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

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

OF 1934

For the transition period from

to

Commission file number 001-34912

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

22-2711928

(State or other jurisdiction of

(I.R.S. Employer Identification No.)

incorporation or organization)

86 Morris Avenue

07901

Summit, New Jersey

(Zip Code)

(Address of principal executive offices)

(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

Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence.

Part III, Item 14. Principal Accountant Fees and Services.

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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	Approvals
Multiple myeloma (MM)	119910 ( 410
Multiple myeloma in combination with dexamethasone, in patients who have received at least one prior therapy	<ul><li> United States</li><li> European Union</li><li> Japan</li><li> Other international markets</li></ul>
	<ul><li> United States</li><li> Japan</li><li> Other international markets</li><li> European Union</li></ul>
Myelodysplastic syndromes (MDS)	_
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5g abnormality with or without additional cytogenetic abnormalities	<ul><li>United States</li><li>Other international markets</li></ul>
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS in patients with isolated deletion 5q cytogenetic abnormality when other options are insufficient or inadequate	- European Union
MDS with a deletion 5q cytogenetic abnormality. The efficacy or safety of REVLIMID® for International Prognostic Scoring System (IPSS) intermediate-2 or high risk MDS has not been established.	- Japan
Mantle cell lymphoma (MCL) in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib	<ul><li>United States</li><li>European Union</li><li>(July 2016)</li><li>Other international markets</li></ul>
In January 2017, the European Medicines Agency's (EMA) Committee for Medicinal Products fo	r Human Use

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	- United States
progression on or within 60 days of completion of the last therapy	
Relapsed and refractory multiple myeloma, in combination with dexamethasone, for adult patients wh	0 Furopean
have received at least two prior therapies including both lenalidomide and bortezomib and have	Union
demonstrated disease progression on the last therapy	Cilion

Geographic

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:

is approved for the following uses.	
Disease	Geographic Approvals
Psoriatic arthritis	
Adult patients with active psoriatic arthritis	<ul><li>- United States</li><li>- Japan (December 2016)</li></ul>
Adult patients with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior DMARD therapy Psoriasis	- European Union
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 chemotherapy product which was developed using our proprietary nab® technology platform. This chemotherapy agent combines paclitaxel with albumin. ABRAXANE® is approved for the following Disease	s protein-bound
Disease	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.	<ul><li>United States</li><li>Other</li><li>international</li><li>markets</li></ul>
Metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease for whom standard, anthracycline containing therapy is not indicated Breast cancer  Non-Small Cell Lung Cancer (NSCLC)	- Japan
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	international markets
NSCLC	- Japan
Pancreatic Cancer  Metastatic adenocarcinoma of the pancreas, a form of pancreatic cancer, as first line treatment in combination with gemcitabine	<ul><li> United States</li><li> European Union</li><li> Other</li><li> international</li><li> markets</li></ul>

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
Intermediate 2 and high rick MDS	- Other
Intermediate-2 and high-risk MDS	international
	markets
MDS	- Japan
	- European Union
Chronic myelomonocytic leukemia with 10% to 29% marrow blasts without myeloproliferative	- Other
disorder	international
	markets
	- European Union
A out a mysleid leukamia (AMI) with 20% to 20% bloots and multi-lineage dyenlosis	- Other
Acute myeloid leukemia (AML) with 20% to 30% blasts and multi-lineage dysplasia	international
	markets
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	- European Union
·	

	Disease	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	- Other
	chemotherapy with autologous stem cell rescue, for the treatment of patients with untreated	international
	multiple myeloma	markets
		- Other
	Multiple myeloma after failure of standard therapies (relapsed or refractory)	international
		markets
	Thalidomide Celgene® in combination with melphalan and prednisone as a first line treatment for	- European Union
patients with		- Other
	patients with untreated multiple myeloma who are aged sixty-five years of age or older or	international
	ineligible for high dose chemotherapy	morkoto

THALOMID® (thalidomide): THALOMID®, sold as THALOMID® or Thalidomide Celgene® outside of the United

Erythema nodosum leprosum

Disease

States, is administered orally for the following uses:

Cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL), an - United States inflammatory complication of leprosy - Other international

Geographic

markets

markets

- United States

- Other international markets

Maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence

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 <sup>1</sup>	Q3 2016
POMALYST®/IMNOVID®	Relapsed/refractory	Post-approval research	2013
THALOMID®/Thalidomide Celgene®	Newly diagnosed	Post-approval research	2006
PD-L1 Inhibitor: durvalumab <sup>2</sup>	MM	Phase I	2015
Cereblon Modulator: avadomide (CC-122)	MM	Phase I	2015
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Area of Research		Status	Entered Current Status
BCMA CAR-T (bb2121) <sup>3</sup>	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 (MI	DS)	D	
VIDAZA®	MDS	Post-approval research	2004
DEVI DAD®	D 1 4 5	Post-approval	2005
REVLIMID®	Deletion 5q	research	2005
CC-486	Lower-risk	Phase III	2013
	Post hypomethylating agent (HMA) failure	Phase II	2015
luspatercept (ACE-536) <sup>4</sup>	MDS	Phase III	Q1 2016
PD-L1 Inhibitor: durvalumab <sup>2</sup>	MDS	Phase II	2015
Anti-CD47 Antibody:		DI I	01.2016
CC-90002	MDS	Phase I	Q1 2016
Acute Myeloid Leukemia (AML	)		
•		Post-approval	2008
VIDAZA®	AML (20%-30% blasts) (EU)	research	
		Post-approval	
	AML (>30% blasts) (EU)	research	2015
CC-486	Post-induction AML maintenance	Phase III	2013
IDH2 Inhibitor: enasidenib	AML	Regulatory	Q4 2016
$(AG-221)^5$	ANL	submission <sup>1</sup>	Q4 2010
PAN-IDH Inhibitor: AG-881 <sup>5</sup>	AML	Phase I	2015
PD-L1 Inhibitor: durvalumab <sup>2</sup>	AML	Phase II	2015
Anti-CD47 Antibody:	AML	Phase I	Q1 2016
CC-90002		r Hase 1	Q1 2010
Cereblon Modulator: CC-90009	AML	Phase I	Q4 2016
Lymphoma			
• •	Mantle cell lymphoma: Relapsed/refractory	Post-approval	
REVLIMID®	(US)	research	2013
	Mantle cell lymphoma: Relapsed/refractory	Post-approval	
	(EU)	research	Q3 2016
	Diffuse large B-cell (ABC-subtype): First	research	
	line	Phase III	2015
	Indolent lymphoma: Relapsed/refractory	Phase III	2013
	Follicular lymphoma: First-line	Phase III	2013
	Tomeutar Tymphoma. Thist-mic	Regulatory	
	Adult T-cell leukemia-lymphoma (Japan)	submission <sup>1</sup>	Q2 2016
	Cutaneous T-cell lymphoma (US) <sup>6</sup> Peripheral T-cell lymphoma:	Post-approval	
ISTODAX®		research	2009
		Post-approval	
	Relapsed/refractory (US) <sup>6</sup>	research	2011
	Relapsed terractory (OS)	1030aron	Q3 2016
			QJ 2010

Cereblon Modulator: avadomide (CC-122)	Peripheral T-cell lymphoma: Relapsed/refractory (Japan) Peripheral T-cell lymphoma: First-line Diffuse large B-cell lymphoma Indolent lymphoma: Relapsed/refractory	Regulatory submission <sup>1</sup> Phase III Phase Ib Phase I	2013 2014 2014
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Area of Research		Status	Entered Current Status
CC-486 PD-L1 Inhibitor: durvalumab <sup>2</sup>	Lymphoma Non-Hodgkin lymphoma (NHL)	Phase I Phase I	2015 Q1 2016
CD19 CAR-T (JCAR017) <sup>7</sup>	Aggressive large B-cell lymphoma: Relapsed/refractory	Phase I	2015
Acute Lymphocytic Leukemia (AL			
CD19 CAR-T (JCAR015) <sup>7</sup>	ALL	Phase II	2015
Chronic Lymphocytic Leukemia (C	LL)		
Cereblon Modulator: avadomide (CC-122)	CLL	Phase I	2015
PD-L1 Inhibitor: durvalumab <sup>2</sup>	CLL	Phase I	2015
Beta Thalassemia luspatercept (ACE-536) <sup>4</sup>	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) <sup>8</sup>	Post-approval research	2013
CC-486	Breast: Metastatic	Phase II	2015
Maximomile	Non-small cell lung: Advanced	Phase II	2015
Marizomib Cereblon Modulator: avadomide	Glioblastoma	Phase II	Q4 2016
(CC-122)	Hepatocellular carcinoma	Phase I	2015
Anti-CD47 Antibody: CC-90002	Solid tumors	Phase I	2015
PAN-IDH Inhibitor: AG-881 <sup>5</sup>	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
CED 0201	Ulcerative colitis	Phase II	2014
GED-0301	Crohn's disease Ulcerative colitis	Phase III Phase II	2015 2015
ozanimod	Relapsing multiple sclerosis	Phase III	2013

	Ulcerative colitis Crohn's disease	Phase III Phase II	2015 2015
RPC-4046	Eosinophilic esophagitis	Phase II	2014
8			

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 <sup>9</sup>	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

<sup>&</sup>lt;sup>1</sup> "Regulatory submission" indicates US and/or EU submission unless another country or region is indicated under Area of Research.

## 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	$2027^{2}$	$2024^{3}$
(U.S. and European use patents)		
THALOMID® brand drug	2023	2019
(U.S. formulation/ European use patents)		
VIDAZA® brand drug	$2011^{4}$	2019
(U.S. use patent and EMA regulatory exclusivities only)		
ABRAXANE® brand drug	2026	$2022^{5}$
(U.S. use patent and European use/formulation patents)		
POMALYST®/IMNOVID® brand drug	$2024^{6}$	$2023^{7}$
(U.S. drug substance/use patent)		
OTEZLA® brand drug	20248	$2028^{3}$
(U.S./European drug substance patent)		

<sup>&</sup>lt;sup>2</sup> In collaboration with MedImmune Limited, a wholly owned subsidiary of AstraZeneca PLC.

<sup>&</sup>lt;sup>3</sup> In collaboration with bluebird bio, Inc.

<sup>&</sup>lt;sup>4</sup> In collaboration with Acceleron Pharma, Inc.

<sup>&</sup>lt;sup>5</sup> In collaboration with Agios Pharmaceuticals, Inc.

<sup>&</sup>lt;sup>6</sup> Regulatory approval based on pivotal phase II data.

<sup>&</sup>lt;sup>7</sup> In collaboration with Juno.

<sup>&</sup>lt;sup>8</sup> Trial conducted by licensee partner, Taiho Pharmaceuticals Co. Ltd.

<sup>&</sup>lt;sup>9</sup> In collaboration with Abide Therapeutics, Inc.

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- 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.
  - 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.
- 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.
- Subject of ongoing supplementary protection certificate (SPC) appeal proceedings in the UK and the Court of
- <sup>5</sup> 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.
- <sup>6</sup> Application for Patent Term Extension pending, receipt of which would extend exclusivity through 2025.
- 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.
- <sup>8</sup> 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<sup>®</sup>. 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<sup>®</sup> 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 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 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:

eredit and foreign exchange risk management;

diquidity;

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.

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:

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increased management, travel, infrastructure and legal compliance costs;

longer payment and reimbursement cycles;

difficulties in enforcing contracts and collecting accounts receivable;

docal marketing and promotional challenges;

łack 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.

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

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.

Primary Usage	Approximate Square Feet
Research	268,300
Office space	81,900
Office space	83,000
Office space and research	73,500
Office space and research	55,800
Office space	29,600
Research	23,400
Office space	9,800
Office space	3,500
Office space	3,000
	Research Office space Office space Office space and research Office space and research Office space Research Office space Office space Office space

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

<sup>\* \$100</sup> 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:

			1 otai			
			Number of	Dollar		
Period		Average	Shares	Value of Shares		
	Total	Average Price	Purchased	That		
	Number of	Paid per Share	as	May Yet Be		
	Shares Purchased		Part of	Purchased		
			Publicly	Under the Plans		
			Announced	or		
			Plans or	Programs		
			Programs			
October 1 - October 31	1,351,779	\$98.79	1,351,779	\$4,731,308,099		
November 1 - November 30		\$ <i>—</i>		\$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 ende	d Decembe	r 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	28.2	22.0	15.3		
Interest (expense)	(500.1)	(310.6)	(176.1)	(91.6)	(63.2	)	
Other income (expense), net	(324.3)	48.4	(43.7)	(73.9)	(17.0	)	
Income before income taxes	2,372.5	2,023.5	2,327.4	1,665.4	1,681.5		
Income tax provision	373.3	421.5	327.5	215.5	225.3		
Net income	\$1,999.2	\$1,602.0	\$1,999.9	\$1,449.9	\$1,456.2		
Net income per share: <sup>1</sup>							
Basic	\$2.57	\$2.02	\$2.49	\$1.75	\$1.69		
Diluted	\$2.49	\$1.94	\$2.39	\$1.68	\$1.65		
Weighted average shares:1							
Basic	777.2	792.2	802.7	827.7	861.9		
Diluted	803.3	824.9	836.0	860.6	881.6		
			As of De	ecember 31	,		
			2016	2015	2014	2013	2012
Consolidated Balance Sheets Data:							
Cash, cash equivalents and marketab	le securities		\$7,969.7	\$6,551.9	\$7,546.7	\$5,687.0	\$3,900.3
Total assets <sup>2</sup>			28,085.6	26,964.4	17,291.2	13,343.5	11,712.4
Short-term borrowings and current p	ortion of lon	g-term debt	500.7		605.9	544.8	308.5
Long-term debt, net of discount <sup>2</sup>			13,788.5	14,161.4	6,216.8	4,161.8	2,749.4
Retained earnings				8,074.4	6,472.4	4,472.5	3,022.6
Total stockholders' equity			•		6,524.8	5,589.9	5,694.5

<sup>&</sup>lt;sup>1</sup> Adjusted to reflect the two-for-one common stock split effected in June 2014.

<sup>&</sup>lt;sup>2</sup> Total assets and Long-term debt, net of discount have been restated as of December 31, 2015, 2014, 2013 and 2012 to reflect the retroactive reclassification of debt issuance costs in accordance with ASU 2015-03, "Simplifying the Presentation of Debt Issuance Costs."

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

**Executive Summary** 

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 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 following table summarizes total revenue and earnings for the years ended December 31, 2016, 2015 and 2014 (dollar amounts in millions, except per share data):

				% Chai	nge
	Years Ended December 31,			2016	2015
	2016	2015	2014	versus	versus
	2010	2013	2014	2015	2014
Total revenue	\$11,229.2	\$9,256.0	\$7,670.4	21.3%	20.7 %
Net income	\$1,999.2	\$1,602.0	\$1,999.9	24.8%	(19.9)%
Diluted earnings per share	\$2.49	\$1.94	\$2.39	28.4%	(18.8)%

Revenue increased by \$1.973 billion in 2016 compared to 2015 primarily due to the continued growth in sales of REVLIMID®, OTEZLA®, and POMALYST®/IMNOVID®. The \$397.2 million increase in net income and \$0.55

increase in diluted earnings per share in 2016 as compared to 2015 were primarily due to a higher level of net product sales and a \$601.9 million reduction in collaboration-related expenses, partly offset by increases in other expenses, including \$892.9 million of research and development asset acquisition expense associated with the purchases of EngMab AG (EngMab), Acetylon Pharmaceuticals, Inc. (Acetylon), and Triphase Research and Development I Corporation (Triphase), \$345.3 million of increased impairment charges related to strategic equity investments, which included \$272.2 million related to our equity investment in Juno Therapeutics, Inc. (Juno), an increase in selling, general and administrative expenses primarily due to a \$198.5 million litigation-related loss contingency accrual expense, and an \$83.1 million impairment charge related to the technology platform obtained in our 2012 acquisition of Avila Therapeutics, Inc. (Avila).

#### **Results of Operations**

Fiscal Years Ended December 31, 2016, 2015 and 2014

Total Revenue: Total revenue and related percentages by product for the years ended December 31, 2016, 2015 and 2014 were as follows (dollar amounts in millions):

				% Change		
				2016	2015	
	2016	2015	2014	versus	versus	
				2015	2014	
Net product sales:						
REVLIMID®	\$6,973.6	\$5,801.1	\$4,980.0	20.2 %	16.5 %	
POMALYST®/IMNOVID®	1,310.7	983.3	679.7	33.3 %	44.7 %	
OTEZLA <sup>®</sup>	1,017.2	471.7	69.8	115.6 %	N/M	
ABRAXANE®	973.4	967.5	848.2	0.6 %	14.1 %	
VIDAZA <sup>®</sup>	608.0	590.7	611.9	2.9 %	(3.5)%	
azacitidine for injection	66.0	83.9	78.2	(21.3)%	7.3 %	
THALOMID®	152.1	185.4	221.2	(18.0)%	(16.2)%	
ISTODAX®	79.3	69.1	65.6	14.8 %	5.3 %	
Other	4.3	8.4	9.2	(48.8)%	(8.7)%	
Total net product sales	\$11,184.6	\$9,161.1	\$7,563.8	22.1 %	21.1 %	
Other revenue	44.6	94.9	106.6	(53.0)%	(11.0)%	
Total revenue	\$11,229.2	\$9,256.0	\$7,670.4	21.3 %	20.7 %	
N/M Not meaningful						

N/M - Not meaningful

The increase in total revenue of \$1.973 billion in 2016 compared to 2015 reflected increases of \$1.406 billion, or 25.1%, in the United States, and \$567.7 million, or 15.5%, in international markets. The increase in total revenue of \$1.586 billion in 2015 compared to 2014 reflected increases of \$1.121 billion, or 25.0%, in the United States, and \$464.4 million, or 14.6%, in international markets.

Net Product Sales: Total net product sales for 2016 increased by \$2.024 billion, or 22.1%, to \$11.185 billion compared to 2015. The increase was comprised of net volume increases of \$1.680 billion and net price increases of \$415.2 million, offset in part by a \$71.2 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity. The increase in volume was driven by increased unit sales of REVLIMID®, OTEZLA®, and POMALYST®/IMNOVID®, partly offset by a decrease in unit sales of THALOMID® and ABRAXANE®. The price impact was primarily attributable to price increases in the U.S. market.

Total net product sales for 2015 increased by \$1.597 billion, or 21.1%, to \$9.161 billion compared to 2014. The increase was comprised of net volume increases of \$1.467 billion and net price increases of \$239.8 million, offset in part by a \$109.4 million unfavorable foreign exchange impact, including the impact of foreign exchange hedging activity. The increase in volume was driven by increased unit sales of REVLIMID®, OTEZLA®,

POMALYST®/IMNOVID®, and ABRAXANE®, partly offset by a decrease in unit sales of THALOMID®. The price impact was primarily attributable to price increases in the U.S. market.

REVLIMID® net sales increased by \$1.173 billion, or 20.2%, to \$6.974 billion in 2016 compared to 2015, primarily due to increased unit sales in both U.S. and international markets and price increases in the U.S. market. Increases in market penetration and treatment duration of patients using REVLIMID® in multiple myeloma contributed to the increase in U.S. unit sales. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains. REVLIMID® launched in the U.S. and EU for the Newly Diagnosed Multiple Myeloma following approval in February 2015.

Net sales of REVLIMID® increased by \$821.1 million, or 16.5%, to \$5.801 billion in 2015 compared to 2014, primarily due to increased unit sales in both U.S. and international markets in addition to price increases in the U.S. market. Increases in market penetration and treatment duration of patients using REVLIMID® in multiple myeloma contributed to the increase in U.S. unit sales. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains.

POMALYST®/IMNOVID® net sales increased by \$327.4 million, or 33.3%, to \$1.311 billion in 2016 compared to 2015, reflecting net sales of \$777.5 million in the United States and \$533.2 million in international markets. Increases in treatment duration

contributed to the increase in U.S. and international net sales of POMALYST®/IMNOVID®. Achieving reimbursement in additional countries, notably in Japan, also continues to contribute to the growth of POMALYST®/IMNOVID® net sales in international markets.

Net sales of POMALYST®/IMNOVID® increased by \$303.6 million, or 44.7%, to \$983.3 million in 2015 compared to 2014, reflecting net sales of \$591.8 million in the United States and \$391.5 million in international markets. Increases in market share and treatment duration contributed to the increase in U.S. and international net sales of POMALYST®/IMNOVID®.

OTEZLA® net sales increased by \$545.5 million to \$1.017 billion in 2016 compared to 2015, reflecting net sales of \$904.4 million in the United States and \$112.8 million in international markets. 2016 was the second full year on the market in the U.S. Growth in the U.S. reflects increased market share and expanding accessibility to patients. Sales in international markets continued to expand during 2016, with growing sales in early launch countries in Europe and additional international approvals.

Net sales of OTEZLA® increased by \$401.9 million to \$471.7 million in 2015 compared to 2014, reflecting net sales of \$440.0 million in the United States and \$31.7 million in international markets. OTEZLA® net sales were \$69.8 million for 2014, primarily from sales in the United States. OTEZLA® was approved by the U.S. Food and Drug Administration (FDA) in March 2014 for the treatment of adult patients with active psoriatic arthritis and in September 2014 for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. OTEZLA® was approved for plaque psoriasis and psoriatic arthritis in the EU in January 2015. Launch activities for OTEZLA® commenced in March 2014 and we began recognizing revenue related to OTEZLA® during the second quarter of 2014.

ABRAXANE® net sales increased by \$5.9 million, or 0.6% to \$973.4 million in 2016 compared to 2015. U.S. sales of \$633.8 million and international sales of \$339.6 million decreased 3.0 percent and increased 8.2 percent, respectively. The increase in international sales was primarily due to increased unit sales, which were partially offset by price decreases. The decrease in U.S. sales was due to volume decreases partly offset by price increases. The decrease in U.S. sales reflects the increased competition in breast cancer and lung cancer indications from new market entrants.

Net sales of ABRAXANE® increased by \$119.3 million, or 14.1%, to \$967.5 million in 2015 compared to 2014, primarily due to increased unit volumes in both the U.S. and international markets reflecting increased acceptance of the product for the treatment of both metastatic adenocarcinoma of the pancreas and non-small cell lung cancer (NSCLC). ABRAXANE® was approved for the treatment of 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 in the European Union in March 2015.

VIDAZA® net sales increased by \$17.3 million, or 2.9%, to \$608.0 million in 2016 compared to 2015, primarily due to a \$26.6 million increase in international markets resulting from increased unit sales which were partly offset by price decreases in international markets and both volume and price decreases in the U.S. market. Net sales of VIDAZA® decreased by \$21.2 million, or 3.5%, to \$590.7 million in 2015 compared to 2014, primarily due to a \$21.6 million decrease in U.S. sales resulting from the September 2013 introduction of a generic version of VIDAZA® by a competitor, which was partly offset by volume increases in international markets. Azacitidine for injection net sales decreased by \$17.9 million, or 21.3%, to \$66.0 million in 2016 compared to 2015, primarily due to price decreases partially offset by an increase in unit volumes. Azacitidine for injection is a generic version of VIDAZA® supplied by us to Sandoz AG (Sandoz).

Azacitidine for injection net sales increased by \$5.7 million, or 7.3%, to \$83.9 million in 2015 compared to 2014, primarily due to increased unit sales to Sandoz, which were partly offset by price decreases.

THALOMID® net sales decreased by \$33.3 million, or 18.0%, to \$152.1 million in 2016 compared to 2015, primarily resulting from lower unit volumes in the U.S.

Net sales of THALOMID® decreased by \$35.8 million, or 16.2%, to \$185.4 million for 2015 compared to 2014, primarily resulting from lower unit volumes and price decreases in both U.S. and international markets.

ISTODAX® net sales increased by \$10.2 million, or 14.8%, to \$79.3 million for 2016 compared to 2015, primarily due to an increase in unit volume as well as price increases.

Net sales of ISTODAX® increased by \$3.5 million, or 5.3%, to \$69.1 million in 2015 compared to 2014, primarily due to an increase in unit sales.

The "other" net product sales category, which includes sales of FOCALIN®, decreased by \$4.1 million, to \$4.3 million in 2016 compared to 2015. The "other" net product sales category decreased by \$0.8 million to \$8.4 million in 2015 compared to 2014.

Other Revenue: Other revenue decreased by \$50.3 million to \$44.6 million for 2016 compared to 2015 primarily due to a \$36.0 million decrease in royalty revenue from Novartis AG (Novartis) based upon its sales of both RITALIN® and FOCALIN XR®, both of which have been negatively impacted by generic competition in certain markets and we expect that trend to continue in 2017. Generic competition entered the market in the United States for certain strengths of FOCALIN XR in the fourth quarter of 2013.

Other revenue decreased by \$11.7 million to \$94.9 million for 2015 compared to 2014 primarily due to a \$14.1 million decrease in royalty revenue. The decrease in royalty revenue was driven by lower royalties earned from Novartis based on its sales of FOCALIN XR® and RITALIN®, which have both been negatively impacted by generic competition in certain markets.

Gross to Net Sales Accruals: We record gross to net sales accruals for sales returns and allowances, sales discounts, government rebates, chargebacks and distributor service fees.

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. OTEZLA®, ABRAXANE®, ISTODAX® and VIDAZA® 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®.

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance. As noted above, REVLIMID®, POMALYST®/IMNOVID® and THALOMID®/Thalidomide Celgene® are distributed primarily through hospitals and contracted pharmacies, which are typically subject to tighter controls of inventory quantities within the supply channel and, thus, resulting in lower returns activity.

Sales discount accruals are based on payment terms extended to customers.

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with

Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We also analyze actual billings received from the states to further support the accrual rates. Manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products as well as the historical invoices. This expense is recognized throughout the year as costs are incurred. In certain international markets government-sponsored programs require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from the date of sale. We record a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are included in chargeback accruals and are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

See Critical Accounting Estimates and Significant Accounting Policies below for further discussion of gross to net sales accruals.

Gross to net sales accruals and the balance in the related allowance accounts for the years ended December 31, 2016, 2015 and 2014 were as follows (in millions):

	Sales Returns	Discounts	Government Rebates	Chargebacks and Distributor Service Fees	Total
Balance at December 31, 2013	\$ 15.5	\$ 12.1	\$ 134.1	\$ 83.2	\$244.9
Allowances for sales during prior periods	(5.4)	_	(7.1)	(8.4)	(20.9)
Allowances for sales during 2014	7.9	87.9	293.1	382.9	771.8
Credits/deductions issued for prior year sales	(4.1)	(8.8)	(78.8)	(43.3)	(135.0)
Credits/deductions issued for sales during 2014	(3.7)	(79.7)	(202.8)	(320.0)	(606.2)
Balance at December 31, 2014	\$ 10.2	\$ 11.5	\$ 138.5	\$ 94.4	\$254.6
Allowances for sales during prior periods	1.0	_	(5.1)	(3.0)	(7.1)
Allowances for sales during 2015	15.3	111.7	423.5	541.6	1,092.1
Credits/deductions issued for prior year sales	(3.9)	(8.2)	(77.7)	(50.6)	(140.4)
Credits/deductions issued for sales during 2015	(5.2)	(102.8)	(254.1)	(440.7)	(802.8)
Balance at December 31, 2015	\$ 17.4	\$ 12.2	\$ 225.1	\$ 141.7	\$396.4
Allowances for sales during prior periods	(6.6)		19.9	(13.4)	(0.1)
Allowances for sales during 2016	17.3	153.5	667.8	763.8	1,602.4
Credits/deductions issued for prior year sales	(6.6)	(10.4)	(174.9)	(56.0)	(247.9)
Credits/deductions issued for sales during 2016	(3.8)	(139.4)	(366.7)	(646.3)	(1,156.2)
Balance at December 31, 2016	\$ 17.7	\$ 15.9	\$ 371.2	\$ 189.8	\$594.6

A comparison of provisions for allowances for sales within each of the four categories noted above for 2016 and 2015 follows:

2016 compared to 2015: Provisions for sales returns decreased by \$5.6 million in 2016 compared to 2015, primarily due to the ABRAXANE® allowances for sales returns being \$5.0 million higher in 2015 than in 2016 due to an increase in inventory levels held by certain distributors in 2015. Provisions for sales returns also decreased by \$1.0 million each for both REVLIMID® and ISTODAX®. These reductions were partially offset by a \$1.5 million increase in the returns allowance for OTEZLA® in 2016 primarily related to returns of product that had reached their expiration dates.

Discount provisions increased by \$41.8 million in 2016 compared to 2015, primarily due to increased sales volumes. The \$41.8 million increase consisted of a \$37.7 million increase in the United States and a \$4.1 million increase related to international markets. The U.S. increases included increases of \$21.0 million for cash discounts related to REVLIMID®, \$12.8 million related to OTEZLA® and \$4.3 million related to POMALYST®.

Government rebate provisions increased by \$269.3 million in 2016 compared to 2015, primarily due to a \$120.8 million increase in international government rebates. The increase in international government rebates was primarily driven by higher sales volumes for our primary products in Europe and increased international rebate rates, as well as

an adjustment of our accrual to reflect higher rebate rates for IMNOVID® in France. The increase in the allowance for sales of IMNOVID® in France related to prior periods was \$15.1 million and the increase for sales of IMNOVID® in the current year due to higher rebate rates in France was \$23.2 million. The \$148.5 million increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, with \$107.7 million due to an increase in Medicaid rebates (primarily in the managed care channel) and \$40.8 million due to an increase in expense related to Medicare Part D Coverage Gap.

Chargebacks and distributor service fees provisions increased by \$211.8 million in 2016 compared to 2015. Chargebacks increased by approximately \$140.4 million and distributor service fees increased by approximately \$71.4 million. The chargeback increases were primarily due to higher sales volumes, including an \$11.4 million increase related to the TRICARE program driven by higher sales volume and increased rebate rates. The distributor service fee increase was primarily attributable to OTEZLA®, which accounted for \$64.1 million of the increase in distributor service fees.

2015 compared to 2014: Provisions for sales returns increased by \$13.8 million in 2015 compared to 2014, primarily due to a \$5.0 million increase in ABRAXANE® returns reserve allowance related to inventory levels held by certain distributors at the end of 2015. Higher net product sales volumes and elevated returns activity in the U.S. market also resulted in \$6.0 million of increases in 2015. In addition, \$4.8 million of reductions in returns reserves were recorded in 2014 for the migration of THALOMID® to specialty pharmacies and for VIDAZA® inventory levels held at distributors following competition from generic versions of VIDAZA®. These increases were partially offset by a \$2.4 million decrease related to POMALYST® in 2015 due to lower returns activity.

Discount provisions increased by \$23.8 million in 2015 compared to 2014, primarily due to increased sales volumes. The \$23.8 million increase consisted of a \$24.3 million increase in the United States, which included increases of \$13.4 million of cash discounts related to REVLIMID®, \$8.9 million related to OTEZLA® and \$3.0 million related to POMALYST®. The U.S. increases were partly offset by a \$0.5 million decrease related to international cash discounts.

Government rebate provisions increased by \$132.4 million in 2015 compared to 2014, primarily due to a \$97.9 million increase in international government rebates, due to higher sales volumes and increased rebate rates, and a \$26.4 million increase related to Medicaid rebates due to increased sales and Medicaid expansion and a \$8.1 million increase in expense related to Medicare Part D Coverage Gap.

Chargebacks and distributor service fees provisions increased by \$164.1 million in 2015 compared to 2014. Chargebacks increased by approximately \$102.1 million and distributor service fees increased by approximately \$62.0 million. The chargeback increases were primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates. The distributor service fee increase was primarily attributable to OTEZLA®, which launched in April 2014, resulting in an increase of \$49.3 million in service fees for 2015.

Cost of Goods Sold (excluding amortization of acquired intangible assets): Cost of goods sold and related percentages for the years ended December 31, 2016, 2015 and 2014 were as follows (dollar amounts in millions):

	2010		2013		2014	
Cost of goods sold (excluding amortization of acquired intangible assets)	\$438.0	)	\$420.1	l	\$385.9	9
Increase from prior year	\$17.9		\$34.2		\$45.5	
Percent increase from prior year	4.3	%	8.9	%	13.4	%
Percent of net product sales	3.9	%	4.6	%	5.1	%

Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$17.9 million to \$438.0 million in 2016 compared to 2015. The increase was primarily due to the higher level of net product sales. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 3.9% for 2016 compared to 4.6% for 2015, primarily due to OTEZLA® and POMALYST®, which have lower cost, making up a higher percentage of net product sales, while sales of ABRAXANE® and azacitidine for injection, which have higher cost, made up a lower percentage of net product sales.

Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$34.2 million to \$420.1 million in 2015 compared to 2014. The increase was primarily due to the higher level of net product sales. The changing mix

of product sales toward lower cost products that was seen in 2016 compared to 2015 also occurred in 2015 compared to 2014. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 4.6% for 2015 compared to 5.1% for 2014, primarily due to OTEZLA® and POMALYST®, which have lower cost, making up a higher percentage of net product sales, while sales of ABRAXANE® and azacitidine for injection, which have higher cost, made up a lower percentage of net product sales.

Research and Development: Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants and fees paid to clinical research organizations, supplies, upfront and milestone payments resulting from collaboration arrangements and expenses for research and development asset acquisitions.

Research and development expenses and related percentages for the years ended December 31, 2016, 2015 and 2014 were as follows (dollar amounts in millions):

	2016	2015	2014
Research and development	\$4,470.1	\$3,697.3	\$2,430.6
Increase from prior year	\$772.8	\$1,266.7	\$204.4
Percent increase from prior year	20.9 %	6 52.1 %	9.2 %
Percent of total revenue	39.8 %	6 39.9 %	31.7 %

Research and development expenses increased by \$772.8 million to \$4.470 billion in 2016, compared to 2015. The increase was primarily due to \$892.9 million of research and development asset acquisition expense associated with the purchases of EngMab, Acetylon, and Triphase as well as increases in activity in support of our early- to mid-stage product pipeline, partially offset by decreases in expenses related to collaboration arrangements. See Note 2 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to our purchases of EngMab, Acetylon, and Triphase.

Research and development expenses increased by \$1.267 billion to \$3.697 billion in 2015 compared to 2014. The increase was primarily due to a \$1.024 billion increase in expenses related to collaboration arrangements.

The following table provides a breakdown of research and development expenses (in millions):

				Increase	
				(Decreas	se)
				2016	2015
	2016	2015	2014	versus	versus
				2015	2014
Human pharmaceutical clinical programs	\$1,113.1	\$1,005.0	\$837.0	\$108.1	\$168.0
Other pharmaceutical programs	823.4	755.2	640.9	68.2	114.3
Drug discovery and development	690.4	384.4	291.4	306.0	93.0
Cellular therapy	23.1	23.6	27.0	(0.5)	(3.4)
Collaboration arrangements	927.2	1,529.1	505.1	(601.9)	1,024.0
Research and development asset acquisitions	892.9	_	_	892.9	_
IPR&D impairment	_	_	129.2	_	(129.2)
Total	\$4,470.1	\$3,697.3	\$2,430.6	\$772.8	\$1,266.7

We make significant investments in research and development in support of multiple ongoing proprietary clinical development programs which support both our existing products and pipeline of new drug candidates. See Item 1. "Business" for a table summarizing the current stage of development of both our commercial stage products and new drug candidates. See Note 17 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to certain of our collaboration arrangements.

We do not collect costs on a project basis or for any category of projects for the majority of costs involved in carrying out research projects. While we do perform cost calculations to facilitate our internal evaluation of individual projects, these calculations include significant estimations and allocations that are not relevant to, or included in, our external financial reporting mechanisms. As a consequence, we do not report research and development costs at the project level.

The following table presents significant developments in our phase III clinical trials and regulatory approval requests that occurred during the three-month period ended December 31, 2016, as well as developments that are expected to occur if the future occurrence is material and reasonably certain:

Major Pagulatory

Regulatory approval requests in major markets:

	Disease Indication	Market	Agency	Action
enasidenib	Relapsed or refractory acute myeloid leukemia with isocitrate dehydrogenase-2 (IDH2) mutation	U.S.	FDA	Q4 2016 (submitted)

#### Regulatory agency actions:

Product	Disease Indication	Major Regulatory Action
Troduct	Discase maleation	Market Agency

REVLIMID® NDMM post-ASCT maintenance EU CHMP¹ Positive Opinion OTEZLA® Psoriasis, Psoriatic arthritis Japan PMDA² Approval

Selling, General and Administrative: Selling, general and administrative expenses primarily include salary and benefit costs for employees included in our sales, marketing, finance, legal and administrative organizations, costs related to the launch of new products or those approved for new indications, outside professional services, donations to independent non-profit patient assistance organizations in the United States and facilities costs.

Selling, general and administrative expenses and related percentages for the years ended December 31, 2016, 2015 and 2014 were as follows (dollar amounts in millions):

	2016	2015	2014
Selling, general and administrative	\$2,657.7	\$2,305.4	\$2,027.9
Increase from prior year	\$352.3	\$277.5	\$343.4
Percent increase from prior year	15.3 %	13.7 %	20.4 %
Percent of total revenue	23.7 %	24.9 %	26.4 %

Selling, general and administrative expenses increased by \$352.3 million to \$2.658 billion for 2016 compared to 2015. The increase was primarily due to a \$198.5 million litigation-related loss contingency accrual expense, and an \$89.1 million increase in selling and marketing activities. See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to the litigation-related loss contingency accrual expense.

Selling, general and administrative expenses increased by \$277.5 million to \$2.305 billion in 2015 compared to 2014. The increase was primarily due to increases in expenses associated with our growing organization to support inflammation and immunology products and product candidates, such as OTEZLA® as well as increases in selling and marketing activities related to recently approved indications for REVLIMID®, OTEZLA® and POMALYST®/IMNOVID®.

<sup>&</sup>lt;sup>1</sup> European Medicines Agency's Committee for Medicinal Products for Human Use

<sup>&</sup>lt;sup>2</sup> Pharmaceuticals and Medical Devices Agency

Amortization of Acquired Intangible Assets: Amortization of intangible assets acquired as a result of business combinations is summarized below for the years ended December 31, 2016, 2015 and 2014 (in millions):

	2016	2015	2014
Avila	\$139.4	\$47.3	\$47.3
Abraxis	151.6	151.8	155.5
Gloucester	91.5	61.5	51.5
Pharmion	4.0	4.0	4.0
Quanticel	72.5	14.4	_
Total amortization	\$459.0	\$279.0	\$258.3
Increase (decrease) from prior year	\$180.0	\$20.7	\$(4.5)

Amortization of acquired intangible assets increased by \$180.0 million to \$459.0 million in 2016 compared to 2015. The increase in amortization expense primarily related to an \$83.1 million impairment charge as well as \$18.4 million of accelerated amortization expense, both related to the technology platform obtained in the Avila acquisition, amortization of the technology platform acquired in the October 2015 acquisition of Quanticel Pharmaceuticals, Inc. (Quanticel), and a reduction in the estimated useful lives of intangible assets obtained in the acquisition of Gloucester Pharmaceuticals, Inc. (Gloucester) following the grant to Fresenius Kabi USA, LLC of a non-exclusive, royalty-free sublicense to manufacture and market a generic version of romidepsin for injection as of February 1, 2018.

Amortization of acquired intangible assets increased by \$20.7 million to \$279.0 million in 2015 compared to 2014 primarily due to the amortization of the technology platform asset recorded in the acquisition of Quanticel and an acceleration of amortization expense related to certain Gloucester related intangible assets, partly offset by certain Abraxis related intangibles becoming fully amortized during the first half of 2014.

Acquisition Related Charges and Restructuring, net: Acquisition related charges and restructuring, net is summarized below for the years ended December 31, 2016, 2015 and 2014 (in millions):

	2016	2015	2014
Acquisition related charges, net	\$21.4	\$289.7	\$48.7
Restructuring charges, net	16.4	9.9	_
Total	\$37.8	\$299.6	\$48.7
Increase (decrease) from prior year	\$(261.8)	\$250.9	\$(122.4)

Acquisition related charges and restructuring, net decreased by \$261.8 million to \$37.8 million in 2016 compared to 2015. The decrease in the net expense for the current year period compared to the prior year period was primarily due to a \$296.7 million reduction in costs related to the acquisition of Receptos which occurred in August 2015 and a \$61.3 million increase in the benefit recorded for adjustments to contingent consideration issued as part of the acquisition of Avila related to adjustments made to estimates of probability and timing of future potential milestone payments payable to the former shareholders of Avila. These benefits were partly offset by a \$77.1 million reduction in benefit recorded for fair value adjustments to our liability related to publicly traded contingent value rights (CVRs) that were issued as part of the acquisition of Abraxis BioScience, Inc. (Abraxis), an \$8.1 million increase in expense related to our contingent liabilities for the Quanticel acquisition, and a \$6.5 million increase in restructuring charges in the current year period related to our relocation of certain operations into our two Summit, NJ locations as well as costs associated with certain headcount reductions.

Acquisition related charges and restructuring, net increased by \$250.9 million to \$299.6 million in 2015 compared to \$48.7 million in 2014. The increase was due to \$296.8 million in costs related to the acquisition of Receptos in August 2015, a \$28.3 million increase in expense in the current year period related to our contingent liabilities for the Nogra Pharma Limited (Nogra) acquisition, which was acquired in the second quarter of 2014, a \$18.7 million reduction in the benefit recorded in the current year period for our contingent liabilities related to the Avila acquisition compared to the prior year period, and \$9.9 million of restructuring charges related to our relocation of certain operations into

our two Summit, NJ locations as well as costs associated with certain headcount reductions. These increases in expense were partly offset by a \$102.6 million reduction in expense in the current year period related to reductions in the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis in 2010.

Interest and Investment Income, Net: Interest and investment income, net is summarized below for the years ended December 31, 2016, 2015 and 2014 (dollar amounts in millions):

	2016	2015	2014
Interest and investment income, net	\$30.3	\$31.1	\$28.2
Increase (decrease) from prior year	\$(0.8)	\$2.9	\$6.2
Percentage increase (decrease) from prior year	(2.6)%	10.3 %	28.2 %

Interest and investment income, net which includes the net income associated with our investments in available-for-sale marketable securities, decreased by \$0.8 million to \$30.3 million in 2016 compared to 2015.

Interest and investment income, net increased by \$2.9 million to \$31.1 million in 2015 compared to 2014 primarily due to lower losses on the sale of marketable securities in 2015 compared to the prior year.

Interest Expense: Interest expense is summarized below for the years ended December 31, 2016, 2015 and 2014 (dollar amounts in millions):

	2016	2015	2014
Interest expense	\$500.1	\$310.6	\$176.1
Increase from prior year	\$189.5	\$134.5	\$84.5
Percentage increase from prior year	61.0 %	76.4 %	92.2 %

Interest expense increased by \$189.5 million to \$500.1 million for 2016 compared to 2015 primarily due to interest expense associated with the issuance of \$8.000 billion of senior notes in August 2015. For more information related to our debt issuances, see "Liquidity and Capital Resources" and Note 11 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Interest expense increased by \$134.5 million to \$310.6 million in 2015 compared to 2014 primarily due to interest expense associated with the issuance of \$8.000 billion of senior notes in August 2015 and \$2.500 billion in May 2014. Other Income (Expense), Net: Other income (expense), net is summarized below for the years ended December 31, 2016, 2015 and 2014 (in millions):

2016 2015 2014	4
\$(2.3 ) \$(11.7) \$(0	5 )
$\varphi(2.3) \varphi(11.7) \varphi(9.$	5)
17.1 23.0 (18.	0)
7.6 (9.9 ) 11.6	: )
(6.0) — $(9.7)$	)
<b>—</b> 12.0 <b>—</b>	
(394.3 ) (49.0 ) (4.0	)
7.1 85.9 —	
37.5 — —	
9.0 (1.9 ) (14.	1)
\$(324.3) \$48.4 \$(43	3.7)
\$(372.7) \$92.1 \$30	.2
	\$(2.3 ) \$(11.7) \$(9.17.1

Other income (expense), net was a net expense of \$324.3 million for 2016 and a net income of \$48.4 million for 2015. The \$372.7 million increase in net expense was primarily due to increased impairment charges recorded in the 2016 period related to certain equity investments and a gain on the sale of our equity investment in Flexus that was recorded in 2015, partly offset by a gain on the sale of our LifebankUSA business and a gain on Celgene puts sold.

Other income (expense), net was a net income of \$48.4 million for 2015 and a net expense of \$43.7 million for 2014. The \$92.1 million increase in net income was primarily due to a gain on the sale of our equity investment in Flexus and currency fluctuations, partly offset by higher impairment charges incurred in 2015 when compared to 2014.

Income Tax Provision: The income tax provision decreased by \$48.2 million to \$373.3 million in 2016 compared to 2015 as a result of a decrease in the effective tax rate, partially offset by an increase in income before taxes. The effective tax rate for 2016 is 15.7%. Our effective tax rate is a function of the distribution of our pre-tax income among the many jurisdictions in which we operate. Our pre-tax income is earned and taxed in either the U.S. at a statutory tax rate of 35%, or outside the U.S. at significantly lower statutory tax rates. The differences in tax rates between jurisdictions can significantly impact our effective tax rate as our business changes and pre-tax earnings shift from year to year. The effective tax rate for 2015 was 20.8%. The 5.1 percentage point decrease in our effective tax rate in 2016 compared to 2015 is primarily the result of tax benefits related to a loss on our investment in Avila, offset by a non-deductible pre-tax charge related to our acquisition of Acetylon and non-recurring charges to tax expense recorded in 2015 related to both the global mix of funding sources for payments to collaboration partners, primarily the initiation of our collaborations with AstraZeneca PLC (AstraZeneca) and Juno, and an increase in the valuation allowance for certain deferred tax assets obtained in our acquisition of Receptos, Inc. (Receptos).

The income tax provision increased by \$94.0 million to \$421.5 million in 2015 compared to 2014 primarily as a result of an increase in the effective tax rate, partially offset by a decrease in income before taxes. The effective tax rate for 2015 was 20.8%. The effective tax rate for 2014 was 14.1%. The 6.7 percentage point increase in our effective tax rate in 2015 compared to 2014 was primarily the result of an increase in tax expense related to the global mix of funding sources for payments to collaboration partners, primarily the initiation of our collaborations with AstraZeneca and Juno, and an increase in the valuation allowance for certain deferred tax assets obtained in our acquisition of Receptos, partially offset by a non-recurring tax expense recorded in 2014 related to the launch of new products.

Accounting Standards Update No. 2016-09, "Compensation-Stock Compensation" (ASU 2016-09) changes several aspects of the accounting for share-based payment transactions including requiring all excess tax benefits and tax deficiencies to be recognized in the income tax provision. The new standard will be effective for us on January 1, 2017. We anticipate that the new standard will have a favorable impact on our effective tax rate in 2017. The amount of the reduction to our effective tax rate will depend upon future movements in our share price as well as the magnitude of stock award exercises, which are both difficult to estimate. See Note 1 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional information related to this accounting standard update.

In addition to our future adoption of ASU 2016-09, our future effective tax rate can be materially impacted by shifts in the distribution of our pre-tax income among the jurisdictions where we operate, as well as payments to collaboration partners, acquisitions, divestitures, changes in tax laws, audit settlements, and many other factors which are difficult to forecast.

Net Income: Net income and per common share amounts for the years ended December 31, 2016, 2015 and 2014 were as follows (dollar amounts in millions, except per share data):

	2016	2015	2014
Net income	\$1,999.2	\$1,602.0	\$1,999.9
Per common share amounts:			
Basic	\$2.57	\$2.02	\$2.49
Diluted	\$2.49	\$1.94	\$2.39
Weighted average shares:			
Basic	777.2	792.2	802.7
Diluted	803.3	824.9	836.0

The \$397.2 million increase in net income to \$1.999 billion in 2016 compared to 2015 was primarily due to a higher level of net product sales and a \$601.9 million reduction in collaboration-related expenses, partly offset by increases in other expenses, including \$892.9 million of research and development asset acquisition expense associated with the purchases of EngMab, Acetylon and Triphase, \$345.3 million of increased impairment charges related to strategic equity investments, which included \$272.2 million related to our equity investment in Juno, an increase in selling, general and administrative expenses primarily due to a \$198.5 million litigation-related loss contingency accrual expense, and an \$83.1 million impairment charge related to the technology platform obtained in our 2012 acquisition of Avila.

The \$397.9 million decrease in net income to \$1.602 billion in 2015 compared to 2014 was primarily due to higher research and development collaboration related expenses, which included upfront expenses of \$575.1 million, \$450.0 million, and \$149.8 million for our collaborations with Juno, AstraZeneca and Nurix, respectively, as well as \$400.4 million of expenses associated with the acquisition and operations of Receptos. The increased collaboration and acquisition related expenses in 2015 were partly offset by higher net product sales as well as an \$85.9 million realized gain on the sale of our equity investment in Flexus Biosciences, Inc. in April 2015. The \$0.45 decrease in diluted earnings per share in 2015 compared to 2014 was favorably impacted by the repurchase of 28.1 million common shares under our common share repurchase program, reducing our outstanding share base.

#### Liquidity and Capital Resources

The following table summarizes the components of our financial condition for the years ended December 31, 2016, 2015 and 2014 (in millions):

				Increase (	Decrease)
				2016	2015
	2016	2015	2014	versus	versus
				2015	2014
Financial assets:					
Cash and cash equivalents	\$6,169.9	\$4,880.3	\$4,121.6	\$1,289.6	\$758.7
Marketable securities available-for-sale	1,799.8	1,671.6	3,425.1	128.2	(1,753.5)
Total financial assets	\$7,969.7	\$6,551.9	\$7,546.7	\$1,417.8	\$(994.8)
Debt:					
Short-term borrowings and current portion of long-term debt	\$500.7	<b>\$</b> —	\$605.9	\$500.7	\$(605.9)
Long-term debt, net of discount	13,788.5	14,161.4	6,216.8	(372.9)	7,944.6
Total debt	\$14,289.2	\$14,161.4	\$6,822.7	\$127.8	\$7,338.7
Working capital <sup>1</sup>	\$7,963.4	\$7,492.6	\$7,617.2	\$470.8	\$(124.6)

Includes cash, cash equivalents and marketable securities available-for-sale, accounts receivable, net of allowances, 1 inventory and other current assets, less short-term borrowings and current portion of long-term debt, accounts payable, accrued expenses and other current liabilities, and income taxes payable.

We rely primarily on positive cash flows from operating activities, proceeds from sales of available-for-sale marketable securities and borrowings in the form of long-term notes payable and short-term commercial paper to provide for our liquidity requirements. We expect continued growth in our expenditures, particularly those related to research and development, clinical trials, commercialization of new products, international expansion and capital investments. However, we anticipate that existing cash and cash equivalent balances, marketable securities available-for-sale, cash generated from operations and existing sources of and access to financing are adequate to fund our operating needs, capital expenditures, debt service requirements and our plans to purchase our stock and pursue strategic business initiatives for the foreseeable future.

Many of our operations are conducted outside the United States and significant portions of our cash, cash equivalents and short-term investments are held internationally. As of December 31, 2016, we held approximately \$6.113 billion of these short-term funds in foreign tax jurisdictions. The amount of funds held in U.S. tax jurisdictions can fluctuate due to the timing of receipts and payments in the ordinary course of business, including intercompany transactions, as well as for other reasons, such as repurchases of our common stock, internal reorganizations, business-development activities and debt issuances. As part of our ongoing liquidity assessments, we regularly monitor the mix of domestic and international cash flows (both inflows and outflows). Repatriation of overseas funds can result in additional U.S. federal, state and local income tax payments. We record U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be permanently reinvested outside of the United States, no accrual for U.S. taxes is provided. Approximately \$900.0 million of our foreign earnings, included in the \$6.113 billion of short-term funds in foreign tax jurisdictions, may not be required for use in offshore operations and may be available

for use in the United States. These earnings are not treated as permanently reinvested and accordingly, our deferred tax liabilities as of December 31, 2016 and December 31, 2015 included \$316.5 million for the estimated U.S. federal and state income taxes that may be incurred should these earnings be repatriated. The remaining foreign earnings are unremitted and expected to be permanently reinvested outside the United States. We do not rely on these earnings as a source of funds for our domestic business as we expect to have sufficient current cash resources combined with future cash flows in the United States to fund our U.S. operational and strategic needs.

Share Repurchase Program: In June 2016, our Board of Directors approved an increase of \$3.000 billion to our authorized share repurchase program, bringing the total amount authorized since April 2009 to an aggregate of up to \$20.500 billion of our common stock of which we have approximately \$4.731 billion remaining for future share repurchases. During 2016, we used \$2.160 billion for repurchases of our common stock, measured on a settlement date basis.

#### Components of Working Capital

Cash, Cash Equivalents and Marketable Securities Available for Sale: We invest our excess cash primarily in money market funds, repurchase agreements, time deposits, U.S. Treasury securities, U.S. government-sponsored agency mortgage-backed securities (MBS), global corporate debt securities and asset backed securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as marketable securities available-for-sale. The \$1.418 billion increase in cash, cash equivalents and marketable securities available for sale at December 31, 2016 compared to 2015 was primarily due to \$3.976 billion of net cash from operating activities, partially offset by \$2.160 billion of payments under our share repurchase program and \$562.5 million of net unrealized holding losses on marketable securities available-for-sale.

Marketable securities available-for-sale are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other than temporary impairment charges, is included in interest and investment income, net. For more information related to the fair value and valuation of our marketable securities, see Note 4 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Accounts Receivable, Net: Accounts receivable, net increased by \$199.7 million to \$1.621 billion at December 31, 2016 compared to December 31, 2015. Sales made outside the United States typically have payment terms that are greater than 60 days, thereby extending collection periods beyond those in the United States. We expect our accounts receivable balance to grow as our international sales continue to expand.

We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt situation in certain European countries and associated impacts on the financial markets and our business. Our current business model in these markets is typically to sell our products directly to principally government owned or controlled hospitals, which in turn directly deliver critical care to patients. Our products are used to treat life-threatening diseases and we believe this business model enables timely delivery and adequate supply of products. Many of the outstanding receivable balances are related to government-funded hospitals and we believe the receivable balances are ultimately collectible. Similarly, we believe that future sales to these customers will continue to be collectible.

Inventory: Inventory balances increased by \$54.5 million to \$497.9 million at the end of 2016 compared to 2015. The increase was primarily due to an increase in ABRAXANE® raw materials.

Other Current Assets: Other current assets decreased by \$205.4 million to \$779.3 million at the end of 2016 compared to 2015 due to a \$47.7 million decrease in the fair value of derivative instruments recorded as Other current assets, a \$115.5 million decrease in prepaid taxes and a \$42.2 million net decrease in other accounts.

Commercial Paper: We have a commercial paper program (Program) under which we issue unsecured commercial paper notes (Commercial Paper) on a private placement basis, the proceeds of which are used for general corporate

purposes. In April 2016 our Board of Directors authorized an increase in the maximum amount of commercial paper issuable to \$2.000 billion. As of December 31, 2016, we had available capacity to issue up to \$2.000 billion of Commercial Paper and there were no borrowings under the Program. The maturities of the Commercial Paper may vary, but may not exceed 270 days from the date of issue. The Commercial Paper is sold under customary terms to a dealer or in the commercial paper market and is issued at a discount from par or, alternatively, is sold at par and bears varying interest rates on a fixed or floating basis. Borrowings under the Program, if any, are accounted for as short-term borrowings.

Senior Unsecured Credit Facility: We maintain a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit in the aggregate amount of \$2.000 billion which was increased from \$1.750 billion in April 2016 and extended from April 17, 2020 to April 17, 2021. Amounts may be borrowed in U.S. Dollars for general corporate purposes. The Credit Facility currently serves as backup liquidity for our Commercial Paper borrowings. At December 31, 2016, there was no outstanding borrowing against the Credit Facility.

The Credit Facility contains affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of December 31, 2016.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities increased by \$473.6 million to \$2.362 billion at the end of 2016 compared to 2015. The increase was primarily due to increases of \$194.5 million for sales adjustment accruals, \$198.5 million for a litigation-related loss contingency accrual, \$86.7 million for clinical trial and research and development expense accruals and \$60.4 million for compensation-related accruals and \$99.5 million of net other increases. These increases were partially offset by decreases of \$103.5 million related to collaboration agreement accruals and \$62.5 million of contingent consideration related accruals.

Income Taxes Payable (Current and Non-Current): Income taxes payable increased by \$117.6 million to \$461.6 million at the end of 2016 compared to 2015, primarily from the current provision for income taxes of \$717.3 million and net deferred intercompany credits of \$21.9 million, offset by income tax payments of \$373.0 million, tax benefits of share-based compensation of \$186.2 million and a decrease in refundable income taxes of \$65.6 million.

Senior Notes: We have an aggregate of \$14.250 billion principal amount of senior notes outstanding with varying maturity dates from 2017 through 2045, with \$500.0 million maturing in August 2017.

Cash flows from operating, investing and financing activities for the years ended December 31, 2016, 2015 and 2014 were as follows (in millions):

				Increase (Decrease)	
				2016	2015
	2016	2015	2014	versus	versus
				2015	2014
Net cash provided by operating activities	\$3,976.3	\$2,483.9	\$2,806.3	\$1,492.4	\$(322.4)
Net cash used in investing activities	\$(1,002.2)	\$(6,259.0)	\$(1,438.0)	\$5,256.8	\$(4,821.0)
Net cash (used in) provided by financing activities	\$(1,645.6)	\$4,584.5	\$(417.4)	\$(6,230.1)	\$5,001.9

Operating Activities: Net cash provided by operating activities increased by \$1.492 billion to \$3.976 billion in 2016 compared to 2015. The increase in net cash provided by operating activities was primarily attributable to an increase in net income of \$397.2 million in 2016 compared to 2015, which included a \$493.5 million net increase in adjustments to reconcile net income to net cash provided by operating activities for items such as impairment charges, derivative activities, changes in deferred income taxes and amortization expenses compared to 2015. Derivative activities during 2016 included cash receipts of \$195.6 million related to the settlement of interest rate swap contracts that had been designated as fair value hedges of certain of our fixed rate notes. Increases in net cash provided by operating activities were also driven by a \$420.4 million increase in change in other operating assets primarily attributable to a \$297.6 million decrease in prepaid taxes and a \$91.9 million increase in change in accounts payable and other operating liabilities primarily attributable to an increase of \$198.5 million of accrued expenses related to a litigation-related loss contingency accrual as well as other balance sheet fluctuations.

Net cash provided by operating activities decreased by \$322.4 million to \$2.484 billion in 2015 compared to 2014 primarily attributable to a decrease in net income of \$397.9 million in 2015 compared to 2014 driven by increased research and development collaboration related expenses.

Investing Activities: Net cash used in investing activities decreased by \$5.257 billion in 2016 compared to 2015. The decrease in net cash used in investing activities was primarily the result of the purchases of Receptos and Quanticel in 2015 without a corresponding purchase in 2016, resulting in a cash usage of \$7.695 billion during 2015, partially offset by a decrease in cash provided by net purchases and sales of marketable securities available for sale. Net

purchases of marketable securities available for sale during 2016 amounted to a net cash usage of \$647.7 million during 2016 compared to net cash proceeds of \$1.910 billion from net sales of marketable securities available for sale during 2015.

Net cash used in investing activities increased by \$4.821 billion in 2015 compared to 2014. The increase in net cash used in investing activities was primarily due to \$7.695 billion of payments for the acquisitions of Receptos and Quanticel, net of cash acquired. This was partially offset by net proceeds of \$1.910 billion from net sales of marketable securities available-for-sale during 2015 compared with \$485.5 million of net purchases of marketable securities available-for-sale during 2014. In addition, \$710.0 million was used for the acquisition of Nogra in 2014.

Financing Activities: Net cash used in financing activities was \$1.646 billion in 2016 compared to net cash provided by financing activities of \$4.585 billion in 2015. The decrease in net cash provided by financing activities was primarily attributable to the 2015 issuance of long-term debt which provided \$7.913 billion.

Net cash provided by financing activities increased by \$5.002 billion in 2015 compared to 2014. The increase in net cash provided by financing activities was primarily attributable to the \$5.443 billion increase in proceeds from the issuance of long-term debt partially offset by the \$513.9 million re-payment of long-term debt.

#### **Contractual Obligations**

The following table sets forth our contractual obligations as of December 31, 2016 (in millions):

	Payment Due By Period				
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
Senior notes <sup>1</sup>	\$1,024.7	\$2,900.0	\$2,884.1	\$14,666.7	\$21,475.5
Operating leases	55.4	74.4	48.4	35.2	213.4
Other contract commitments	172.9	65.3	_	_	238.2
Total	\$1,253.0	\$3,039.7	\$2,932.5	\$14,701.9	\$21,927.1

<sup>1</sup> The senior note obligation amounts include future principal and interest payments for both current and non-current obligations.

Senior Notes: In August 2015, we issued an additional \$8.000 billion principal amount of senior notes consisting of \$1.000 billion aggregate principal amount of 2.125% Senior Notes due 2018, \$1.500 billion aggregate principal amount of 2.875% Senior Notes due 2020, \$1.000 billion aggregate principal amount of 3.550% Senior Notes due 2022, \$2.500 billion aggregate principal amount of 3.875% Senior Notes due 2025 and \$2.000 billion aggregate principal amount of 5.000% Senior Notes due 2045.

In May 2014, we issued a total of \$2.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.250% Senior Notes due 2019, \$1.000 billion aggregate principal amount of 3.625% Senior Notes due 2024 and \$1.000 billion aggregate principal amount of 4.625% Senior Notes due 2044.

In August 2013, we issued a total of \$1.500 billion principal amount of senior notes consisting of \$400.0 million aggregate principal amount of 2.300% Senior Notes due 2018, \$700.0 million aggregate principal amount of 4.000% Senior Notes due 2023 and \$400.0 million aggregate principal amount of 5.250% Senior Notes due 2043.

In August 2012, we issued a total of \$1.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017, and \$1.000 billion aggregate principal amount of 3.25% Senior Notes due 2022.

In October 2010, we issued a total of \$1.250 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.45% Senior Notes which matured and were repaid in 2015, \$500.0 million aggregate principal amount of 3.95% Senior Notes due 2020 and \$250.0 million aggregate principal amount of 5.7% Senior Notes due 2040.

Operating Leases: We lease office and research facilities under various operating lease agreements in the United States and various international markets. The non-cancelable lease terms for operating leases expire at various dates between 2017 and 2025 and include renewal options. In general, we are also required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs associated with the leases. For more information on the major facilities that we occupy under lease arrangements refer to Part I, Item 2. "Properties" of this

#### Annual Report on Form 10-K.

Other Contract Commitments: Other contract commitments of \$238.2 million as of December 31, 2016 primarily included \$172.2 million in contractual obligations related to product supply contracts. In addition, we have committed to invest an aggregate \$66.0 million in investment funds, which are callable at any time.

Collaboration Arrangements and Acquired Research and Development Assets: We have entered into certain research and development collaboration agreements with third parties and have acquired research and development assets from third parties with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature of these arrangements, the future potential payments related to the attainment of specified development, regulatory approval and sales-based milestones

over a period of several years are inherently uncertain, and accordingly, no amounts have been recorded for these future potential payments in our Consolidated Balance Sheets at December 31, 2016 and 2015 contained in this Annual Report on Form 10-K. Potential milestone payments (not including potential royalty payments) total approximately \$8.568 billion, including approximately \$4.006 billion contingent on the achievement of various research, development and regulatory approval milestones and approximately \$4.562 billion in sales-based milestones. For additional information about our collaboration arrangements and acquisitions of research and development assets, see Note 17 and Note 2, respectively, of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

#### New Accounting Standards

For a discussion of new accounting standards please see Note 1 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Critical Accounting Estimates and Significant Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 1 of Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K, we believe the following accounting estimates and policies to be critical:

Revenue Recognition: Revenue from the sale of products is recognized when title and risk of loss of the product is transferred to the customer and the sales price is fixed and determinable. Provisions for discounts, early payments, rebates, sales returns and distributor chargebacks under terms customary in the industry are provided for in the same period the related sales are recorded. We record estimated reductions to revenue for volume-based discounts and rebates at the time of the initial sale. The estimated reductions to revenue for such volume-based discounts and rebates are based on the sales terms, historical experience and trend analysis.

We recognize revenue from royalties based on licensees' sales of our products or products using our technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

Gross to Net Sales Accruals: We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance. REVLIMID®, POMALYST®/IMNOVID® and THALOMID®/Thalidomide Celgene® are distributed primarily through hospitals and contracted pharmacies, which are typically subject to tighter controls of inventory quantities within the supply channel and, thus, resulting in lower returns activity.

Sales discount accruals are based on payment terms extended to customers.

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We also analyze actual billings received from the states to further support the accrual rates. We will continue to adjust the rebate accruals as more information becomes available and to reflect actual claims experience.

Manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products as well as the historical invoices. This expense is recognized throughout the year as costs are incurred. In certain international markets government-

sponsored programs require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from the date of sale. We record a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are included in chargeback accruals and are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

Allowance for Doubtful Accounts: We estimate an allowance for doubtful accounts primarily based on the credit worthiness of our customers, historical payment patterns, aging of receivable balances and general economic conditions, including publicly available information on the credit worthiness of countries themselves and provinces or areas within such countries where they are the ultimate customers.

Income Taxes: We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized.

We account for interest and penalties related to uncertain tax positions as part of our provision for income taxes. These unrecognized tax benefits relate primarily to issues common among multinational corporations in our industry. We apply a variety of methodologies in making these estimates which include studies performed by independent economists, advice from industry and subject experts, evaluation of public actions taken by the U.S. Internal Revenue Service and other taxing authorities, as well as our own industry experience. We provide estimates for unrecognized tax benefits. If our estimates are not representative of actual outcomes, our results of operations could be materially impacted.

We periodically evaluate the likelihood of the realization of deferred tax assets, and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of deferred tax assets, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and, to the extent future expectations change, we would have to assess the recoverability of our deferred tax assets at that time. At December 31, 2016, it was more likely than not that we would realize our deferred tax assets, net of valuation allowances.

Share-Based Compensation: We utilize share based compensation in the form of stock options, restricted stock units, or RSUs, and performance-based restricted stock units, or PSUs. Compensation expense is recognized in the Consolidated Statements of Income based on the estimated fair value of the awards at grant date. Compensation

expense recognized reflects an estimate of the number of awards expected to vest after taking into consideration an estimate of award forfeitures based on actual experience and is recognized on a straight-line basis over the requisite service period, which is generally the vesting period required to obtain full vesting. Management expectations related to the achievement of performance goals associated with PSU grants is assessed regularly and that assessment is used to determine whether PSU grants are expected to vest. If performance-based milestones related to PSU grants are not met or not expected to be met, any compensation expense recognized to date associated with grants that are not expected to vest will be reversed.

Other-Than-Temporary Impairments of Available-For-Sale Marketable Securities: A decline in the market value of any available-for-sale marketable security below its cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires significant judgment and requires consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Factors evaluated to determine whether the investment is other-than-temporarily impaired include: significant deterioration in the issuer's earnings performance, credit rating, asset quality, business prospects of the issuer, adverse changes in the general market conditions in which the issuer operates, length of time that the fair value has been below our cost, our expected future cash flows from the

security, our intent not to sell, an evaluation as to whether it is more likely than not that we will not have to sell before recovery of our cost basis, and issues that raise concerns about the issuer's ability to continue as a going concern. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment.

Derivatives and Hedging Activities: All derivative instruments are recognized on the balance sheet at their fair value. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, we formally document the nature and relationships between the hedging instruments and hedged item. We assess, both at inception and on an on-going basis, whether the derivative instruments that are used in cash flow hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. We assess hedge effectiveness on a quarterly basis and record the gain or loss related to the ineffective portion of derivative instruments, if any, to current earnings. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings. We use derivative instruments, including those not designated as part of a hedging transaction, to manage our exposure to movements in foreign exchange, our stock price and interest rates. The use of these derivative instruments modifies the exposure of these risks with the intent to reduce our risk or cost.

Investments in Other Entities: We hold a portfolio of investments in equity securities and certain investment funds that are accounted for under either the equity method or cost method. Investments in companies or certain investment funds over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other income (expense), net. Investments in equity securities of companies that become publicly traded are accounted for as available-for-sale marketable securities prospectively from the date of such companies' initial public offering.

Our cost method and equity method investments are included in other assets on the Consolidated Balance Sheets.

All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value and the decline is determined to be other-than-temporary, the investment is written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value has occurred include: market value or exit price of the investment based on either market-quoted prices or future rounds of financing by the investee; length of time that the market value was below its cost basis; financial condition and business prospects of the investee; our intent and ability to retain the investment for a sufficient period of time to allow for recovery in market value of the investment; issues that raise concerns about the investee's ability to continue as a going concern; any other information that we may be aware of related to the investment.

Accounting for Long-Term Incentive Plans: We have established a Long-Term Incentive Plan, or LTIP, designed to provide key officers and executives with performance-based incentive opportunities contingent upon achievement of pre-established corporate performance objectives covering a three-year period. At December 31, 2016, we had recorded liabilities for three separate three-year performance cycles running concurrently and ending December 31, 2016, 2017 and 2018. Performance measures for each of the performance cycles are based on the following components: 37.5% on non-GAAP earnings per share (as defined in the LTIP); 37.5% on total non-GAAP revenue (as defined in the LTIP); and 25% on relative total shareholder return, which is a measurement of our stock price performance during the applicable three-year period compared with a group of other companies in the biopharmaceutical industry.

Threshold, target and maximum cash payout levels are calculated as a percentage between 0% to 200% of each participant's base salary at the time the LTIP was approved by the Compensation Committee. Such awards are payable in cash or common stock or a mixture of cash and common stock, which will be determined by the Compensation Committee at the time of award delivery. Share-based payout levels are calculated using the cash-based threshold, target and maximum levels, divided by the average closing price of Celgene stock for the 30 trading days prior to the commencement of each performance cycle. Therefore, final share-based award values are reflective of the stock price at the end of the measurement period. The Compensation Committee may determine that payments made in common stock are restricted from trading for a period of time. We accrue the long-term incentive liability over each three-year cycle. Prior to the end of a three-year cycle, the accrual is based on an estimate of our level of achievement during the cycle. Upon a change in control, participants will be entitled to an immediate payment equal to their target award or, if higher, an award based on actual performance through the date of the change in control.

Accruals recorded for the LTIP entail making certain assumptions concerning future non-GAAP earnings per share, non-GAAP revenues and relative total shareholder return, as defined; the actual results of which could be materially different than the assumptions used. Accruals for the LTIP are reviewed on a regular basis and revised accordingly so that the liability recorded reflects updated estimates of future payouts. In estimating the accruals, management considers actual results to date for the

performance period, expected results for the remainder of the performance period, operating trends, product development, pricing and competition.

Valuation of Goodwill, Acquired Intangible Assets, Other Assets and In-Process Research and Development (IPR&D): We have recorded goodwill, acquired intangible assets and IPR&D through acquisitions accounted for as business combinations. When identifiable intangible assets, including in-process research and development and technology platforms are acquired, we determine the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations if quoted market prices are not available, and the models require the use of significant estimates and assumptions including but not limited to:

#### projecting regulatory approvals;

estimating future cash flows from product sales resulting from completed products and in-process projects or estimating future cash flows expected to be collected; and developing appropriate discount rates and probability rates.

Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination accounted for by the acquisition method of accounting and is not amortized, but is subject to impairment testing. We test our goodwill for impairment at least annually or when a triggering event occurs that could indicate a potential impairment by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that the fair value of net assets are below their carrying amounts.

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur. Intangible assets related to IPR&D product rights are treated as indefinite-lived intangible assets and not amortized until the product is approved for sale by regulatory authorities in specified markets. At that time, we will determine the useful life of the asset, reclassify the asset out of IPR&D and begin amortization. Impairment testing is also performed at least annually or when a triggering event occurs that could indicate a potential impairment. Such test entails completing an updated discounted cash flow model to estimate the fair value of the IPR&D asset. If required, the impairment test for intangible assets with definite useful lives is completed by comparing an updated non-discounted cash flow model to the book value of the intangible asset.

Valuation of Contingent Consideration Resulting from a Business Combination: We record contingent consideration resulting from a business combination at its fair value on the acquisition date, and for each subsequent reporting period revalue these obligations and record increases or decreases in their fair value as an adjustment to operating earnings in the consolidated statements of income. Changes to contingent consideration obligations can result from movements in publicly traded share prices of CVRs, adjustments to discount rates and periods, updates in the assumed achievement or timing of any development milestones or changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval. The assumptions related to determining the value of a contingent consideration include a significant amount of judgment and any changes in the assumptions could have a material impact on the amount of contingent consideration expense recorded in any given period. Our contingent consideration liabilities were recorded in the acquisitions of Gloucester, Abraxis, Avila, Nogra, and Quanticel. The fair values of the Gloucester, Avila, Nogra, and Quanticel contingent consideration liabilities are based on the discount rate, probability and estimated timing of cash milestone payments to the former shareholders of each business. The fair value of the Abraxis contingent consideration liability is based on the quoted market price of the publicly traded CVRs.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion provides forward-looking quantitative and qualitative information about our potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings.

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. At December 31, 2016, our market risk sensitive instruments consisted of marketable securities available-for-sale, our long-term debt and certain derivative contracts.

Marketable Securities Available-for-Sale: At December 31, 2016, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency mortgage-backed (MBS) securities, global corporate debt securities, asset backed securities, time deposits with original maturities of greater than three months and marketable equity securities. U.S. government-sponsored agency MBS include mortgage backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Corporate debt – global includes obligations issued by investment-grade corporations including some issues that have been guaranteed by governments and government agencies. Asset backed securities consist of triple-A rated securities with cash flows collateralized by credit card receivables and auto loans.

Our marketable securities available for sale are primarily equity investments in the publicly traded common stock of companies, including common stock of companies with whom we have entered into collaboration agreements. In addition, we invest in debt securities that are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other than temporary impairment charges related to debt securities, is included in Interest and investment income, net. Realized gains and losses and other than temporary impairment charges related to equity securities are included in Other income (expense), net.

As of December 31, 2016, the principal amounts, fair values and related weighted-average interest rates of our investments in debt securities, excluding time deposits, classified as marketable securities available-for-sale were as follows (dollar amounts in millions):

	Duration			
	Less than	1 to 3	3 to 5	Total
	1 Year	Years	Years	Total
Principal amount	\$218.5	\$314.0	\$10.6	\$543.1
Fair value	\$219.1	\$314.9	\$10.7	\$544.7
Weighted average interest rate	1.3 %	1.6 %	2.6 %	1.5 %

#### **Debt Obligations**

Short-Term Borrowings and Current Portion of Long-Term Debt: We had no outstanding short-term borrowing as of December 31, 2016 or December 31, 2015. The carrying value of the current portion of long-term debt outstanding at December 31, 2016 and December 31, 2015 includes (in millions):

Long-Term Debt: Our outstanding senior notes with maturity dates in excess of one year after December 31, 2016 have an aggregate principal amount of \$13.750 billion with varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of December 31, 2016 are summarized below (in millions):

	Principal	Carrying
	Amount	Value
2.125% senior notes due 2018	\$1,000.0	\$997.9
2.300% senior notes due 2018	400.0	401.9
2.250% senior notes due 2019	500.0	509.3
2.875% senior notes due 2020	1,500.0	1,492.7
3.950% senior notes due 2020	500.0	518.5
3.250% senior notes due 2022	1,000.0	1,053.5
3.550% senior notes due 2022	1,000.0	993.5
4.000% senior notes due 2023	700.0	743.5
3.625% senior notes due 2024	1,000.0	1,001.0
3.875% senior notes due 2025	2,500.0	2,475.3
5.700% senior notes due 2040	250.0	247.2
5.250% senior notes due 2043	400.0	392.9
4.625% senior notes due 2044	1,000.0	986.9
5.000% senior notes due 2045	2,000.0	1,974.4
Total long-term debt	\$13,750.0	\$13,788.5

At December 31, 2016, the fair value of our senior notes outstanding was \$14.572 billion.

#### MARKET RISK MANAGEMENT

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We actively manage the impact of foreign exchange rate and interest rate movements through operational means and through the use of various financial instruments, including derivative instruments such as foreign currency option contracts, foreign currency forward contracts, treasury rate lock agreements and interest rate swap contracts. In instances where these financial instruments are accounted for as cash flow hedges or fair value hedges we may from time to time terminate the hedging relationship. If a hedging relationship is terminated we generally either settle the instrument or enter into an offsetting instrument.

#### Foreign Currency Risk Management

We maintain a foreign exchange exposure management program to mitigate the impact of volatility in foreign exchange rates on future foreign currency cash flows, translation of foreign earnings and changes in the fair value of assets and liabilities denominated in foreign currencies.

Through our revenue hedging program, we endeavor to reduce the impact of possible unfavorable changes in foreign exchange rates on our future U.S. Dollar cash flows that are derived from foreign currency denominated sales. To achieve this objective, we hedge a portion of our forecasted foreign currency denominated sales that are expected to occur in the foreseeable future, typically within the next three years, with a maximum of five years. We manage our anticipated transaction exposure principally with foreign currency forward contracts, a combination of foreign currency put and call options, and occasionally purchased foreign currency put options.

Foreign Currency Forward Contracts: We use foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies, manage exchange rate volatility in the translation of foreign earnings,

and reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies.

We manage a portfolio of foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at December 31, 2016

and December 31, 2015 had settlement dates within 31 months and 36 months, respectively. The spot rate components of these foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses are reported in other comprehensive income (OCI) and reclassified to operations in the same periods during which the underlying hedged transactions affect earnings. If a hedging relationship is terminated with respect to a foreign currency forward contract, accumulated gains or losses associated with the contract remain in OCI until the hedged forecasted transaction occurs and are reclassified to operations in the same periods during which the underlying hedged transaction affects earnings. Any ineffectiveness on these foreign currency forward contracts is reported on the Consolidated Statements of Income in Other income (expense), net. The forward point components of these foreign currency forward contracts are not designated as cash flow hedges and all fair value adjustments of forward point amounts are recorded to other income (expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at December 31, 2016 and December 31, 2015 (in millions):

	Notional	Amount
Foreign Currency:	2016	2015
Australian Dollar	\$48.7	\$45.1
British Pound	199.0	289.3
Canadian Dollar	192.5	135.9
Euro	1,811.9	2,934.3
Japanese Yen	597.4	510.4
Total	\$2,849.5	\$3,915.0

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of December 31, 2016, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also manage a portfolio of foreign currency contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies and, from time to time, we enter into foreign currency contracts to manage exposure related to translation of foreign earnings. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in Other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at December 31, 2016 and December 31, 2015 were \$933.8 million and \$920.0 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the December 31, 2016 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$336.8 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in OCI and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability.

Foreign Currency Option Contracts: From time to time, we may hedge a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales denominated in that local currency. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and local currency notional amounts but with different strike prices. This combination of transactions is generally referred to as a "collar." The expiration dates and notional amounts correspond to the amount and timing of forecasted foreign currency sales. The foreign currency option contracts outstanding at December 31, 2016 and December 31, 2015 had

settlement dates within 48 months and 36 months, respectively. If the U.S. Dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. Dollar equivalent value of our anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call, which forms the upper end of the collar. The premium collected from the sale of the call option is equal to the premium paid for the purchased put option, resulting in a net zero cost for each collar.

Outstanding foreign currency option contracts entered into to hedge forecasted revenue were as follows at December 31, 2016 and December 31, 2015:

Notional Amount<sup>1</sup> 2016 2015

Foreign currency option contracts designated as hedging activity:

Purchased Put \$1,790.1 \$641.5 Written Call \$2,009.4 \$690.0

We also have entered into foreign currency put option contracts to hedge forecasted revenue which were not part of a collar strategy. Such put option contracts had a notional value of \$386.8 million at December 31, 2016 and settlement dates within 24 months.

Assuming that the December 31, 2016 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts would increase by approximately \$153.4 million if the U.S. Dollar were to strengthen and decrease by approximately \$139.0 million if the U.S. Dollar were to weaken. However, since the contracts hedge specific forecasted intercompany transactions denominated in foreign currencies, any change in the fair value of the contract would be reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings.

#### Interest Rate Risk Management

Forward Starting Interest Rate Swaps and Treasury Rate Locks: In anticipation of issuing fixed-rate debt, we may use forward starting interest rate swaps (forward starting swaps) or treasury rate lock agreements (treasury rate locks) that are designated as cash flow hedges to hedge against changes in interest rates that could impact expected future issuances of debt. To the extent these hedges of cash flows related to anticipated debt are effective, any realized or unrealized gains or losses on the forward starting swaps or treasury rate locks are reported in OCI and are recognized in income over the life of the anticipated fixed-rate notes.

During 2014, we entered into forward starting swaps that were designated as cash flow hedges to hedge against changes in interest rates that could impact an anticipated issuance of debt in 2015. During 2015, we entered into additional forward starting swaps and treasury rate locks. Forward starting swaps and treasury rate locks with a combined aggregate notional amount of \$2.900 billion were settled upon the issuance of debt in August 2015, when the net fair value of the forward starting swaps and treasury rate locks in accumulated OCI was in a loss position of \$21.6 million. The net loss will be recognized as interest expense over the life of the associated senior notes. At December 31, 2016 and December 31, 2015, we had outstanding forward starting swaps with effective dates in 2017 and 2018 and maturing in ten years that were designated as cash flow hedges with notional amounts as shown in the table below:

Notional Amount December 31, December 2016 31, 2015

Forward starting interest rate swap contracts:

Forward starting swaps with effective dates in 2017 \$500.0 \$ 200.0 Forward starting swaps with effective dates in 2018 \$500.0 \$ —

A sensitivity analysis to measure potential changes in the market value of our forward starting interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates at December

<sup>&</sup>lt;sup>1</sup> U.S. dollar notional amounts are calculated as the hedged local currency amount multiplied by the strike value of the foreign currency option. The local currency notional amounts of our purchased put and written call that are designated as hedging activities are equal to each other.

31, 2016 would have increased the fair value of our contracts by \$80.2 million. A one percentage point decrease at December 31, 2016 would have decreased the aggregate fair value of our contracts by \$90.4 million.

Interest Rate Swap Contracts: From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in interest rates. Since the specific terms and notional amount of the swap are intended to match those of the debt being hedged, it is assumed to be a highly effective hedge and all changes in fair value of the swap are recorded on the Consolidated Balance Sheets with no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense. If a hedging relationship is terminated for an interest rate swap contract, accumulated gains or losses associated with the contract are measured and recorded as a reduction or increase of current and future interest expense associated with the previously hedged debt obligations.

We had entered into swap contracts that were designated as hedges of certain of our fixed rate notes and also terminated the hedging relationship by settling certain of those swap contracts during 2016 and 2015. In July 2016, we terminated the hedging relationship on all of our then outstanding swap contracts, amounting to \$3.600 billion notional amount, by settling such swap contracts. The settlement of swap contracts resulted in the receipt of net proceeds of \$195.6 million and \$10.8 million during the years ended December 31, 2016 and 2015, respectively, which are accounted for as a reduction of current and future interest expense associated with these notes. See Note 11 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to reductions of current and future interest expense.

A sensitivity analysis to measure potential changes in the market value of our debt and interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2016 would have reduced the aggregate fair value of our net payable by \$992.5 million. A one percentage point decrease at December 31, 2016 would have increased the aggregate fair value of our net payable by \$1.151 billion.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA CELGENE CORPORATION AND SUBSIDIARIES INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Celgene Corporation:

We have audited the accompanying consolidated balance sheets of Celgene Corporation and subsidiaries (the Company) as of December 31, 2016 and 2015, and the related consolidated statements of income, comprehensive income, cash flows, and stockholders' equity for each of the years in the three-year period ended December 31, 2016. In connection with our audits of the consolidated financial statements, we also have audited the consolidated financial statement schedule, "Schedule II – Valuation and Qualifying Accounts." These consolidated financial statements and consolidated financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and consolidated financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Celgene Corporation and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 and our report dated February 10, 2017 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP Short Hills, New Jersey February 10, 2017

# CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

(Dollars in millions, except per share amounts)

(2 onus in minors, crospoper sinus unisums)	December 2016	31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$6,169.9	\$4,880.3
Marketable securities available-for-sale	1,799.8	1,671.6
Accounts receivable, net of allowances of \$30.9 and \$30.3 at December 31, 2016 and 2015,	1,620.6	1,420.9
respectively	407.0	4.42.4
Inventory	497.9	443.4
Other current assets	779.3	984.7
Total current assets	10,867.5	9,400.9
Property, plant and equipment, net	929.8	814.1
Intangible assets, net	10,391.8	10,858.1
Goodwill	4,865.8	4,879.0
Other assets	1,030.7	1,012.3
Total assets	\$28,085.6	\$26,964.4
Liabilities and Stockholders' Equity		
Current liabilities:	<b></b>	
Short-term borrowings and current portion of long-term debt	\$500.7	\$— •
Accounts payable	247.1	240.8
Accrued expenses and other current liabilities	2,115.0	1,647.7
Income taxes payable	41.3	19.8
Current portion of deferred revenue	55.1	60.6
Total current liabilities	2,959.2	1,968.9
Deferred revenue, net of current portion	27.9	30.0
Income taxes payable	420.3	324.2
Other non-current tax liabilities	2,519.2	2,519.2
Other non-current liabilities	1,771.2	2,041.7
Long-term debt, net of discount	13,788.5	14,161.4
Total liabilities	21,486.3	21,045.4
Commitments and Contingencies (Note 18)		
Stockholders' Equity:		
Preferred stock, \$.01 par value per share, 5.0 million shares authorized; none outstanding at		_
December 31, 2016 and 2015, respectively		
Common stock, \$.01 par value per share, 1,150.0 million shares authorized; issued 954.1	9.5	9.4
million and 940.1 million shares at December 31, 2016 and 2015, respectively	- 12	
Common stock in treasury, at cost; 175.5 million and 153.5 million shares at December 31,	(16.281.1)	(14,051.8)
2016 and 2015, respectively		, ,
Additional paid-in capital	12,378.2	11,119.3
Retained earnings	10,073.6	8,074.4
Accumulated other comprehensive income	419.1	767.7
Total stockholders' equity	6,599.3	5,919.0
Total liabilities and stockholders' equity	\$28,085.6	\$26,964.4
See accompanying Notes to Consolidated Financial Statements		

# CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF INCOME

(In millions, except per share amounts)

	Years Ended December 31,			
	2016	2014		
Revenue:				
Net product sales	\$11,184.6	\$9,161.1	\$7,563.8	
Other revenue	44.6	94.9	106.6	
Total revenue	11,229.2	9,256.0	7,670.4	
Expenses:				
Cost of goods sold (excluding amortization of acquired intangible assets)	438.0	420.1	385.9	
Research and development	4,470.1	3,697.3	2,430.6	
Selling, general and administrative	2,657.7	2,305.4	2,027.9	
Amortization of acquired intangible assets	459.0	279.0	258.3	
Acquisition related charges and restructuring, net	37.8	299.6	48.7	
Total costs and expenses	8,062.6	7,001.4	5,151.4	
Operating income	3,166.6	2,254.6	2,519.0	
Other income and (expense):				
Interest and investment income, net	30.3	31.1	28.2	
Interest (expense)	(500.1	(310.6)	(176.1)	
Other income (expense), net	(324.3	48.4	(43.7)	
Income before income taxes	2,372.5	2,023.5	2,327.4	
Income tax provision	373.3	421.5	327.5	
Net income	\$1,999.2	\$1,602.0	\$1,999.9	
Net income per share:				
Basic	\$2.57	\$2.02	\$2.49	
Diluted	\$2.49	\$1.94	\$2.39	
Weighted average shares:				
Basic	777.2	792.2	802.7	
Diluted	803.3	824.9	836.0	
See accompanying Notes to Consolidated Financial Statements				
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### CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (Dollars in millions)

	Years Ended December 31,		
	2016	2015	2014
Net income	\$1,999.2	\$1,602.0	\$1,999.9
Other comprehensive income (loss):			
Foreign currency translation adjustments	(25.7	(26.1	) (49.8
Pension liability adjustment	(24.0	1.6	(8.6)
Net unrealized gains related to cash flow hedges:			
Unrealized holding gains	145.3	410.5	568.1
Tax (expense) benefit	(13.8	7.2	12.3
Unrealized holding gains, net of tax	131.5	417.7	580.4
Reclassification adjustment for (gains) included in net income	(300.3	(348.7	) (23.1
Tax (benefit)	(2.6	(2.2	) (1.7
Reclassification adjustment for (gains) included in net income, net of tax	(302.9		(24.8)
Net unrealized (losses) gains on marketable securities available for sale:			
Unrealized holding (losses) gains	(562.5	(314.4	) 494.0
Tax benefit (expense)	202.9	109.8	(173.9)
Unrealized holding (losses) gains, net of tax	(359.6	(204.6	320.1
Reclassification adjustment for losses included in net income	357.9	23.4	5.4
Tax (benefit)	(125.8	(8.2	) (1.9
Reclassification adjustment for losses included in net income, net of tax	232.1	15.2	3.5
Total other comprehensive (loss) income	(348.6	(147.1	820.8
Comprehensive income	\$1,650.6	\$1,454.9	\$2,820.7
See accompanying Notes to Consolidated Financial Statements			

# CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in millions)

	Years End	ded Decemb	ber 31,
	2016	2015	2014
Cash flows from operating activities:			
Net income	\$1,999.2	\$1,602.0	\$1,999.9
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	121.1	114.9	104.3
Amortization	383.6	287.1	265.1
Deferred income taxes	(344.0)	(33.4)	(272.3)
Impairment charges	488.6	48.9	133.2
Change in value of contingent consideration	21.2		48.7
(Gain) on sale of business		· —	
Net (gain) loss on sale of investments	. ,		5.4
Share-based compensation expense	606.2	576.6	447.6
Share-based employee benefit plan expense	40.2	35.1	40.7
Derivative instruments	169.1		(54.1)
Other, net		25.7	(9.3)
Change in current assets and liabilities, excluding the effect of acquisitions:	( )		( )
Accounts receivable	(222.4)	(304.7)	(166.3)
Inventory			(56.5)
Other operating assets	94.2		52.6
Accounts payable and other operating liabilities	618.9	527.0	234.5
Payment of contingent consideration		· —	(14.3)
Income tax payable	111.7	61.2	39.1
Deferred revenue	7.1	37.1	8.0
Net cash provided by operating activities	3,976.3	2,483.9	2,806.3
Cash flows from investing activities:	,	,	,
Proceeds from sales of marketable securities available for sale	632.8	3,799.6	2,175.9
Purchases of marketable securities available for sale	(1,280.5)		(2,661.4)
Payments for acquisition of businesses, net of cash acquired		(7,695.1)	
Capital expenditures	(236.2)	(286.3)	(150.3)
Proceeds from sales of investment securities	14.6	92.0	_
Purchases of investment securities	(132.3)	(272.5)	(67.4)
Other investing activities	(0.6)	(7.4)	(24.8)
Net cash used in investing activities	(1,002.2)	(6,259.0)	(1,438.0)
Cash flows from financing activities:			
Payment for treasury shares	(2,160.0)	(3,256.8)	(2,975.1)
Proceeds from short-term borrowing	100.3	6,111.5	2,566.9
Principal repayments on short-term borrowing	(100.3)	(6,213.2)	(3,012.2)
Proceeds from the issuance of long-term debt		7,913.3	2,470.6
Repayments of long-term debt		(513.9)	) —
Net proceeds (payments) from common equity put options	7.6	(8.6)	10.3
Payment of contingent consideration	(41.1)		(25.7)
Net proceeds from share-based compensation arrangements	359.1	251.7	297.2
Excess tax benefit from share-based compensation arrangements	188.8	300.5	250.6
Net cash (used in) provided by financing activities	(1,645.6)	4,584.5	(417.4)
Effect of currency rate changes on cash and cash equivalents	(38.9)	(50.7)	(63.7)
· · · · · · · · · · · · · · · · · · ·	·	·	

Net increase in cash and cash equivalents	1,289.6	758.7	887.2
Cash and cash equivalents at beginning of period	4,880.3	4,121.6	3,234.4
Cash and cash equivalents at end of period	\$6,169.9	\$4,880.3	\$4,121.6
See accompanying Notes to Consolidated Financial Statements			

### CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS – (Continued) (Dollars in millions)

	Years Ended December		ecember
	31,		
	2016	2015	2014
Supplemental schedule of non-cash investing and financing activity:			
Fair value of contingent consideration issued in business combinations	<b>\$</b> —	\$166.0	\$1,060.0
Change in net unrealized (gain) loss on marketable securities available for sale	\$562.5	\$314.4	\$(494.0)
Investment in NantBioScience, Inc. preferred equity	<b>\$</b> —	\$—	\$90.0
Investment in Human Longevity, Inc. common stock	\$39.6	\$—	<b>\$</b> —
Supplemental disclosure of cash flow information:			
Interest paid	\$527.2	\$243.3	\$196.2
Income taxes paid	\$373.0	\$361.1	\$294.6
See accompanying Notes to Consolidated Financial Statements			

# CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Dollars in millions)

(Donars in initions)								
Years Ended December 31, 2016, 2015 and 2014	Commo Stock	onTreasury Stock	Additional Paid-in Capital	Retained Earnings	Accumulate Other Comprehen Income		Stockhold Ve Equity	ers'
Balances at December 31, 2013 Net income Other comprehensive income	\$ 9.1	\$(7,662.1	\$8,676.4	\$4,472.5 1,999.9	(Loss) \$ 94.0 820.8		\$ 5,589.9 1,999.9 820.8	
Exercise of stock options and conversion of restricted stock units	0.1	(126.1	) 424.2		020.0		298.2	
Shares purchased under share repurchase program		(2,929.5	)				(2,929.5	)
Issuance of common stock for employee benefit plans		18.9	26.5				45.4	
Expense related to share-based compensation			447.5				447.5	
Income tax benefit upon exercise of stock options			252.6				252.6	
Balances at December 31, 2014 Net income	\$ 9.2	\$(10,698.8)	\$9,827.2	\$6,472.4 1,602.0	\$ 914.8		\$ 6,524.8 1,602.0	
Other comprehensive (loss) Exercise of stock options and conversion of					(147.1	)	(147.1	)
restricted stock units	0.2	(135.4	394.9				259.7	
Shares purchased under share repurchase program		(3,256.8	)				(3,256.8	)
Issuance of common stock for employee benefit plans		39.2	18.5				57.7	
Expense related to share-based compensation			576.6				576.6	
Income tax benefit upon exercise of stock options			302.1				302.1	
Balances at December 31, 2015 Net income	\$ 9.4	\$(14,051.8)	\$11,119.3	\$8,074.4 1,999.2	\$ 767.7		\$ 5,919.0 1,999.2	
Other comprehensive (loss) Exercise of stock options and conversion of					(348.6	)	(348.6	)
restricted stock units	0.1	(105.0	) 452.9				348.0	
Shares purchased under share repurchase program		(2,160.0	)				(2,160.0	)
Issuance of common stock for employee benefit plans		35.7	14.4				50.1	
Expense related to share-based compensation			606.2				606.2	
Income tax benefit upon exercise of stock options			185.4				185.4	
Balances at December 31, 2016 See accompanying Notes to Consolidated Fi	\$ 9.5 nancial S		\$12,378.2	\$10,073.6	\$ 419.1		\$ 6,599.3	

## CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in millions, except per share amounts, unless otherwise indicated)

1. Nature of Business, Basis of Presentation and Summary of Significant Accounting Policies 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.

The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. Investments in limited partnerships and interests where we have an equity interest of 50% or less and do not otherwise have a controlling financial interest are accounted for by either the equity or cost method.

We operate in a single segment engaged in the discovery, development, manufacturing, marketing, distribution and sale of innovative therapies for the treatment of cancer and inflammatory diseases. Consistent with our operational structure, our Chief Executive Officer (CEO), as the chief operating decision maker, manages and allocates resources at the global corporate level. Our global research and development organization is responsible for discovery of new drug candidates and supports development and registration efforts for potential future products. Our global supply chain organization is responsible for the manufacturing and supply of products. Regional/therapeutic area commercial organizations market, distribute and sell our products. The business is also supported by global corporate staff functions. Managing and allocating resources at the global corporate level enables our CEO to assess both the overall level of resources available and how to best deploy these resources across functions, therapeutic areas, regional commercial organizations and research and development projects in line with our overarching long-term corporate-wide strategic goals, rather than on a product or franchise basis. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, allocating resources, setting incentive compensation targets, as well as forecasting future period financial results.

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates. We are subject to certain risks and uncertainties related to, among other things, product development, regulatory approval, market acceptance, scope of patent and proprietary rights, competition, outcome of legal and governmental proceedings, European credit risk, technological change and product liability.

Certain prior year amounts have been reclassified to conform to the current year's presentation.

Financial Instruments: Certain financial instruments reflected in the Consolidated Balance Sheets, (e.g., cash, cash equivalents, accounts receivable, certain other assets, accounts payable, short-term borrowings and certain other liabilities) are recorded at cost, which approximates fair value due to their short-term nature. The fair values of financial instruments other than marketable securities are determined through a combination of management estimates and information obtained from third parties using the latest market data. The fair value of available-for-sale marketable securities is determined utilizing the valuation techniques appropriate to the type of security (see Note 4).

Derivative Instruments and Hedges: All derivative instruments are recognized on the balance sheet at their fair value. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, we formally document the nature and relationships between the hedging instruments and hedged item. We assess, both at inception and on an on-going basis, whether the derivative instruments that are used in cash flow hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. We assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion of derivative instruments, if any, to current earnings. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings. We use derivative instruments, including those not designated as part of a hedging transaction, to manage our exposure to movements

# CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

in foreign exchange, our stock price and interest rates. The use of these derivative instruments modifies the exposure of these risks with the intent to reduce our risk or cost.

Cash, Cash Equivalents and Marketable Securities Available for Sale: We invest our excess cash primarily in money market funds, repurchase agreements, time deposits, U.S. Treasury securities, U.S. government-sponsored agency mortgage-backed securities (MBS), global corporate debt securities and asset backed securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from date of purchase are classified as marketable securities available for sale. We determine the appropriate classification of our investments in marketable debt and equity securities at the time of purchase. In addition, our equity investments in the publicly traded common stock of companies, including common stock of companies with whom we have entered into collaboration agreements, are designated as marketable securities available for sale.

Our marketable securities available for sale are primarily equity investments in the publicly traded common stock of companies, including common stock of companies with whom we have entered into collaboration agreements. In addition, we invest in debt securities that are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other-than-temporary impairment charges related to debt securities, is included in Interest and investment income, net. Realized gains and losses and other than temporary impairment charges related to equity securities are included in Other income (expense), net.

A decline in the market value of any available-for-sale security below its carrying value that is determined to be other-than-temporary would result in a charge to earnings and decrease in the security's carrying value down to its newly established fair value. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in earnings performance, credit rating, asset quality or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; our intent to hold to maturity and an evaluation as to whether it is more likely than not that we will not have to sell before recovery of its cost basis; our expected future cash flows from the security; and issues that raise concerns about the issuer's ability to continue as a going concern.

Concentration of Credit Risk: Cash, cash equivalents and marketable securities are financial instruments that potentially subject the Company to concentration of credit risk. We invest our excess cash primarily in money market funds, repurchase agreements, time deposits, U.S. Treasury securities, U.S. government-sponsored agency MBS, global corporate debt securities and asset backed securities (see Note 6). We have established guidelines relative to diversification and maturities to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified to take advantage of trends in yields and interest rates.

We sell our products in the United States primarily through wholesale distributors and specialty contracted pharmacies. Therefore, wholesale distributors and large pharmacy chains account for a large portion of our U.S. trade receivables and net product revenues (see Note 19). International sales are primarily made directly to hospitals, clinics and retail chains, many of which in Europe are government owned and have extended their payment terms in recent years given the economic pressure these countries are facing. We continuously monitor the creditworthiness of our customers, including these governments, and have internal policies regarding customer credit limits. We estimate an allowance for doubtful accounts primarily based on the credit worthiness of our customers, historical payment patterns, aging of receivable balances and general economic conditions, including publicly available information on

the credit worthiness of countries themselves and provinces or areas within such countries where they are the ultimate customers.

We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt situation in certain European countries and associated impacts on the financial markets and our business. Our current business model in these markets is typically to sell our products directly to principally government owned or controlled hospitals, which in turn directly deliver critical care to patients. Our products are used to treat life-threatening diseases and we believe this business model enables timely delivery and adequate supply of products. Many of the outstanding receivable balances are related to government-funded hospitals and we believe the receivable balances are ultimately collectible. Similarly, we believe that future sales to these customers will continue to be collectible.

Inventory: Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the decline in value is first recognized. Included in inventory are raw materials used in the production of preclinical and clinical products, which are charged to research and development expense when consumed.

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

We capitalize inventory costs associated with certain products prior to regulatory approval of products, or for inventory produced in new production facilities, when management considers it highly probable that the pre-approval inventories will be saleable. The determination to capitalize is based on the particular facts and circumstances relating to the expected regulatory approval of the product or production facility being considered, and accordingly, the time frame within which the determination is made varies from product to product. The assessment of whether or not the product is considered highly probable to be saleable is made on a quarterly basis and includes, but is not limited to, how far a particular product or facility has progressed along the approval process, any known safety or efficacy concerns, potential labeling restrictions and other impediments. We could be required to write down previously capitalized costs related to pre-launch inventories upon a change in such judgment, or due to a denial or delay of approval by regulatory bodies, a delay in commercialization or other potential factors.

Property, Plant and Equipment: Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation of plant and equipment is recorded using the straight-line method. Building improvements are depreciated over the remaining useful life of the building. Leasehold improvements are depreciated over the lesser of the economic useful life of the asset or the remaining term of the lease, including anticipated renewal options. The estimated useful lives of capitalized assets are as follows:

Buildings 40 years
Building and operating equipment 15 years
Manufacturing machinery and equipment 10 years
Other machinery and equipment 5 years
Furniture and fixtures 5 years
Computer equipment and software 3-7 years

Maintenance and repairs are charged to operations as incurred, while expenditures for improvements which extend the life of an asset are capitalized.

Capitalized Software Costs: We capitalize software costs incurred in connection with developing or obtaining software. Capitalized software costs are included in property, plant and equipment, net and are amortized over their estimated useful life of three to seven years from the date the systems are ready for their intended use.

Investments in Other Entities: We hold a portfolio of investments in equity securities and certain investment funds that are accounted for under either the equity method or cost method. Investments in companies or certain investment funds over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other income (expense), net. Our equity investments in the publicly traded common stock of companies, including common stock of companies with whom we have entered into collaboration agreements, are designated as marketable securities available for sale. Investments in equity securities of companies that become publicly traded are accounted for as available-for-sale marketable securities prospectively from the date of such companies' initial public offering if we are not restricted from selling our investment for greater than one year. Our cost method and equity method investments are included in other assets on the Consolidated Balance Sheets.

All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value and the decline is determined to be other-than-temporary, the investment is written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value has occurred include: market value or exit price of the investment based on either market-quoted prices or future rounds of financing by the investee; length of time that the market value was below its cost basis; financial condition and business prospects of the investee; our

intent and ability to retain the investment for a sufficient period of time to allow for recovery in market value of the investment; issues that raise concerns about the investee's ability to continue as a going concern; any other information that we may be aware of related to the investment.

Other Intangible Assets: Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Amortization is initiated for in-process research and development (IPR&D) intangible assets when their useful lives have been determined. IPR&D intangible assets which are determined to have had a drop in their fair value are adjusted downward and an expense recognized in the income statement. These IPR&D intangible assets are tested at least annually or when a triggering event occurs that could indicate a potential impairment.

Goodwill: Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination accounted for by the acquisition method of accounting and is not amortized, but is subject to impairment testing. We test our

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

goodwill for impairment at least annually or when a triggering event occurs that could indicate a potential impairment by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that the fair value of net assets are below their carrying amounts.

Impairment of Long-Lived Assets: Long-lived assets, such as property, plant and equipment and certain other long-term assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the estimated undiscounted future cash flows expected to be generated by the asset or asset group. If the carrying amount of the assets exceed their estimated future undiscounted net cash flows, an impairment charge is recognized for the amount by which the carrying amount of the assets exceed the fair value of the assets.

Contingent Consideration from Business Combinations: Subsequent to the acquisition date, we measure contingent consideration arrangements at fair value for each period with changes in fair value recognized in income as Acquisition related charges, net. Changes in contingent consideration obligation values can result from movements in publicly listed prices of our Contingent Value Rights (CVRs), adjustments to discount rates, updates in the assumed achievement or timing of milestones or changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval. In the absence of new information, changes in fair value reflect only the passage of time as development work towards the achievement of the milestones progresses, and is accrued based on an accretion schedule.

Foreign Currency Translation: Operations in non-U.S. entities are recorded in the functional currency of each entity. For financial reporting purposes, the functional currency of an entity is determined by a review of the source of an entity's most predominant cash flows. The results of operations for non-U.S. dollar functional currency entities are translated from functional currencies into U.S. dollars using the average currency rate during each month, which approximates the results that would be obtained using actual currency rates on the dates of individual transactions. Assets and liabilities are translated using currency rates at the end of the period. Adjustments resulting from translating the financial statements of our foreign entities into the U.S. dollar are excluded from the determination of net income and are recorded as a component of other comprehensive income (loss). Transaction gains and losses are recorded in other income (expense), net in the Consolidated Statements of Income.

Research and Development Costs: Research and development costs are expensed as incurred. These include all internal and external costs related to services contracted by us. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Milestone payments made to third parties upon regulatory approval are capitalized and amortized over the remaining useful life of the related product. Upfront payments are recorded when incurred, and milestone payments are recorded when the specific milestone has been achieved. Asset acquisition expenses, including expenses to acquire rights to pre-commercial compounds from a collaboration partner when there will be no further participation from the collaboration partner or other parties, are recorded as incurred.

Income Taxes: We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. We recognize the benefit of an uncertain tax position that we have taken or expect to take on income tax returns we file if such tax position is more likely than not to be sustained.

Revenue Recognition: Revenue from the sale of products is recognized when title and risk of loss of the product is transferred to the customer and the sales price is fixed and determinable. Provisions for discounts, early payments, rebates, sales returns and distributor chargebacks under terms customary in the industry are provided for in the same period the related sales are recorded. We record estimated reductions to revenue for volume-based discounts and rebates at the time of the initial sale. The estimated reductions to revenue for such volume-based discounts and rebates are based on the sales terms, historical experience and trend analysis.

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits,

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance.

Sales discount accruals are based on payment terms extended to customers.

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We also analyze actual billings received from the states to further support the accrual rates. Manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products as well as the historical invoices. This expense is recognized throughout the year as costs are incurred. In certain international markets government-sponsored programs require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from the date of sale. We record a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are included in chargeback accruals and are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

We record estimated reductions to revenue for free goods and volume-based discounts at the time of the initial sale. The estimated reductions to revenue for such free goods and volume-based discounts are based on the sales terms, historical experience and trend analysis. The cost of free goods is included in cost of goods sold (excluding amortization of acquired intangible assets).

We recognize revenue from royalties based on licensees' sales of our products or products using our technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

Share-Based Compensation: We utilize share based compensation in the form of stock options, restricted stock units (RSUs) and performance-based restricted stock units (PSUs). Compensation expense is recognized in the

Consolidated Statements of Income based on the estimated fair value of the awards at grant date. Compensation expense recognized reflects an estimate of the number of awards expected to vest after taking into consideration an estimate of award forfeitures based on actual experience and is recognized on a straight-line basis over the requisite service period, which is generally the vesting period required to obtain full vesting. Management expectations related to the achievement of performance goals associated with PSU grants is assessed regularly and that assessment is used to determine whether PSU grants are expected to vest. If performance-based milestones related to PSU grants are not met or not expected to be met, any compensation expense recognized to date associated with grants that are not expected to vest will be reversed.

The fair values of stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The fair values of RSU and PSU grants that are not based on market performance are based on the market value of our Common Stock on the date of grant. Certain of our PSU grants are measured based on the achievement of specified performance and market targets, including non-GAAP revenue, non-GAAP earnings per share, and relative total shareholder return. The grant date fair value for the portion of the PSUs related to non-GAAP revenue and non-GAAP earnings per share is estimated using the fair market value of our common stock on the grant date. The grant date fair value for the portion of the PSUs related to relative total shareholder return is estimated using the Monte Carlo valuation model.

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Earnings Per Share: Basic earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period, assuming potentially dilutive common shares resulting from option exercises, RSUs, PSUs, warrants and other incentives had been issued and any proceeds thereof used to repurchase common stock at the average market price during the period. The assumed proceeds used to repurchase common stock is the sum of the amount to be paid to us upon exercise of options, the amount of compensation cost attributed to future services and not yet recognized and, if applicable, the amount of excess income tax benefit that would be credited to paid-in capital upon exercise.

New accounting standards which have been adopted

In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs" (ASU 2015-03). ASU 2015-03 more closely aligns the presentation of debt issuance costs under U.S. GAAP with the presentation under comparable IFRS standards by requiring that debt issuance costs be presented on the balance sheet as a direct deduction from the carrying amount of the related debt liability, similar to the presentation of debt discounts or premiums. We adopted ASU 2015-03 in the first quarter of 2016. Other assets and Long-term debt, net of discount have been restated as of December 31, 2015 to reflect the retroactive reclassification of \$89.0 million of debt issuance costs that have been reclassified from Other assets to Long-term debt, net of discount.

In April 2015, the FASB issued Accounting Standards Update No. 2015-05, "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement" (ASU 2015-05). ASU 2015-05 provides guidance to help companies evaluate the accounting for fees paid by a customer in a cloud computing arrangement. The new guidance clarifies that if a cloud computing arrangement includes a software license, the customer should account for the license consistent with its accounting for other software licenses. If the arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 was effective for us beginning in the first quarter of 2016. The adoption of this updated standard did not have a material impact on our consolidated financial statements and related disclosures.

In September 2015, the FASB issued Accounting Standards Update No. 2015-16, "Simplifying the Accounting for Measurement-Period Adjustments" (ASU 2015-16). ASU 2015-16 replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. ASU 2015-16 was effective for us beginning in the first quarter of 2016. During the third quarter of 2016 we recorded a measurement period adjustment related to the valuation of contingent consideration and goodwill associated with the 2015 acquisition of Quanticel Pharmaceuticals, Inc. (Quanticel) that reduced the acquisition date fair values of both contingent consideration and goodwill by \$10.7 million. There was no material impact on 2016 net income.

New accounting standards which have not yet been adopted

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09) and has subsequently issued a number of amendments to ASU 2014-09. The new standard, as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with

customers and supersedes current revenue recognition guidance, including industry-specific guidance. The standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASU 2014-09 includes provisions within a five step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard will be effective for us beginning January 1, 2018 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. We currently anticipate adopting the standard using the modified retrospective method.

We have substantially completed an analysis of existing contracts with our customers and assessed the differences in accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards. Based on our review of current customer contracts, we do not expect the implementation of ASU 2014-09 to have a material quantitative impact on our consolidated

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

financial statements as the timing of revenue recognition for product sales is not expected to significantly change. In limited instances, we may recognize revenue earlier than under the current standard. Currently, we defer certain revenue where the price pursuant to the underlying customer arrangement is not fixed and determinable. Under the new standard, such customer arrangements will be accounted for as variable consideration, which may result in revenue being recognized earlier provided we can reliably estimate the ultimate price expected to be realized from the customer. The new standard will result in additional revenue-related disclosures in the footnotes to our consolidated financial statements. We will continue to assess new customer contracts during 2017. Adoption of this standard will require changes to our business processes, systems and controls to support the additional required disclosures. We are in the process of identifying such changes.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory" (ASU 2015-11). ASU 2015-11 applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new standard will be effective for us on January 1, 2017. We do not expect the implementation of the updated standard to have a material impact on our consolidated financial statements and related disclosures.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, "Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU 2016-01). ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. ASU 2016-01 does not apply to equity investments in consolidated subsidiaries or those accounted for under the equity method of accounting. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value or at cost adjusted for changes in observable prices minus impairment. Changes in measurement under either alternative will be recognized in net income. Companies that elect the fair value option for financial liabilities must recognize changes in fair value related to instrument-specific credit risk in other comprehensive income. Companies must assess valuation allowances for deferred tax assets related to available-for-sale debt securities in combination with their other deferred tax assets. ASU 2016-01 will be effective for us beginning in the first quarter of 2018 and early adoption is available to publicly traded companies for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. We expect the implementation of this standard to have an impact on our consolidated financial statements and related disclosures, as we held publicly traded equity investments at December 31, 2016 with a fair value of \$891.1 million, as well as equity investments accounted for under the cost method. A cumulative-effect adjustment to the balance sheet will be recorded as of the beginning of the fiscal year of adoption. The implementation of ASU 2016-01 is expected to increase volatility in our net income as the volatility currently recorded in other comprehensive income related to changes in the fair market value of available for sale equity investments will be reflected in net income after adoption.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, "Leases" (ASU 2016-02). ASU 2016-02 provides accounting guidance for both lessee and lessor accounting models. Among other things, lessees will recognize a right-of-use asset and a lease liability for leases with a duration of greater than one year. For income statement purposes, ASU 2016-02 will require leases to be classified as either operating or finance. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. The new standard

will be effective for us on January 1, 2019 and will be adopted using a modified retrospective approach which will require application of the new guidance at the beginning of the earliest comparative period presented. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures. We expect the implementation of this standard to have an impact on our consolidated financial statements and related disclosures as we have aggregate future minimum lease payments of \$213.4 million at December 31, 2016 under our current portfolio of non-cancelable leased office and research facilities with various expirations dates between 2017 and 2025. We anticipate recognition of additional assets and corresponding liabilities related to these leases on our consolidated balance sheet.

In March 2016, the FASB issued Accounting Standards Update No. 2016-07, "Investments-Equity Method and Joint Ventures" (ASU 2016-07). ASU 2016-07 eliminates the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively as if the equity method had been in effect during all previous periods that the investment had been held. Under the new guidance, available-for-sale equity securities that become qualified for the equity method of accounting will result in the recognition through earnings of the unrealized holding gain or loss in accumulated other comprehensive income at the date the investment becomes qualified for use of the equity method. The new standard will be

## CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

effective for us on January 1, 2017 and will be adopted on a prospective basis. We do not expect the implementation of the updated standard to have a material impact on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, "Compensation-Stock Compensation" (ASU 2016-09). ASU 2016-09 changes several aspects of the accounting for share-based payment transactions including requiring all excess tax benefits and tax deficiencies to be recognized in the Statement of Income as a discrete item in the reporting period in which they occur, classification of awards as either equity or liabilities, employee tax withholding, calculation of shares for use in diluted earnings per share, and classification on the Statement of Cash Flows. The new standard will be effective for us on January 1, 2017. Changes introduced by ASU 2016-09 related to the timing of when unrecognized tax benefits are recognized, minimum statutory withholding requirements, forfeitures, and intrinsic value will be applied using a modified retrospective transition method by means of a cumulative-effect adjustment to equity as of the beginning of the first quarter of 2017. We anticipate that the updated standard will result in an increase in the shares used in the calculation of diluted earnings per share in an amount that will vary depending primarily on the share price of our common stock during future periods as well as the strike prices of outstanding employee stock options during future periods. We expect the adoption of ASU 2016-09 to have a number of impacts on our consolidated financial statements, the most notable being a decrease in our income tax provision, an increase in the number of shares used in the calculation of diluted earnings per share and a decrease in cash provided by financing activities with a corresponding increase in cash provided by operating activities. The magnitude of such impacts will depend upon future movements in our share price as well as the timing of stock award exercises, which are both difficult to estimate.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, "Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments" (ASU 2016-13). ASU 2016-13 requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective for us on January 1, 2020. Early adoption will be available on January 1, 2019. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments" (ASU 2016-15). ASU 2016-15 clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. ASU 2016-15 is effective for us in our first quarter of fiscal 2018 and earlier adoption is permitted. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In October 2016, the FASB issued Accounting Standards Update No. 2016-16, "Intra-Entity Transfers of Assets Other Than Inventory" (ASU 2016-16). ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets other than inventory to be recognized as current period income tax expense or benefit and removes the requirement to defer and amortize the consolidated tax consequences of intra-entity transfers. The new standard will be effective for us on January 1, 2018 and will be adopted using a modified retrospective approach which requires a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. Early adoption is permitted at the beginning of a fiscal year. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued Accounting Standards Update No. 2017-01, "Business Combinations" (ASU 2017-01). ASU 2017-01 provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities (a "set") does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing elements. The new standard will be effective for us on January 1, 2018 and will be adopted on a prospective basis. Early adoption is permitted. We are currently evaluating the effect that the standard will have on our consolidated financial statements and related disclosures.

#### 2. Acquisitions and Divestitures

Acquisitions and Divestitures of Businesses

Receptos, Inc. (Receptos): On August 27, 2015 (Acquisition Date), we acquired all of the outstanding common stock of Receptos, resulting in Receptos becoming our wholly-owned subsidiary. Receptos' lead drug candidate, ozanimod, is a small molecule that modulates sphingosine 1-phosphate 1 and 5 receptors and it is in development for immune-inflammatory indications, including

# CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

inflammatory bowel disease and relapsing multiple sclerosis (RMS). The acquisition of Receptos also included RPC4046, an anti-interleukin-13 (IL-13) antibody in development for eosinophilic esophagitis (EoE), an allergic/immune-mediated orphan disease. RPC4046 was licensed from AbbVie Bahamas Ltd. and AbbVie Inc. (collectively referred to as AbbVie). The results of operations and cash flows for Receptos are included in our consolidated financial statements from the Acquisition Date and the assets and liabilities of Receptos have been recorded at their respective fair values on the Acquisition Date and consolidated with our assets and liabilities.

We paid approximately \$7.626 billion, consisting of \$7.311 billion for common stock outstanding and \$0.315 billion for the portion of equity compensation attributable to the pre-combination period. In addition, we paid \$0.197 billion for the portion of equity compensation attributable to the post-combination service period, which has been recorded as expense over the required service period ending in the fourth quarter of 2015.

The acquisition has been accounted for using the acquisition method of accounting which requires that assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and requires the fair value of acquired IPR&D to be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts.

The total consideration for the acquisition of Receptos is summarized as follows:

	Total
	Consideration
Cash paid for outstanding common stock	\$ 7,311.3
Cash for equity compensation attributable to pre-combination service	314.9
Total consideration	\$ 7,626.2

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the Acquisition Date based upon their respective fair values summarized below. During the fourth quarter of 2015, adjustments were recorded to increase the amounts initially recorded for deferred tax assets, deferred tax liabilities and goodwill as of the Acquisition Date.

Amounts	
Recognize	d
as of the	
Acquisition	n
Date	
\$ 479.2	
5.0	
6,842.0	
241.3	
7.9	
(2,519.2	)
5,056.2	
2,570.0	
\$ 7,626.2	
	Recognize as of the Acquisition Date \$ 479.2 5.0 6,842.0 241.3 7.9 (2,519.2 5,056.2 2,570.0

<sup>&</sup>lt;sup>1</sup> Includes cash and cash equivalents, available for sale marketable securities, other current assets, accounts payable, and accrued expenses and other current liabilities.

The fair values of current and other non-current assets, current liabilities and property, plant and equipment were determined to approximate their book values.

<sup>&</sup>lt;sup>2</sup> Following adoption of Accounting Standards Update No. 2015-17, "Balance Sheet Classification of Deferred Taxes" in the fourth quarter of 2015 all deferred tax assets and liabilities and associated valuation allowances are classified as non-current.

<sup>&</sup>lt;sup>3</sup> Upon integration of the acquired intangible assets into our offshore research, manufacturing, and commercial operations, the deferred tax liability was reclassified to a non-current tax liability.

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The fair value assigned to acquired IPR&D was based on the present value of expected after-tax cash flows attributable to ozanimod, which is in phase II and III testing. The present value of expected after-tax cash flows attributable to ozanimod and assigned to IPR&D was determined by estimating the after-tax costs to complete development of ozanimod into a commercially viable product, estimating future revenue and ongoing expenses to produce, support and sell ozanimod, on an after-tax basis, and discounting the resulting net cash flows to present value. The revenue and costs projections used were reduced based on the probability that compounds at similar stages of development will become commercially viable products. The rate utilized to discount the net cash flows to their present value reflects the risk associated with the intangible asset and is benchmarked to the cost of equity. Acquired IPR&D will be accounted for as an indefinite-lived intangible asset until regulatory approval in a major market or discontinuation of development.

The excess of purchase price over the fair value amounts assigned to identifiable assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is primarily attributable to the broadening of our product portfolio and research capabilities in the inflammation and immunology therapeutic area, the assembled workforce and the deferred tax consequences of the IPR&D asset recorded for financial statement purposes. We do not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition has been recorded as a non-current asset in our Consolidated Balance Sheets and is not amortized, but is subject to review for impairment annually.

From the Acquisition Date through December 31, 2015, our Consolidated Statements of Income included expenses of \$380.5 million associated with the acquisition and operations of Receptos as follows<sup>1</sup>:

Acquisition
Date
Through
December
31, 2015
\$ 78.6
5.1
296.8
\$ 380.5

<sup>&</sup>lt;sup>1</sup> In addition, Celgene incurred \$19.9 million of acquisition related costs prior to the acquisition date.

#### Pro Forma Financial Information:

Total revenue

Net income

The following table provides unaudited pro forma financial information for the twelve-month periods ended December 31, 2015 as if the acquisition of Receptos had occurred on January 1, 2014.

Twelve-Month
Periods Ended
December 31,
2015 2014
\$9,256.0 \$7,676.3
\$1,630.8 \$1,499.9

Net income per common share: basic \$2.06 \$1.87 Net income per common share: diluted \$1.98 \$1.79

<sup>&</sup>lt;sup>2</sup> Consists of acquisition-related compensation expense and transaction costs.

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of Celgene and Receptos. The pro-forma financial information assumes that the acquisition-related transaction fees and costs incurred were removed from the twelve-month period ended December 31, 2015 and were assumed to have been incurred during the first quarter of 2014. The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings that may result from the combined operations of Celgene and Receptos. Accordingly, these unaudited pro forma results are presented for illustrative purposes and are not intended to represent or be indicative of the actual results of operations of the combined company that would have been achieved had the acquisition occurred at the beginning of the period presented, nor are they intended to represent or be indicative of future results of operations.

Quanticel Pharmaceuticals, Inc. (Quanticel): On October 19, 2015, we completed our acquisition of Quanticel, a privately held biotechnology company focused on cancer drug discovery, for consideration consisting of \$95.9 million in cash at closing plus contingent consideration consisting of future payments of up to \$385.0 million for achieving specified discovery and development targets. We had a research collaboration arrangement with Quanticel since 2011. Through this purchase, Quanticel has become

#### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

our wholly-owned subsidiary, and we will benefit from full access to Quanticel's proprietary platform for the single-cell genomic analysis of human cancer, as well as Quanticel's programs that target specific epigenetic modifiers, which we expect will advance our pipeline of innovative cancer therapies.

The acquisition was accounted for using the acquisition method of accounting for business combinations which requires the assets and liabilities of Quanticel to be recorded at their respective fair values on the acquisition date and consolidated into our Consolidated Balance Sheets. The results of operations and cash flows for Quanticel have been included in our consolidated financial statements from the date of acquisition. Pro-forma results of operations for this acquisition have not been presented because this acquisition is not material to our consolidated results of operations.

Fair value amounts allocated to contingent consideration and goodwill presented below have been reduced by \$10.7 million during 2016. These measurement period adjustments were not significant and did not have a significant impact on our financial condition, results of operations or cash flows.

The fair value of consideration transferred in the acquisition of Quanticel is shown in the table below:

Fair Value at October 19, 2015 (as adjusted) \$ 95.9 Fair value of pre-existing equity ownership 11.4 155.3 \$ 262.6

Cash

Contingent consideration

Working capital<sup>1</sup>

Property, plant and equipment

Total fair value of consideration

Prior to the acquisition of Quanticel, we had an equity interest equal to approximately 5% of the company's total capital stock (on an "as converted" basis). Based on the fair market value of this interest derived from the purchase price, we recognized a gain of \$10.3 million, which was reflected as a component of Other income (expense), net within our Consolidated Statement of Income for the year ended December 31, 2015.

Our potential contingent consideration payments are classified as liabilities, which were measured at fair value as of the acquisition date. We estimated the fair value of potential contingent consideration using a probability-weighted discounted cash flow approach, which reflects the probability and timing of future potential payments. This fair value measurement is based on significant inputs that are not observable in the market and thus represents a level three liability within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a discount rate based on a market participant assumption. See Note 4 for post-acquisition changes in fair value. The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the acquisition date based upon their respective fair values summarized below.

> Fair Value at October 19, 2015 (as adjusted) \$7.0 1.9

Other non-current assets	0.8	
Technology platform intangible asset <sup>2</sup>	232.0	
Debt obligations	(13.9	)
Non-current deferred tax liabilities	(72.3	)
Total identifiable net assets	155.5	
Goodwill	107.1	
Total net assets acquired	\$ 262.6	

<sup>&</sup>lt;sup>1</sup> Includes cash and cash equivalents, available-for-sale marketable securities, other current assets, accounts payable and accrued expenses and other current liabilities.

The fair values of current and other non-current assets, property, plant and equipment, current liabilities and debt were determined to approximate their book values.

<sup>&</sup>lt;sup>2</sup> Technology platform related to Quanticel's proprietary technology platform for the single-cell genomic analysis of human cancer.

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

The fair value of the technology platform intangible asset is equal to the present value of the after-tax cash flows attributable to the intangible asset, which was calculated based on the multi-period excess earnings method of the income approach. The multi-period excess earnings method of the income approach included estimating probability adjusted annual after-tax net cash flows through the cycle of development and commercialization of potential products generated by the technology platform then discounting the resulting probability adjusted net post-tax cash flows using a discount rate commensurate with the risk of our overall business operations to arrive at the net present value.

The excess of purchase price over the fair value amounts assigned to the identifiable assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is largely attributable to the deferred tax consequences of the finite-lived technology platform intangible asset recorded for financial statement purposes, as well as intangible assets that do not qualify for separate recognition at the time of the acquisition. We do not expect any portion of this goodwill to be deductible for tax purposes. Goodwill attributable to the acquisition has been recorded as a non-current asset in our Consolidated Balance Sheets and is not amortized, but is subject to review for impairment annually.

Nogra Pharma Limited (Nogra): On April 23, 2014, we entered into a license agreement with Nogra, pursuant to which Nogra granted us an exclusive, royalty-bearing license for its intellectual property relating to GED-0301, an antisense oligonucleotide targeting Smad7, to develop and commercialize products containing GED-0301 for the treatment of Crohn's disease and other indications. A phase II trial of GED-0301 in patients with active Crohn's disease has been completed and we have initiated a multi-trial clinical program that is designed to support global registrations of GED-0301 in Crohn's disease.

Under the terms of the agreement, which became effective on May 14, 2014 after receipt of certain governmental clearances and approvals, we made an upfront payment of \$710.0 million and may make additional contingent developmental, regulatory and sales milestone payments as well as payments based on percentages of annual sales of licensed products. The maximum aggregate amount payable for development and regulatory milestones is approximately \$815.0 million, which covers such milestones relating to Crohn's disease and other indications. Starting from global annual net sales of \$500.0 million, aggregate tiered sales milestone payments could total a maximum of \$1.050 billion if global annual net sales reach \$4.000 billion.

The development and application of the intellectual property covered under the license agreement will be managed by joint committees composed of members from each of Nogra and us. We have the tie-breaking vote on the joint steering committee and as such have ultimate decision-making authority for development, regulatory and commercialization decisions. The agreement also includes provisions for access to employees of Nogra, technical assistance, transfer of manufacturing agreements and transfer of Nogra know-how related to GED-0301. Based on the foregoing factors, for accounting purposes, we have concluded that the acquired assets meet the definition of a business and have accounted for the GED-0301 license as IPR&D acquired in a business combination. The acquisition method of accounting requires that (a) the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and (b) the fair value of IPR&D be classified as an indefinite-lived asset until the successful completion or abandonment of the associated research and development efforts. Pro-forma results of operations for this acquisition have not been presented because this acquisition is not material to our consolidated results of operations.

The fair value of consideration transferred to acquire the license amounted to:

Fair Value at

April 23, 2014
Cash \$710.0
Contingent consideration 1,060.0
Total fair value of consideration \$1,770.0

Our potential contingent consideration payments were measured at fair value as of the acquisition date and classified as liabilities. We estimated the fair value of potential contingent consideration using a probability-weighted income approach, which reflects the probability and timing of future potential payments. This fair value measurement is based on significant inputs that are not observable in the market and thus represents a level three liability within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a discount rate based on a market participant assumption. See Note 4 for post-acquisition changes in fair value. The purchase price allocation resulted in the following amounts being allocated to the assets acquired at the acquisition date based on their respective fair values:

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Fair Value at April 23, 2014 In-process research and development product rights \$1,620.0 Current deferred tax assets 1.3 Non-current deferred tax liabilities, net (1.3)) Total identifiable net assets 1,620.0 Goodwill 150.0 \$1,770.0 Total net assets acquired

The fair value of the acquired IPR&D asset was based on the present value of expected net cash flows from the GED-0301 product candidate. Net cash flows were determined by estimating future sales, net of the costs to complete development of GED-0301 into a commercially viable product. Estimated net cash flows were adjusted to reflect the probability of successfully developing a new drug from a product candidate that has completed a phase II trial. Additionally, the projections considered the relevant market sizes and growth factors and the nature and expected timing of a new product introduction. The resulting net cash flows from such potential products include our estimates of cost of sales, operating expenses, and income taxes. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the project and uncertainties in the economic estimates used in the projections described above. The acquired IPR&D asset is accounted for as an indefinite-lived intangible asset until regulatory approval in a major market or discontinuation.

The excess of purchase price over the fair value amounts assigned to the assets acquired represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is largely attributable to intangible assets that do not qualify for separate recognition. We expect this goodwill to be deductible for tax purposes.

The license agreement may be terminated (i) at our discretion upon 180 days' written notice to Nogra, provided that such termination will not become effective before May 14, 2017, and (ii) by either party upon material breach of the other party, subject to cure periods. Upon the expiration of our royalty payment obligations under the license agreement, on a country-by-country and licensed product-by-licensed product basis, the license granted under the license agreement will become fully paid-up, irrevocable, perpetual, and non-terminable with respect to such licensed product in such country.

LifebankUSA: In February 2016, we completed the sale of certain assets of Celgene Cellular Therapeutics (CCT) comprising CCT's biobanking business known as LifebankUSA, CCT's biomaterials portfolio of assets, including Biovance®, and CCT's rights to PSC-100, a placental stem cell program, to Human Longevity, Inc. (HLI), a genomics and cell therapy-based diagnostic and therapeutic company based in San Diego, California. We received 3.4 million shares of HLI Class A common stock with a fair value of \$39.6 million as consideration in the transaction. The fair value of the shares common stock we received was determined based on the most recent preferred share offering and reduced for the estimated value of the liquidation preference not offered to common share-holders. The transaction generated a \$37.5 million gain that was recorded on our Consolidated Statements of Income in Other income (expense), net. As of December 31, 2016 our total investment in HLI represents approximately 16% of HLI's outstanding capital stock.

Other Acquisitions

EngMab AG (EngMab): On September 27, 2016, we acquired all of the outstanding shares of EngMab, a privately held biotechnology company focused on T-cell bi-specific antibodies. EngMab's lead molecule, EM901 is a preclinical T-cell bi-specific antibody targeting B-cell maturation antigen (BCMA). The acquisition also included another early stage program.

The consideration included an initial payment of 606.9 million Swiss Francs (CHF) (approximately \$625.3 million at the time of acquisition), contingent development and regulatory milestones of up to CHF 150.0 million (approximately \$154.7 million) and contingent commercial milestones of up to CHF 2.250 billion (approximately \$2.320 billion) based on cumulative sales levels of between \$1.000 billion and \$40.000 billion. The acquisition of EngMab did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The initial payment was allocated primarily to the EM901 molecule and another early stage program, resulting in a \$623.3 million research and development asset acquisition expense and \$2.0 million of net working capital acquired.

Acetylon Pharmaceuticals, Inc. (Acetylon): On December 16, 2016, we acquired all of the remaining outstanding equity interests we did not already own (approximately 86%) in Acetylon, a privately held biotechnology company focused on developing next-generation selective small molecule histone deacetylase ("HDAC") inhibitors, which allow for epigenetic regulation of gene and protein function. Acetylon's lead molecule, ACY-241 is a HDAC6 inhibitor in Phase 1 trials for relapsed and/or refractory multiple

# CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

myeloma. The acquisition also included another early stage molecule. Prior to the acquisition, we had an equity interest equal to approximately 14% of Acetylon's total capital stock with a carrying value of approximately \$30.0 million.

The consideration transferred included an initial payment of \$196.3 million. In addition, the sellers of Acetylon are eligible to receive contingent regulatory milestones of up to \$375.0 million per eligible product, contingent commercial milestones of up to \$1.500 billion based on achieving annual net sales in excess of \$1.000 billion and tiered royalties on annual net sales of eligible products. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The initial payment and carrying value of our previous equity interest were allocated primarily to ACY-241 and another early stage molecule, resulting in a \$226.1 million research and development asset acquisition expense and \$0.2 million of net assets acquired.

Triphase Research and Development I Corporation (Triphase): On November 17, 2016, we acquired from Triphase Accelerator, L.P. (Sellers) all of the outstanding shares of Triphase by exercising the option we acquired on October 22, 2012. Triphase is a privately held, biotechnology company focusing on the development of marizomib for glioblastoma and relapsed and/or refractory multiple myeloma.

The consideration transferred was valued at \$42.4 million including the value of the exercised option of \$17.6 million. In addition, the sellers are eligible to receive contingent development and regulatory milestones of up to \$125.0 million, contingent commercial milestones of up to \$300.0 million based on achieving annual net sales equal in excess of \$1.000 billion and royalties on annual net sales. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The consideration transferred was allocated primarily to the marizomib asset, resulting in a \$43.5 million research and development asset acquisition expense and \$1.1 million of net liabilities acquired.

#### 3. Earnings Per Share

	2016	2015	2014
Net income	\$1,999.2	\$1,602.0	\$1,999.9
Weighted-average shares:			
Basic	777.2	792.2	802.7
Effect of dilutive securities:			
Options, RSUs, PSUs, warrants and other	26.1	32.7	33.3
Diluted	803.3	824.9	836.0
Net income per share:			
Basic	\$2.57	\$2.02	\$2.49
Diluted	\$2.49	\$1.94	\$2.39

The total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 23.8 million in 2016, 14.1 million in 2015 and 18.7 million in 2014.

During the period of April 2009 through December 2016, our Board of Directors approved repurchases of up to an aggregate of \$20.500 billion of our common stock, including the authorization in June 2016 to repurchase an additional \$3.000 billion of our common stock.

As part of the management of our share repurchase program, we may, from time to time, sell put options on our common stock with strike prices that we believe represent an attractive price to purchase our shares. If the trading price of our shares exceeds the strike price of the put option at the time the option expires, we will have economically reduced the cost of our share repurchase program by the amount of the premium we received from the sale of the put option. If the trading price of our stock is below the strike price of the put option at the time the option expires, we would purchase the shares covered by the option at the strike price of the put option. During 2016, 2015 and 2014 we recorded net gains of \$7.6 million, net losses of \$9.9 million, and net gains of \$11.6 million, respectively, from selling put options on our common stock on the Consolidated Statements of Income in Other income (expense), net. At December 31, 2016, we had no outstanding put options.

We repurchased 21.4 million shares of common stock under the program from all sources during 2016 at a total cost of \$2.160 billion. As of December 31, 2016, we had a remaining open-ended repurchase authorization of \$4.731 billion.

### CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

#### 4. Financial Instruments and Fair Value Measurement

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2016 and 2015, and the valuation techniques we utilized to determine such fair value.

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Our level 1 assets consist of marketable equity securities. Our level 1 liability relates to our publicly traded CVRs. See Note 18 for a description of the CVRs.

Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Our level 2 assets consist primarily of U.S. Treasury securities, U.S. government-sponsored agency MBS, global corporate debt securities, asset backed securities, time deposits with original maturities of greater than three months, foreign currency forward contracts, purchased foreign currency options and interest rate swap contracts. Our level 2 liabilities relate to written foreign currency options.

Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. We do not have any level 3 assets. Our level 3 liabilities consist of contingent consideration related to undeveloped product rights and technology platforms resulting from the acquisitions of Gloucester Pharmaceuticals, Inc. (Gloucester), Nogra, Avila Therapeutics, Inc. (Avila) and Quanticel.

Our contingent consideration obligations are recorded at their estimated fair values and we revalue these obligations each reporting period until the related contingencies are resolved. The fair value measurements are estimated using probability-weighted discounted cash flow approaches that are based on significant unobservable inputs related to product candidates acquired in business combinations and are reviewed quarterly. These inputs include, as applicable, estimated probabilities and timing of achieving specified development and regulatory milestones, estimated annual sales and the discount rate used to calculate the present value of estimated future payments. Significant changes which increase or decrease the probabilities of achieving the related development and regulatory events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of these obligations. Changes in the fair value of contingent consideration obligations are recognized in Acquisition related charges, net in the Consolidated Statements of Income. The fair value of our contingent consideration as of December 31, 2016 and December 31, 2015 was calculated using the following significant unobservable inputs:

	as of:	as of			
Inputs	December 31,	December 31,			
	2016	2015			
Discount rate	1.5% to 12.0%	0.8% to 12.0%			
Discoulit rate	(8.6%)	(8.8%)			
Probability of payment	0% to 95% (42%)	6) 0% to 95% (53%)			
Projected year of payment for development and regulatory milestones	2017 to 2029	2016 to 2029			
Projected year of payment for development and regulatory innestones	(2019)	(2019)			
Projected year of payment for sales-based milestones and other amounts	2019 to 2033	2019 to 2033			
calculated as a percentage of annual sales	(2024)	(2024)			

The maximum remaining potential payments related to the contingent consideration from the acquisitions of Gloucester, Avila and Quanticel are estimated to be \$120.0 million, \$475.0 million and \$313.6 million, respectively, and \$1.865 billion plus other amounts calculated as a percentage of annual sales pursuant to the license agreement

with Nogra.

# CELGENE CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

A	Balance at December 31, 2016	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobserval Inputs (Level 3)	
Assets: Available-for-sale securities	\$ 1.799.8	\$891.1	\$ 908.7	\$	
Forward currency contracts	378.9	φ 0 9 1 . 1	378.9	Ψ	
Purchased currency options	139.6		139.6	_	
Interest rate swaps	31.4		31.4		
Total assets	\$ 2,349.7	\$891.1	\$ 1,458.6	\$	_
Liabilities:	+ -,,-	7 07 -11	+ -,	7	
Contingent value rights	\$ (44.6)	\$ (44.6)	\$ —	\$	_
Written currency options	(53.9)			•	