- our failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate, the facilities or the process used to manufacture the product candidate;
- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive;
- the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers; and
- the development of a competitive product or therapy.

If a product were to fail to be approved or if sales fail to materialize for a newly approved product, we may incur losses related to the write-down of inventory, impairment of property, plant and equipment dedicated to the product or expenses related to restructuring.

Disruptions of our manufacturing and distribution operations could significantly interrupt our production and distribution capabilities.

We have our own manufacturing facilities for many of our products and we have contracted with third parties to provide other manufacturing, finishing, and packaging services. Any of those manufacturing processes could be partially or completely disrupted by fire, contamination, natural disaster, terrorist attack or governmental action. A disruption could lead to substantial production delays and the need to establish alternative manufacturing sources for the affected products requiring additional regulatory approvals. In the interim, our finished goods inventories may be insufficient to satisfy customer orders on a timely basis. Further, our business interruption insurance may not adequately compensate us for any losses that may occur.

In all the countries where we sell our products, governmental regulations define standards for manufacturing, packaging, labeling, distributing and storing pharmaceutical products. Our failure to comply, or the failure of our contract manufacturers and distributors to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions.

We have contracted with various distributors to distribute most of our branded products. If our distributors fail to perform and we cannot secure a replacement distributor within a reasonable period of time, our revenue could be adversely affected.

The consolidation of drug wholesalers and other wholesaler actions could increase competitive and pricing pressures.

We sell our pharmaceutical products in the United States primarily through wholesale distributors and contracted pharmacies. These wholesale customers comprise a significant part of our distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation. As a result, a smaller number of large wholesale distributors and pharmacy chains control a significant share of the market. We expect that consolidation of drug wholesalers and pharmacy chains will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements and their purchases may exceed customer demand, resulting in increased returns or reduced wholesaler purchases in later periods.

Risks from the improper conduct of employees, agents, contractors or collaborators could adversely affect our business or reputation.

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that violate the laws or regulations of the jurisdictions in which we operate, including employment, anti-corruption, environmental, competition and privacy laws. Such improper actions, particularly with respect to foreign healthcare professionals and government officials, could subject us to civil or criminal investigations, monetary and injunctive penalties, adversely impact our ability to conduct business in certain markets, negatively affect our results of operations and damage our reputation.

We are subject to a variety of risks related to the conduct and expansion of our business internationally, particularly in emerging markets.

As our operations expand globally, we are subject to risks associated with conducting business in foreign markets, particularly in emerging markets. Those risks include:

•

increased management, travel, infrastructure and legal compliance costs;

- longer payment and reimbursement cycles;
- difficulties in enforcing contracts and collecting accounts receivable;
- local marketing and promotional challenges;
- lack of consistency, and unexpected changes, in foreign regulatory requirements and practices;
- increased risk of governmental and regulatory scrutiny and investigations;
- increased exposure to fluctuations in currency exchange rates;
- the burdens of complying with a wide variety of foreign laws and legal standards;

- operating in locations with a higher incidence of corruption and fraudulent business practices;
- difficulties in staffing and managing foreign sales and development operations;
- import and export requirements, tariffs, taxes and other trade barriers;
- weak or no protection of intellectual property rights;
- possible enactment of laws regarding the management of and access to data and public networks and websites;
- possible future limitations on foreign-owned businesses;
- increased financial accounting and reporting burdens and complexities; and
- other factors beyond our control, including political, social and economic instability, popular uprisings, war, terrorist attacks and security concerns in general.

As we continue to expand our business into multiple international markets, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. Any of these risks could harm our international operations and reduce our sales, adversely affecting our business, results of operations, financial condition and growth prospects.

We may not realize the anticipated benefits of acquisitions and strategic initiatives.

We may face significant challenges in effectively integrating entities and businesses that we acquire and we may not realize the benefits anticipated from such acquisitions. Achieving the anticipated benefits of our acquired businesses will depend in part upon whether we can integrate our businesses in an efficient and effective manner. Our integration of acquired businesses involves a number of risks, including:

- demands on management related to the increase in our size after an acquisition;
- the diversion of management's attention from daily operations to the integration of acquired businesses and personnel;
- higher than anticipated integration costs;
- failure to achieve expected synergies and costs savings;
- difficulties in the assimilation and retention of employees;
- difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and
- difficulties in the integration of departments, systems, including accounting systems, technologies, books and records and procedures, as well as in maintaining uniform standards and controls, including internal control over financial reporting, and related procedures and policies.

In addition, we may not be able to realize the projected benefits of corporate strategic initiatives we may pursue in the future.

We may not be able to continue to attract and retain highly qualified managerial, scientific, manufacturing and commercial talent.

The success of our business depends, in large part, on our continued ability to attract and retain highly qualified managerial, scientific, medical, manufacturing, commercial and other professional personnel, and competition for these types of personnel is intense. We cannot be sure that we will be able to attract or retain skilled personnel or that the costs of doing so will not materially increase.

Risks associated with using hazardous materials in our business could subject us to significant liability.

We use certain hazardous materials in our research, development, manufacturing and other business activities. If an accident or environmental discharge occurs, or if we discover contamination caused by prior owners and operators of properties we acquire, we could be liable for remediation obligations, damages and fines that could exceed our insurance coverage and financial resources.

24

Additionally, the cost of compliance with environmental and safety laws and regulations may increase in the future, requiring us to expend more financial resources either in compliance or in purchasing supplemental insurance coverage.

We are subject to various legal proceedings, claims and investigative demands in the ordinary course of our business, the ultimate outcome of which may result in significant expense, payments and penalties.

We and certain of our subsidiaries are involved in various legal proceedings that include patent, product liability, consumer, commercial, antitrust and other claims that arise from time to time in the ordinary course of our business. Litigation is inherently unpredictable. Although we believe we have substantial defenses in these matters, we could in the future be subject to adverse judgments, enter into settlements of claims or revise our expectations regarding the outcomes of certain matters, and such developments could have a material adverse effect on our results of operations in the period in which such judgments are received or settlements occur. For more information regarding settlement of certain legal proceedings, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Our activities relating to the sale and marketing and the pricing of our products are subject to extensive regulation under the U.S. Federal Food, Drug, and Cosmetic Act, the Medicaid Drug Rebate Program, the False Claims Act, the Foreign Corrupt Practices Act and other federal and state statutes, including those discussed elsewhere in this report, as well as anti-kickback and false claims laws, and similar laws in international jurisdictions. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information demands from government authorities, and been subject to claims and other actions related to our business activities brought by governmental authorities, as well as by consumers, third-party payers, stockholders and others. There can be no assurance that existing or future proceedings will not result in significant expense, civil payments, fines or other adverse consequences. For more information relating to governmental investigations and other legal proceedings and recent settlements of legal proceedings, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Product liability claims could adversely affect our business, results of operations and financial condition.

Product liability claims could result in significant damage awards or settlements. Such claims can also be accompanied by consumer fraud claims or claims by third-party payers seeking reimbursement of the cost of our products. In addition, adverse determinations or settlements of product liability claims may result in suspension or withdrawal of a product marketing authorization or changes to our product labeling, including restrictions on therapeutic indications, inclusion of new contraindications, warnings or precautions, which would have a material adverse effect on sales of such product. We have historically purchased product liability coverage from third-party carriers for a portion of our potential liability. Such insurance has become increasingly difficult and costly to obtain. In this context and in light of the strength of our balance sheet we now self-insure these risks beginning in 2016. Product liability claims, regardless of their merits or ultimate outcome, are costly, divert management's attention, may harm our reputation and can impact the demand for our products. There can be no assurance that we will be able to recover under any existing third-party insurance policy or that such coverage will be adequate to fully cover all risks or damage awards or settlements. Additionally, if we are unable to meet our self-insurance obligations for claims that are more than we estimated or reserved for that require substantial expenditures, there could be a material adverse effect on our financial statements and results of operations.

Changes in our effective income tax rate could adversely affect our results of operations.

We are subject to income taxes in both the United States and various foreign jurisdictions and our domestic and international tax liabilities are largely dependent upon the distribution of income among these different jurisdictions.

Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include interpretations of existing tax laws, the accounting for stock options and other share-based compensation, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of examinations by the U.S. Internal Revenue Service and other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings.

Currency fluctuations and changes in exchange rates could adversely affect our revenue growth, increase our costs and cause our profitability to decline.

We collect and pay a substantial portion of our sales and expenditures in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates affect our operating results. We utilize foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased put options, all of which are derivative instruments, to manage foreign currency risk. We use these derivative instruments to hedge certain forecasted transactions, manage exchange rate volatility in the translation of foreign earnings and reduce exposures to foreign currency fluctuations of certain balance sheet items denominated in foreign currencies. The use of these derivative instruments is intended to mitigate a portion of the exposure of

these risks with the intent to reduce our risk or cost, but generally would not fully offset any change in operating results as a consequence of fluctuations in foreign currencies. Any significant foreign exchange rate fluctuations could adversely affect our financial condition and results of operations. See Note 5 of Notes to Consolidated Financial Statements and Item 7A. “Quantitative and Qualitative Disclosures About Market Risk” contained in this Annual Report on Form 10-K.

We may experience an adverse market reaction if we are unable to meet our financial reporting obligations.

As we continue to expand at a rapid pace, the development of new and/or improved automated systems will remain an ongoing priority. During this expansion period, our internal control over financial reporting may not prevent or detect misstatements in our financial reporting. Such misstatements may result in litigation and/or negative publicity and possibly cause an adverse market reaction that may negatively impact our growth plans and the value of our common stock.

Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on our results of operations and financial condition.

The value allocated to certain of our assets could be substantially impaired due to a number of factors beyond our control. Also, if any of our strategic equity investments decline in value, we may be required to write down such investments. In addition, new or revised accounting standards, rules and interpretations could result in changes to the recognition of income and expense that may materially and adversely affect our financial results.

The price of our common stock may fluctuate significantly.

The market for our shares of common stock may fluctuate significantly. The following key factors may have an adverse impact on the market price of our common stock:

- results of our clinical trials or adverse events associated with our marketed products;
- fluctuations in our commercial and operating results;
- announcements of technical or product developments by us or our competitors;
- market conditions for pharmaceutical and biotechnology stocks in particular;
- changes or anticipated changes in laws and governmental regulations, including changes in tax, healthcare, environmental, competition and patent laws;
- new accounting pronouncements or regulatory rulings;
- public announcements regarding medical advances in the treatment of the disease states that we are targeting;
- patent or proprietary rights developments;
- changes in pricing and third-party reimbursement policies for our products;
- the outcome of litigation involving our products, processes or intellectual property;
- the existence and outcome of governmental investigations and proceedings;
- regulatory actions that may impact our products or potential products;
- disruptions in our manufacturing processes or supply chain;
- failure of our collaboration partners to successfully develop potential drug candidates;
- competition; and
- investor reaction to announcements regarding business or product acquisitions.

In addition, a market downturn in general and/or in the biopharmaceutical sector in particular, may adversely affect the market price of our securities, which may not necessarily reflect the actual or perceived value of our Company.

Our business would be adversely affected if we are unable to service our debt obligations.

We have incurred various forms of indebtedness, including senior notes, commercial paper and a senior unsecured credit facility. Our ability to pay interest and principal amounts when due, comply with debt covenants or repurchase the senior notes if a change of control occurs, will depend upon, among other things, continued commercial success of our products and other factors that affect our future financial and operating performance, including prevailing economic conditions and financial, business and regulatory factors, many of which are beyond our control.

If we are unable to generate sufficient cash flow to service the debt service requirements under our debt instruments, we may be forced to take remedial actions such as:

- restructuring or refinancing our debt;
- seeking additional debt or equity capital;
- reducing or delaying our business activities, acquisitions, investments or capital expenditures, including research and development expenditures; or
- selling assets, businesses, products or other potential revenue streams.

Such measures might not be successful and might not enable us to service our debt obligations. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms, if at all.

A breakdown or breach of our information technology systems and cyber security efforts could subject us to liability, reputational damage or interrupt the operation of our business.

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown and unauthorized intrusion. We could also experience a business interruption, theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Similarly, data privacy breaches by those who access our systems may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, employees, customers or other business partners, may be exposed to unauthorized persons or to the public. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue. We continuously monitor our data, information technology systems (and those of our third-party providers where appropriate) and our personnel's usage of these systems to reduce these risks and potential threats. However, cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems (or that of our third-party providers) that could adversely affect our business and result in financial and reputational harm to us, theft of trade secrets and other proprietary information, legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties.

The illegal distribution and sale by third parties of counterfeit versions of our products or stolen products could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit drug may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our brand name. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

We have certain charter and by-law provisions that may deter a third-party from acquiring us and may impede the stockholders' ability to remove and replace our management or board of directors.

Our board of directors has the authority to issue, at any time, without further stockholder approval, up to 5.0 million shares of preferred stock and to determine the price, rights, privileges and preferences of those shares. An issuance of preferred stock could discourage a third-party from acquiring a majority of our outstanding voting stock. Additionally, our by-laws contain provisions intended to strengthen the board's position in the event of a hostile takeover attempt. These provisions could impede the stockholders' ability to remove and replace our management and/or board of directors. Furthermore, we are subject to the provisions of Section

203 of the Delaware General Corporation Law, an anti-takeover law, which may also dissuade a potential acquirer of our common stock.

In addition to the risks relating to our common stock, holders of our CVRs are subject to additional risks.

On October 15, 2010, we acquired all of the outstanding common stock of Abraxis BioScience, Inc. (Abraxis) and in connection with our acquisition, contingent value rights (CVRs) were issued entitling each holder of a CVR to a pro rata portion of certain milestone and net sales payments if certain specified conditions are satisfied. In addition to the risks relating to our common stock, CVR holders are subject to additional risks, including:

- an active public market for the CVRs may not continue to exist or the CVRs may trade at low volumes, both of which could have an adverse effect on the market price of the CVRs;
- if the net sales targets specified in the CVR Agreement are not achieved within the time periods specified, no payment will be made and the CVRs will expire valueless;
- since the U.S. federal income tax treatment of the CVRs is unclear, any part of a CVR payment could be treated as ordinary income and the tax thereon may be required to be paid prior to the receipt of the CVR payment;
- any payments in respect of the CVRs are subordinated to the right of payment of certain of our other indebtedness;
- we may under certain circumstances redeem the CVRs; and
- upon expiration of our obligations under the CVR Agreement to continue to commercialize ABRAXANE® or any of the other Abraxis pipeline products, we may discontinue such efforts, which would have an adverse effect on the value of the CVRs.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Summit, New Jersey and our international headquarters are located in Boudry, Switzerland. Summarized below are the locations, primary usage and approximate square footage of the facilities we own worldwide:

Location	Primary Usage	Approximate Square Feet
Summit, New Jersey (two locations)	Administration, marketing, research	1,880,000
Boudry, Switzerland	Manufacturing, administration and warehousing	269,000
Phoenix, Arizona	Manufacturing and warehousing	254,000
Zofingen, Switzerland	Manufacturing	8,100

We occupy the following facilities, located in the United States, under operating lease arrangements, none of which are individually material to us. Under these lease arrangements, we may be required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs. All leases are with unaffiliated parties.

Location	Primary Usage	Approximate Square Feet
San Diego, California	Research	268,300
Berkeley Heights, New Jersey	Office space	81,900
Cambridge, Massachusetts	Office space	83,000
Warren, New Jersey	Office space and research	73,500
San Francisco, California	Office space and research	55,800
Overland Park, Kansas	Office space	29,600
Seattle, Washington	Research	23,400
Los Angeles, California	Office space	9,800
Washington, D.C.	Office space	3,500
Dallas, Texas	Office space	3,000

We also lease a number of offices under various lease agreements outside of the United States for which the minimum annual rents may be subject to specified annual rent increases. At December 31, 2016, the non-cancelable lease terms for our operating leases expire at various dates between 2017 and 2025 and in some cases include renewal options. The total amount of rent expense recorded for all leased facilities in 2016 was $55.3 million.

ITEM 3. LEGAL PROCEEDINGS

See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

(a) MARKET INFORMATION

Our common stock is traded on the NASDAQ Global Select Market under the symbol "CELG." The following table sets forth, for the periods indicated, the intra-day high and low prices per share of common stock on the NASDAQ Global Select Market:

	High	Low
2016:		
Fourth Quarter	$127.00	$96.93
Third Quarter	117.90	98.25
Second Quarter	111.90	94.42
First Quarter	119.59	93.05
2015:		
Fourth Quarter	$128.39	$105.67
Third Quarter	140.72	92.98
Second Quarter	121.47	106.45
First Quarter	129.06	109.46

	Cumulative Total Return					
	12/11	12/12	12/13	12/14	12/15	12/16
Celgene Corporation	$100.00	$116.08	$249.95	$330.95	$354.32	$342.46
S&P 500	100.00	115.88	153.01	173.69	176.07	196.78
NASDAQ Composite	100.00	117.70	164.65	188.87	202.25	220.13
NASDAQ Biotechnology	100.00	132.72	220.22	295.88	330.71	260.12

* $100 Invested on 12/31/11 in Stock or Index – Including Reinvestment of Dividends, Fiscal Year Ended December 31.

(b) HOLDERS

The closing sales price per share of common stock on the NASDAQ Global Select Market on February 3, 2017 was $115.64. As of February 3, 2017, there were approximately 404 holders of record of our common stock.

(c) DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and have no present intention to pay a cash dividend on our common stock.

(d) EQUITY COMPENSATION PLAN INFORMATION

We incorporate information regarding the securities authorized for issuance under our equity compensation plan into this section by reference from the section entitled "Equity Compensation Plan Information" to be included in the proxy statement for our 2017 Annual Meeting of Stockholders.

(e) REPURCHASE OF EQUITY SECURITIES

From April 2009 through December 2016, our Board of Directors approved purchases of up to $20.500 billion of our common stock, including an approved increase of $3.000 billion in June 2016. Approved amounts exclude share purchase transaction fees.

The following table presents the number of shares purchased during the three-month period ended December 31, 2016, the average price paid per share, the number of shares that were purchased and the dollar value of shares that still could have been purchased, pursuant to our repurchase authorization:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs
October 1 - October 31	1,351,779	$ 98.79	1,351,779	$4,731,308,099
November 1 - November 30	—	$ —	—	$4,731,308,099
December 1 - December 31	—	$ —	—	$4,731,308,099
	1,351,779	$ 98.79	1,351,779	

During the three-month period ended December 31, 2016, we purchased 1.4 million shares of common stock under the share repurchase program at a cost of $133.5 million, excluding commissions. As of December 31, 2016, we had a remaining purchase authorization of $4.731 billion.

During the period covered by this report, we did not sell any of our equity shares that were not registered under the Securities Act of 1933, as amended.

ITEM 6. SELECTED FINANCIAL DATA

The following Selected Consolidated Financial Data should be read in conjunction with our Consolidated Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included in this Annual Report on Form 10-K. The data set forth below with respect to our Consolidated Statements of Income for the years ended December 31, 2016, 2015 and 2014 and the Consolidated Balance Sheet data as of December 31, 2016 and 2015 are derived from our Consolidated Financial Statements which are included in this Annual Report on Form 10-K and are qualified by reference to such Consolidated Financial Statements and related Notes thereto. The data set forth below with respect to our Consolidated Statements of Income for the years ended December 31, 2013 and 2012 and the Consolidated Balance Sheet information as of December 31, 2014, 2013 and 2012 are derived from our Consolidated Financial Statements, which are not included in this Annual Report on Form 10-K (amounts in millions, except per share data).

	Years ended December 31,				
	2016	2015	2014	2013	2012
Consolidated Statements of Income:					
Total revenue	$11,229.2	$9,256.0	$7,670.4	$6,493.9	$5,506.7
Costs and operating expenses	8,062.6	7,001.4	5,151.4	4,685.0	3,760.3
Operating income	3,166.6	2,254.6	2,519.0	1,808.9	1,746.4
Interest and investment income, net	30.3	31.1			