CELGENE CORP /DE/
Form 10-K
February 07, 2018

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, 2017
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number 001-34912
CELGENE CORPORATION
(Exact name of registrant as specified in its charter)

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

(908) 673-9000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $.01 per share	NASDAQ Global Select Market
Contingent Value Rights	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company
x	o	o	o	o

(Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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, 2017, the last business day of the registrant's most recently completed second quarter, was $101,580,696,211 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

There were 752,175,608 shares of Common Stock outstanding as of February 2, 2018.

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, 2017. The proxy statement is incorporated herein by reference into the following parts of the Form 10-K:

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

CELGENE CORPORATION
ANNUAL REPORT ON FORM 10-K
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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®), THALOMID® (sold as THALOMID® or Thalidomide Celgene® outside of the U.S.) and IDHIFA®. IDHIFA® was approved by the U.S. Food and Drug Administration (FDA) in August 2017 for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) or (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved diagnostic test. We began recognizing revenue related to IDHIFA® during the third quarter of 2017. 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 and lymphomas. Also, within hematological malignancies, POMALYST® is in several phase III and post-approval trials for relapsed/refractory multiple myeloma (RRMM). In solid tumors, ABRAXANE® is currently in various stages of investigation for pancreatic and non-small cell lung cancers. In inflammation and immunology, OTEZLA® is being evaluated in phase III trials for Behçet's disease and scalp psoriasis, and is continuing to be studied in ulcerative colitis (UC), 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), UC and a phase III trial in Crohn's Disease (CD) that is initiating. In hematology, phase III trials are underway for CC-486 and luspatercept in myelodysplastic syndromes (MDS), for CC-486 in AML and for luspatercept in beta-thalassemia. In July 2017, Celgene Corporation entered into global strategic immuno-oncology collaboration with BeiGene, Ltd. (BeiGene) to advance a PD-1 Inhibitor (BGB-A317) program for solid tumor cancers. In collaboration with bluebird bio, bb2121, a BCMA CAR T cell therapy, has shown impressive efficacy in RRMM with a manageable safety profile. Breakthrough Therapy designation has been granted by the FDA and bb2121 has been given access to the Priority Medicines scheme by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP). A pivotal study in RRMM was initiated in December 2017.

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.

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

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

Disease	Geographic Approvals
Multiple myeloma (MM)	
MM in combination with dexamethasone, in patients who have received at least one prior therapy	- United States - European Union - Japan - Other international markets
MM in combination with dexamethasone for newly diagnosed patients	- United States - Japan - Other international markets
Adult patients with previously untreated multiple myeloma who are not eligible for transplant	- European Union - Other international markets
Monotherapy for the maintenance treatment of patients with Newly Diagnosed Multiple Myeloma (NDMM) after autologous stem cell transplant (ASCT)	- United States (February 2017) - European Union (February 2017)
Myelodysplastic syndromes (MDS)	
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities	- United States - Other international markets
Transfusion-dependent anemia due to low- or intermediate-1-risk MDS in patients with isolated deletion 5q cytogenetic abnormality when other options are insufficient or inadequate MDS with a deletion 5q cytogenetic abnormality. The efficacy or safety of REVLIMID® for International Prognostic Scoring System (IPSS) intermediate-2 or high risk MDS has not been established.	- European Union - Japan
Mantle cell lymphoma (MCL) in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib	- United States - European Union - Other international markets
R/R Adult T-cell leukemia/lymphoma (ATLL)	- Japan (March 2017)

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
MM, in combination with dexamethasone, for patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy	- United States - European Union - Other international markets
Relapsed and refractory multiple myeloma (RRMM), in combination with dexamethasone, for adult patients who have received at least two prior therapies including both lenalidomide and bortezomib and have demonstrated disease progression on the last therapy	
RRMM for patients who have received REVLIMID® or bortezomib	- Japan

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

OTEZLA® (apremilast): OTEZLA® is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels. OTEZLA® is approved for the following uses:

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

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

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

IDHIFA® (enasidenib): IDHIFA® is a small molecule inhibitor of the isocitrate dehydrogenase 2 (IDH2) enzyme allowing young red blood cells to mature normally. IDHIFA® is approved for the following uses:

Disease	Geographic Approvals
Acute Myeloid Leukemia (AML)	
Relapsed or refractory AML with an isocitrate dehydrogenase-2 mutation	- United States (August 2017)

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

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

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

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

REVLIMID®, POMALYST® and THALOMID® are distributed in the United States primarily through contracted pharmacies under the REVLIMID® Risk Evaluation and Mitigation Strategy (REMS), POMALYST REMS® and THALOMID REMS® programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID®, POMALYST® and THALOMID®. Internationally, REVLIMID®, THALOMID®/Thalidomide Celgene® and IMNOVID® are distributed under mandatory risk-management distribution programs tailored to meet local authorities' specifications to provide for the product's safe and appropriate distribution and use. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies. VIDAZA®, ABRAXANE®, IDHIFA® 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 includes small molecule and biologics therapeutics, and cell therapies. 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 phase III clinical trials in Behçet's disease and scalp psoriasis, and is continuing to be studied in UC, psoriatic arthritis and plaque psoriasis. In 2018, Celgene plans to initiate a phase III trial with OTEZLA® in UC based on the efficacy and safety results demonstrated in a phase II randomized, double-blind, placebo-controlled proof of concept study evaluating OTEZLA® in UC. Differentiated oral therapies are advancing through mid- to late-stage trials in inflammatory diseases, including ozanimod, a potential best-in-class S1P receptor modulator. In December, a New Drug Application (NDA) was submitted with the FDA for ozanimod in RMS based on data from the phase III trials evaluating ozanimod in patients with RMS. In addition, ozanimod has a phase III trial in UC underway and a phase III trial in CD that is initiating. Other potential oral therapies include, GED-0301 with a phase II trial in UC, CC-220 for systemic lupus erythematosus (SLE), CC-90001 for idiopathic pulmonary fibrosis and ABX-1431 for multiple sclerosis spasticity.

A phase I trial in healthy volunteers has been completed and a phase Ib in psoriasis patients is being initiated for CC-90006, an injectable PD-1 agonist antibody for autoimmune disorders. In collaboration with FORMA Therapeutics Holdings LLC (FORMA), a phase Ib in healthy volunteers is in progress for FT-4101, targeted for development in nonalcoholic steatohepatitis (NASH).

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. Enrollment for these trials completed in 2017.

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. We are currently evaluating ivosidenib or IDHIFA® combined with standard induction chemotherapy (7+3 regimen) in patients with newly diagnosed AML with an isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation from a phase I trial.

A phase I trial of a lysine-specific histone demethylase inhibitor (LSD1i, CC-90011) is under way in solid tumors. Additionally, two bromodomain and extra-terminal motif (BET) inhibitors CC-90010, and FT-1101 in collaboration with FORMA, are in phase I dose escalation trials under investigation in non-Hodgkins lymphoma (NHL), solid tumors and acute leukemia indications. Navicixizumab, OncoMed Pharmaceuticals, Inc.'s (OncoMed) anti-DLL4/VEGF bispecific targeting DLL4 in the Notch cancer stem cell pathway and vascular endothelial growth factor (VEGF) receptors, is being investigated in phase Ib clinical trials in ovarian and colorectal cancers.

Protein Homeostasis: CC-122 (Cereblon Modulator, or CELMoD®) and CC-220 are 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. CC-220 is also in development in SLE. They are 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 modulator, currently in phase I in patients with relapsed AML, whose activity is related to the depletion of the novel substrate GSPT1. CC-92480 is another

novel CELMoD® targeted for multiple myeloma with a differentiated preclinical profile, initiating phase I in 2018.

Immuno-Oncology: bb2121, a BCMA CAR T cell therapy being developed in collaboration with bluebird bio, has shown impressive efficacy in RRMM with a manageable safety profile. Breakthrough Therapy designation has been granted by the FDA and bb2121 has been given access to the Priority Medicines scheme by the EMA CHMP. A pivotal study in RRMM was initiated in December 2017. Bluebird bio is also running a phase I study with bb21217, a second CAR T cell therapy directed against BCMA. JCAR017, a CD19 CAR T cell therapy in development in collaboration with Juno Therapeutics, Inc. (Juno), has also 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 JCAR017 shows high complete response rates in NHL, with a potentially differentiated safety profile. A pivotal study in diffuse large B-cell lymphoma (DLBCL) initiated in 2017.

In September, Celgene and partner AstraZeneca announced that the FDA placed a partial clinical hold on five trials and a full clinical hold on one trial in the FUSION™ clinical program evaluating IMFINZI™ (durvalumab) in combination with immunomodulatory and chemotherapy agents in hematological malignancies. The decision by the FDA was based on risks

identified in other trials evaluating pembrolizumab in combination with immunomodulatory agents in patients with multiple myeloma. The two trials evaluating IMFINZI™ in patients with MDS and AML are continuing as planned.

Since BCMA is emerging as a compelling target in multiple myeloma (MM), we are also developing a BCMA-targeted T cell engager program in MM, CC-93269; an investigational new drug (IND) application and a clinical trial application (CTA) were filed in 2017 with a phase I trial initiating in 2018. Our anti-CD47 antibody targeting macrophage activity, CC-90002, is currently in phase I trials being evaluated for the treatment of NHL, AML, and solid tumors. A number of additional programs from our collaboration partners are in phase I clinical testing in multiple solid tumor indications, including LYC-55716, a RORgt agonist (Lycera Corp.), and JTX-2011, an anti-ICOS-agonist, (Jounce Therapeutics, Inc). OncoMed is also investigating OMP-313M32, an anti-TIGIT antibody, in a phase I study in solid tumors.

In July 2017, Celgene Corporation entered into global strategic immuno-oncology collaboration with BeiGene to advance a PD-1 Inhibitor (BGB-A317) program for solid tumor cancers.

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 $5.9 billion in 2017, $4.5 billion in 2016, and $3.7 billion in 2015. 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	Post-approval research	Q1 2017
POMALYST®/IMNOVID®	Relapsed/refractory	Post-approval research	2013
THALOMID®/Thalidomide Celgene®	Newly diagnosed	Post-approval research	2006
PD-L1 Inhibitor: durvalumab[2,1]	MM	Phase I	2015
BCMA CAR-T (bb2121)[3]	MM	Phase II/Pivotal	Q4 2017
BCMA CAR-T (bb21217)[3]	MM	Phase I	Q3 2017
Cereblon Modulator: CC-220	MM	Phase I	2016
Cereblon Modulator: CC-92480	MM	Phase I	Q4 2017
Myelodysplastic Syndromes (MDS)			
VIDAZA®	MDS	Post-approval research	2004
REVLIMID®	Deletion 5q	Post-approval research	2005
CC-486	Lower-risk	Phase III	2013
	Post hypomethylating agent (HMA) failure	Phase II	2015
luspatercept (ACE-536)[4]	MDS	Phase III	2016
PD-L1 Inhibitor: durvalumab[2]	MDS	Phase II	2015
Acute Myeloid Leukemia (AML)			
VIDAZA®	AML (20%-30% blasts) (EU)	Post-approval research	2008
	AML (>30% blasts) (EU)	Post-approval research	2015
IDHIFA®	AML	Post-approval research	Q3 2017
CC-486	Post-induction AML maintenance	Phase III	2013
PD-L1 Inhibitor: durvalumab[2]	AML	Phase II	2015
Anti-CD47 Antibody: CC-90002	AML	Phase I	2016
Cereblon Modulator: CC-90009	AML	Phase I	2016
Lymphoma			
REVLIMID®			2013

Mantle cell lymphoma: Relapsed/refractory (US)	Post-approval research	
Mantle cell lymphoma: Relapsed/refractory (EU)	Post-approval research	2016
Diffuse large B-cell (ABC-subtype): First line	Phase III	2015
Indolent lymphoma: Relapsed/refractory	Phase III	2013

Area of Research		Status	Entered Current Status
	Adult T-cell leukemia-lymphoma (Japan)	Post-approval research	Q1 2017
ISTODAX®	Cutaneous T-cell lymphoma (US)[6]	Post-approval research	2009
	Peripheral T-cell lymphoma: Relapsed/refractory (US)[6]	Post-approval research	2011
	Peripheral T-cell lymphoma: Relapsed/refractory (Japan)	Post-approval research	Q3 2017
	Peripheral T-cell lymphoma: First-line	Phase III	2013
Cereblon Modulator: avadomide (CC-122)	Diffuse large B-cell lymphoma	Phase I	2014
	Indolent lymphoma: Relapsed/refractory	Phase I	2014
CC-486	Lymphoma	Phase I	2015
PD-L1 Inhibitor: durvalumab[2,t]	Non-Hodgkin lymphoma (NHL)	Phase I	2016
CD19 CAR-T (JCAR017)[7]	Aggressive large B-cell lymphoma: Relapsed/refractory	Phase I-II	2015
Anti-CD47 Antibody: CC-90002	Non-Hodgkin lymphoma (NHL)	Phase I	2015
Chronic Lymphocytic Leukemia (CLL)			
Cereblon Modulator: avadomide (CC-122)	CLL	Phase I-II	2015
PD-L1 Inhibitor: durvalumab[2,t]	CLL	Phase I	2015
Beta Thalassemia			
luspatercept (ACE-536)[4]	Beta-thalassemia	Phase III	2016
Myelofibrosis			
luspatercept (ACE-536)[4]	Myelofibrosis	Phase II	Q3 2017
Solid Tumors			
ABRAXANE®	Breast: Metastatic	Post-approval research	2005
	Non-small cell lung: Advanced (first-line)	Post-approval research	2012
	Pancreatic: Metastatic (first-line)	Post-approval research	2013
	Pancreatic: Adjuvant	Phase III	2014
	Gastric: Metastatic (Japan)[8]	Post-approval research	2013
CC-486	Breast: Metastatic	Phase II	2015
	Non-small cell lung: Advanced	Phase II	2015
Marizomib	Glioblastoma	Phase II	2016
Cereblon Modulator: avadomide (CC-122)	Hepatocellular carcinoma	Phase I	2015
Anti-CD47 Antibody: CC-90002	Solid tumors	Phase I	2015
PAN-IDH Inhibitor: AG-881[5]	Glioma	Phase I	2015
LSD1 Inhibitor: CC-90011	Solid tumors	Phase I	2016

BET Inhibitor: CC-90010	Glioblastoma	Phase I	Q3 2017

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Area of Research		Status	Entered Current Status
Inflammation and Immunology			
OTEZLA® (apremilast)	Psoriatic arthritis	Post-approval research	2014
	Plaque psoriasis	Post-approval research	2014
	Behçet's disease	Phase III	2014
	Ulcerative colitis	Phase II	2014
GED-0301	Ulcerative colitis	Phase II	2015
ozanimod[1]	Relapsing multiple sclerosis	Regulatory submission	Q4 2017
	Ulcerative colitis	Phase III	2015
	Crohn's disease	Phase II	2015
RPC-4046	Eosinophilic esophagitis	Phase II	2014
Cereblon Modulator: CC-220	Systemic lupus erythematosus (SLE)	Phase IIb	Q3 2017
CC-90001	Fibrosis	Phase II	Q2 2017
ABX-1431[9]	Tourettes	Phase I	2016
CC-90006	Psoriasis	Phase I	2016
FT-4101[10]	Targeted toward nonalcoholic steatohepatitis (NASH)	Phase I	2016

[1] "Regulatory submission" indicates US and/or EU submission unless another country or region is indicated under Area of Research.
[2] In collaboration with MedImmune Limited, a wholly owned subsidiary of AstraZeneca PLC.
[3] In collaboration with bluebird bio, Inc.
[4] In collaboration with Acceleron Pharma, Inc.
[5] In collaboration with Agios Pharmaceuticals, Inc.
[6] Regulatory approval based on pivotal phase II data.
[7] In collaboration with Juno Therapeutics, Inc.
[8] Trial conducted by licensee partner, Taiho Pharmaceuticals Co. Ltd.
[9] In collaboration with Abide Therapeutics, Inc.
[10] In collaboration with Forma Therapeutics Holdings, LLC
[l] Three of four durvalumab studies are in partial clinical hold, one study is in full clinical hold
[t] Study in partial clinical hold

PATENTS AND PROPRIETARY TECHNOLOGY

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

Key patent expirations and exclusivities:

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

	U.S.[1]	Europe
REVLIMID® brand drug (U.S. and European use patents)	2027[2]	2024[3]
POMALYST®/IMNOVID® brand drug (U.S. drug substance/use patent)	2025[4]	2023[5]
OTEZLA® brand drug (U.S./European drug substance patent)	2024[6]	2028[3]
ABRAXANE® brand drug (U.S. use patent and European use/formulation patents)	2026[7]	2022[8]
VIDAZA® brand drug (U.S. use patent and EMA regulatory exclusivities only)	2011[9]	2019

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

[2] In December 2015, we announced the settlement of litigations with Natco Pharma Ltd. and its partners and affiliates, relating to certain patents for REVLIMID®. As part of the settlement, we agreed to provide Natco with a volume-limited license to sell generic lenalidomide in the U.S. commencing in March 2022. Natco's ability to market generic lenalidomide in the U.S. will be contingent on its obtaining approval of an Abbreviated New Drug Application. See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for more information.

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

[4] Patent Term Extension granted in October 2017. Exclusivity extended through 2025.

[5] Based on ten years regulatory exclusivity.

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

[7] In January 2018, we entered into a settlement with Actavis LLC to terminate patent litigation and Inter Partes Review (IPR) challenges between the parties relating to certain patents for ABRAXANE®. As part of the settlement, we have agreed to provide Actavis with a license to certain patents required to manufacture and sell a generic paclitaxel protein-bound particles for injectable suspension product in the United States beginning on March 31, 2022. See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for more information.

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

9 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.

The term of individual patents and patent applications will depend upon the legal term of the patents in the countries in which they are obtained. In the United States, the patent term is 20 years from the date of filing of the patent application although term extensions are available. We may obtain patents for certain products many years before marketing approval is obtained for those products. Because of the limited life of patents, which ordinarily commences prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to obtain patent term extensions upon marketing

approval. For example, SPCs on some of our products have been granted in a number of European countries, compensating in part for delays in obtaining marketing approval. Also, under the Hatch-Waxman Act, the term of a patent that covers an FDA-approved drug may also be eligible for patent term extension (for up to five years, but not beyond a total of 14 years from the date of product approval) as compensation for patent term lost during the FDA regulatory review process. When possible, depending upon the length of clinical trials and other factors involved in the filing of a NDA with the FDA, we expect to apply for patent term extensions for patents covering our drug products and their use in treating various diseases.

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

Patent term extensions have been granted in other markets for certain of our patents related to REVLIMID®. Patent term extensions for certain of our patents related to lenalidomide have been granted in Europe, Australia, Japan and Russia. Further, patent term extensions for certain of our patents related to ABRAXANE® have been secured and/or are actively being sought in Europe, Australia, Japan, Russia and Korea. We are also considering alternative exclusivity strategies, mostly through international treaties, in a variety of countries throughout Latin America.

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

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

As of December 31, 2017, we owned or had exclusively licensed 803 issued U.S. patents and 565 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 and/or reimbursement of unapproved uses of a product 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 or to update the product label. 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 OTEZLA®, REVLIMID® and THALOMID® as well as work with several third-party contract manufacturers to provide backup API manufacturing services for certain products.

In addition, for certain products, we have contracted with several third-party API and drug product manufacturing and packaging service providers, to provide primary and/or back-up sources including the API manufacturing for ABRAXANE®, POMALYST®/IMNOVID®, IDHIFA®, VIDAZA® (azacitidine for injection) and ISTODAX®, and the drug product manufacturing and packaging for IDHIFA®, VIDAZA® (azacitidine for injection) and ISTODAX®.

Manufacturing services for REVLIMID®, POMALYST®/IMNOVID®, THALOMID® and OTEZLA® which consists of bulk production, packaging, warehousing and distribution, are performed at our drug product manufacturing facility in Boudry, Switzerland. Manufacturing services for ABRAXANE® which consists of bulk production, packaging, warehousing and distribution, are performed at our drug product manufacturing facility in Arizona, U.S. We have contracted with several third-party drug product manufacturing service providers and packaging service providers to provide backup manufacturing and packaging services for these products.

We have established, or are in the process of establishing, primary and back up suppliers and/or manufacturing sites for late phase development programs. We are leveraging a combination of owned and third-party manufacturing service providers for OTEZLA® QD (once daily), ozanimod and luspatercept. We are also investing in our own as well as third-party manufacturing services for our CAR T product candidates, including bb2121 and JCAR017.

All Celgene owned and third-party facilities are approved by the regulatory authorities for the geographies that they serve.

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 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, 2017, we had 7,467 full-time employees, of whom 2,829 were engaged primarily in research and development activities, 2,440 were engaged primarily in sales and commercialization activities, 678 were engaged primarily in manufacturing, and the remaining 1,520 were engaged primarily in management and general and administrative activities. The number of full-time employees in our international operations has grown from 3,039 at the end of 2016 to 3,091 at the end of 2017. 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 2017 that are required to be disclosed pursuant to ITRSHRA.

FORWARD-LOOKING STATEMENTS

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

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

- competition; and
- operational and legal risks.

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

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

ITEM 1A. RISK FACTORS

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

Our operating results may be subject to significant fluctuations.

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

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

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

Our business is largely dependent on the commercial success of REVLIMID®, POMALYST®/IMNOVID®, OTEZLA®, ABRAXANE®, and VIDAZA®. 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 federal and state 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 at both the federal and state level 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 possible 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 received the attention of U.S. policymakers, state legislators 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.

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 of covered outpatient drugs 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. Additionally, in early 2016, HRSA finalized a regulation regarding the 340B pricing methodology and providing guidelines for when civil monetary penalties may be issued for "knowing and intentional" manufacturer overcharges of 340B covered entities. HRSA has delayed the effective date of this regulation to July 1, 2018.

We have received an inquiry from HRSA regarding our limited distribution networks for REVLIMID®, POMALYST®, and THALOMID® and our compliance with the 340B program. We have cooperated fully in responding to this inquiry and believe that we have complied with applicable legal requirements. If, however, we are ultimately required to change our sales or pricing practices with regard to the distribution of these drugs, 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 by certain provisions of the America Invents Act (“AIA”) enacted in 2011. For example, under the AIA, members of the public may seek to challenge an issued patent by petitioning the USPTO to institute a post grant proceeding, such as a Post Grant Review (PGR) or Inter Partes Review (IPR). Once a post grant proceeding is instituted, the USPTO may find grounds to revoke the challenged patent or specific claims therein. 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 similar procedure (known as a patent opposition) has existed in Europe for many years and we have defended our European patents in certain of those proceedings. We cannot predict whether any other Celgene patents will ever become the subject of a post grant proceeding or patent opposition. If a significant product patent is successfully challenged in a post grant proceeding or patent opposition, 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 receivable balances relating to government-owned or -controlled hospitals in European countries, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

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

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

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

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

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

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

Many of our drug candidates are in the early or mid-stages of research and development and will require the commitment of substantial financial resources, extensive research, development, preclinical testing, clinical trials,

manufacturing scale-up and regulatory approval prior to being ready for sale. This process takes many years of effort without any assurance of ultimate success. Our product development efforts with respect to a product candidate may fail for many reasons, including:

- the failure of the product candidate in preclinical or clinical studies;
- adverse patient reactions to the product candidate or indications of other safety concerns;
- insufficient clinical trial data to support the effectiveness or superiority of the product candidate;

- our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner;

- our failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate, the facilities or the process used to manufacture the product candidate;

- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive;

- the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers; and

- the development of a competitive product or therapy.

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

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

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

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

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

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

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

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

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

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

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

- increased management, travel, infrastructure and legal compliance costs;
- longer payment and reimbursement cycles;
- difficulties in enforcing contracts and collecting accounts receivable;
- local marketing and promotional challenges;
- lack of consistency, and unexpected changes, in foreign regulatory requirements and practices;
- increased risk of governmental and regulatory scrutiny and investigations;
- increased exposure to fluctuations in currency exchange rates;
- the burdens of complying with a wide variety of foreign laws and legal standards;
- operating in locations with a higher incidence of corruption and fraudulent business practices;
- difficulties in staffing and managing foreign sales and development operations;
- import and export requirements, tariffs, taxes and other trade barriers;
- weak or no protection of intellectual property rights;
- possible enactment of laws regarding the management of and access to data and public networks and websites;
- possible future limitations on foreign-owned businesses;
- increased financial accounting and reporting burdens and complexities; and
- other factors beyond our control, including political, social and economic instability, popular uprisings, war, terrorist attacks and security concerns in general.

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

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

We may face significant challenges in effectively integrating entities and businesses that we acquire, including the pending acquisitions of Impact BioMedicines, Inc. and Juno Therapeutics, Inc., 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 including the recently enacted U.S. tax reform on December 22, 2017 formerly known as the Tax Cuts and Jobs Act (2017 Tax Act), 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. See ‘Executive Summary’ and ‘Liquidity and Capital Resources’ within Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations as well as Note 16 of Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to the 2017 Tax Act.

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 elsewhere in this report.

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

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

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

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

The price of our common stock may fluctuate significantly.

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

- results of our clinical trials or adverse events associated with our marketed products;
- fluctuations in our commercial and operating results;
- announcements of technical or product developments by us or our competitors;
- market conditions for pharmaceutical and biotechnology stocks in particular;

- changes or anticipated changes in laws and governmental regulations, including changes in tax, healthcare, environmental, competition and patent laws;
- new accounting pronouncements or regulatory rulings;
- public announcements regarding medical advances in the treatment of the disease states that we are targeting;
- patent or proprietary rights developments;
- changes in pricing and third-party reimbursement policies for our products;
- the outcome of litigation involving our products, processes or intellectual property;
- the existence and outcome of governmental investigations and proceedings;
- regulatory actions that may impact our products or potential products;
- disruptions in our manufacturing processes or supply chain;
- failure of our collaboration partners to successfully develop potential drug candidates;
- competition; and
- investor reaction to announcements regarding business or product acquisitions.

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

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

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

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

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

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

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

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown and unauthorized intrusion. We could also experience a business interruption, theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Similarly, data privacy breaches by those who access our systems may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, employees, customers or other business partners, may be exposed to unauthorized persons or to the public. Although the aggregate impact on our operations and financial condition has

not been material to date, we have been the target of events of this nature and expect them to continue. We continuously monitor our data, information technology systems (and those of our third-party providers where appropriate) and our personnel's usage of these systems to reduce these risks and potential threats. However, cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems (or that of our third-party providers) that could adversely affect our business and result in financial and reputational harm to us, theft of trade secrets and other proprietary information, legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties.

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

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

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

Our board of directors has the authority to issue, at any time, without further stockholder approval, up to 5.0 million shares of preferred stock and to determine the price, rights, privileges and preferences of those shares. An issuance of preferred stock could discourage a third-party from acquiring a majority of our outstanding voting stock. Additionally, our by-laws contain provisions intended to strengthen the board’s position in the event of a hostile takeover attempt. These provisions could impede the stockholders’ ability to remove and replace our management and/or board of directors. Furthermore, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law, which may also dissuade a potential acquirer of our common stock.

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

On October 15, 2010, we acquired all of the outstanding common stock of Abraxis BioScience, Inc. (Abraxis) and in connection with our acquisition, contingent value rights (CVRs) were issued entitling each holder of a CVR to a pro rata portion of certain 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	1,933,000
Boudry, Switzerland	Manufacturing, administration and warehousing	269,000
Phoenix, Arizona	Manufacturing and warehousing	254,000
Zofingen, Switzerland	Manufacturing	8,100

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

Location	Primary Usage	Approximate Square Feet
San Diego, California	Office space and research	271,500
Berkeley Heights, New Jersey	Office space	98,800
Cambridge, Massachusetts	Office space and research	83,000
Warren, New Jersey	Office space and research	73,500
San Francisco, California	Office space and research	55,800
Overland Park, Kansas	Office space	29,600
Seattle, Washington	Research	30,800
Emeryville, California	Office space and research	4,900
Los Angeles, California	Office space	3,800
Washington, D.C.	Office space	3,500
Dallas, Texas	Office space	3,100

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. As of December 31, 2017, the non-cancelable lease terms for our operating leases expire at various dates between 2018 and 2025 and in some cases include renewal options. The total amount of rent expense recorded for all leased facilities in 2017 was $54 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
2017:		
Fourth Quarter	$147.17	$94.55
Third Quarter	146.13	126.86
Second Quarter	135.18	113.63
First Quarter	127.64	111.06
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

	Cumulative Total Return					
	12/12	12/13	12/14	12/15	12/16	12/17
Celgene Corporation	$100.00	$215.33	$285.10	$305.24	$295.02	$265.99
S&P 500	100.00	132.04	149.89	151.94	169.82	206.49
NASDAQ Composite	100.00	139.89	160.47	171.83	187.03	242.34
NASDAQ Biotechnology	100.00	165.93	222.94	249.18	196.00	238.39

* $100 Invested on 12/31/12 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 2, 2018 was $99.80. As of February 2, 2018, there were approximately 378 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 2018 Annual Meeting of Stockholders.

(e) REPURCHASE OF EQUITY SECURITIES

From April 2009 through December 2017, our Board of Directors approved purchases of up to $20.5 billion of our common stock. Approved amounts exclude share purchase transaction fees.

The following table presents the number of shares purchased during the three-month period ended December 31, 2017, the average price paid per share, the number of shares that were purchased and the dollar value of shares that still could have been purchased, pursuant to our repurchase authorization:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs
October 1 - October 31	4,963,879	$101.70	4,963,879	$3,303,014,461
November 1 - November 30	17,614,593	$102.02	17,614,593	$1,505,953,347
December 1 - December 31	6,455,783	$105.87	6,455,783	$822,471,283
	29,034,255	$102.82	29,034,255	

During the three-month period ended December 31, 2017, we purchased approximately 29.0 million shares of common stock under the share repurchase program from all sources at a cost of approximately $3.0 billion, excluding commissions. As of December 31, 2017, we had a remaining purchase authorization of approximately $822 million. 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, 2017, 2016 and 2015 and the Consolidated Balance Sheet data as of December 31, 2017 and 2016 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, 2014 and 2013 and the Consolidated Balance Sheet information as of December 31, 2015, 2014 and 2013 are derived from our Consolidated Financial Statements, which are not included in this Annual Report on Form 10-K (amounts in millions, except per share data).

	Years ended December 31,				
	2017[1]	2016	2015	2014	2013[2]
Consolidated Statements of Income:					
Total revenue	$13,003	$11,229	$9,256	$7,670	$6,494
Costs and operating expenses	8,296	8,063	7,001	5,151	4,685
Operating income	4,707	3,166	2,255	2,519	1,809
Interest and investment income, net	105	30	31	28	22
Interest (expense)	(522)	(500)	(311)	(176)	(92)
Other income (expense), net	24	(324)	48	(44)	(74)
Income before income taxes	4,314	2,372	2,023	2,327	1,665
Income tax provision	1,374	373	421	327	215
Net income	$2,940	$1,999	$1,602	$2,000	$1,450
Net income per share:					
Basic	$3.77	$2.57	$2.02	$2.49	$1.75
Diluted	$3.64	$2.49	$1.94	$2.39	$1.68
Weighted average shares:					
Basic	779.2	777.2	792.2	802.7	827.7
Diluted	808.7	803.3	824.9	836.0	860.6

	As of December 31,				
	2017	2016	2015	2014	2013
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	$12,042	$7,970	$6,552	$7,547	$5,687
Total assets[3]	30,141	28,086	26,964	17,291	13,344
Short-term borrowings and current portion of long-term debt	—	501	—	606	545
Long-term debt, net of discount[3]	15,838	13,789	14,161	6,217	4,162
Retained earnings	13,061	10,074	8,075	6,473	4,473
Total stockholders' equity	6,921	6,600	5,919	6,525	5,590

[1] The Income tax provision for fiscal 2017 includes income tax expense of approximately $1,269 million as a result of U.S. tax reform legislation, formerly known as the Tax Cuts and Jobs Act (2017 Tax Act), which was enacted on December 22, 2017. In addition, the Income tax provision also includes $290 million of excess tax benefits arising from share-based compensation awards that vested or were exercised during 2017, and are recorded in the income tax provision following the adoption of ASU 2016-09, "Compensation-Stock Compensation". See ‘Executive Summary’ and ‘Liquidity and Capital Resources’ within Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations as well as Note 16 and Note 1 of Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to the 2017 Tax Act and the adoption of ASU 2016-09, respectively.

[2] Adjusted to reflect the two-for-one common stock split effected in June 2014.

(3) Total assets and Long-term debt, net of discount have been restated as of December 31, 2015, 2014 and 2013 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®), THALOMID® (sold as THALOMID® or Thalidomide Celgene® outside of the U.S.) and IDHIFA®. IDHIFA® was approved by the U.S. Food and Drug Administration (FDA) in August 2017 for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) or (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved diagnostic test. We began recognizing revenue related to IDHIFA® during the third quarter of 2017. 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 and lymphomas. Also, within hematological malignancies, POMALYST® is in several phase III and post-approval trials for relapsed/refractory multiple myeloma (RRMM). In solid tumors, ABRAXANE® is currently in various stages of investigation for pancreatic and non-small cell lung cancers. In inflammation and immunology, OTEZLA® is being evaluated in phase III trials for Behçet's disease and scalp psoriasis, and is continuing to be studied in ulcerative colitis (UC), 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), UC and a phase III trial in Crohn's Disease (CD) that is initiating. In hematology, phase III trials are underway for CC-486 and luspatercept in myelodysplastic syndromes (MDS), for CC-486 in AML and for luspatercept in beta-thalassemia. In July 2017, Celgene Corporation entered into global strategic immuno-oncology collaboration with BeiGene, Ltd. (BeiGene) to advance a PD-1 Inhibitor (BGB-A317) program for solid tumor cancers. In collaboration with bluebird bio, bb2121, a BCMA CAR T cell therapy, has shown impressive efficacy in RRMM with a manageable safety profile. Breakthrough Therapy designation has been granted by the FDA and bb2121 has been given access to the Priority Medicines scheme by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP). A pivotal study in RRMM was initiated in December 2017.

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.

Recent Developments

2017 Tax Act: In December 2017, the President signed U.S. tax reform legislation (2017 Tax Act), which includes a broad range of provisions, many of which significantly differ from those contained in previous U.S. tax law. Changes

in tax law are accounted for in the period of enactment. As such, the 2017 consolidated financial statements reflect the immediate tax effect of the 2017 Tax Act, which was enacted on December 22, 2017. The 2017 Tax Act contains several key provisions including, among other things:

- A one-time tax on the mandatory deemed repatriation of post-1986 untaxed foreign earnings and profits (E&P), referred to as the toll charge;
- Reduction in the Corporate tax rate from 35% to 21% for tax years beginning after December 31, 2017;
- Introduction of a new U.S. tax on certain off-shore earnings referred to as Global Intangible Low-Taxed Income (GILTI) at an effective tax rate of 10.5% for tax years beginning after December 31, 2017 (increasing to 13.125% for tax years beginning after December 31, 2025) with a partial offset by foreign tax credits; and
- Introduction of a territorial tax system beginning in 2018 by providing a 100% dividends received deduction on certain qualified dividends from foreign subsidiaries.

During the fourth quarter of 2017, we recorded an income tax expense of approximately $1,269 million, which was comprised of the following:

- An income tax expense of approximately $1,890 million for the one-time deemed repatriation of E&P. In accordance with the 2017 Tax Act, the toll charge liability may be paid over eight years. As such, we have recorded $1,732 million and $150 million in non-current and current income tax liability on an undiscounted basis, respectively, as of December 31, 2017; and
- An income tax benefit of $621 million, primarily for the remeasurement of our deferred tax assets and liabilities at the enacted tax rate of 21%.

The net charge recorded was based on currently available information and interpretations of applying the provisions of the 2017 Tax Act as of the time of filing this Annual Report on Form 10-K. In accordance with authoritative guidance issued by the Securities and Exchange Commission (SEC), the income tax effect for certain aspects of the 2017 Tax Act represent provisional amounts for which our accounting is incomplete but a reasonable estimate could be determined and recorded during the fourth quarter of 2017. Our actual results may materially differ from our current estimate due to, among other things, further guidance that may be issued by U.S. tax authorities or regulatory bodies including the SEC and the Financial Accounting Standards Board to interpret the 2017 Tax Act. We will continue to analyze the 2017 Tax Act and any additional guidance that may be issued so we can finalize the full effects of applying the new legislation on our financial statements in the measurement period. See Note 16 to Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to the 2017 Tax Act.

Discontinuance of Certain GED-0301 Phase III Trials: On October 19, 2017, we announced our decision to discontinue the GED-0301 phase III REVOLVE (CD-002) trial in CD and the SUSTAIN (CD-004) extension trial (the Trials). At that time, we concluded we would record a significant impairment of our GED-0301 in-process research and development (IPR&D) asset, incur wind-down costs associated with discontinuing the Trials and certain development activities, and record a benefit related to the significant reduction of GED-0301 contingent consideration liabilities. At the date GED-0301 was acquired by Celgene, a phase II trial of GED-0301 in patients with active CD had been completed and a multi-year clinical program designed to support global registrations of GED-0301 in CD was planned, while other indications were not as advanced. As such, substantially all of the IPR&D asset and contingent consideration liabilities were attributed to the development and commercialization of GED-0301 for the treatment of CD. As a result of the discontinuance of the Trials, the Company recorded a net pre-tax charge to earnings of approximately $411 million during the fourth quarter of 2017. The net pre-tax charge was comprised of the following:

- An impairment charge relating to the entire GED-0301 IPR&D asset of approximately $1,620 million. See Note 10 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for further details on the impairment of the GED-0301 IPR&D asset;
- Other one-time charges of approximately $188 million that will require cash payments primarily related to wind-down costs associated with discontinuing the Trials and certain development activities; and
- A reduction in contingent consideration liabilities of approximately $1,397 million related to GED-0301. See Note 4 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for further details on contingent consideration liabilities.

The following tables present significant developments in our pivotal and phase III clinical trials and regulatory approval requests that occurred during the three-month period ended December 31, 2017, as well as developments that are expected to occur if the future occurrence is material and reasonably certain:

Regulatory Approval Requests in Major Markets:

Product	Disease Indication/ New Formulation	Major Market	Regulatory Agency	Action
ozanimod	Relapsing multiple sclerosis	U.S.	FDA	Q4 2017 (submitted)
OTEZLA® QD	Once-daily formulation	U.S.	FDA	Q4 2017 (submitted)

Pivotal and Phase III Trials:

Product Candidate	Trial	Disease Indication	Action
GED-0301[(1)]	Phase III - REVOLVE (CD-002)	Crohn's disease	Discontinued
GED-0301[(1)]	Phase III - SUSTAIN (CD-004)	Crohn's disease	Discontinued
bb2121	Pivotal - KarMMa™	RRMM	Initiated

[(1)] In October 2017, we announced that the GED-0301 (mongersen) phase III REVOLVE (CD-002) trial in Crohn's disease (CD) and the SUSTAIN (CD-004) extension trial (Trials) will discontinue. We decided to stop the Trials following an October recommendation of the Data Monitoring Committee, which assessed overall benefit/risk during a recent interim futility analysis. There were no meaningful safety imbalances identified in the interim futility analysis. In addition, at this time, the phase III DEFINE (CD-003) trial in CD will not be initiated. We are waiting to review the full dataset from the phase II trial with GED-0301 in UC to determine next steps.

Recent Transactions

Impact Biomedicines, Inc. (Impact): On January 7, 2018, we entered into a definitive agreement to acquire Impact, a privately held biotechnology company which is developing fedratinib, a highly selective JAK2 kinase inhibitor, for myelofibrosis and polycythemia vera. Under the terms of the agreement, we will make an upfront cash payment of approximately $1.1 billion. In addition, Impact Biomedicines' shareholders are eligible to receive contingent regulatory approval milestones up to $1.4 billion and contingent commercial milestones up to $4.5 billion based on cumulative sales levels of between $1.0 billion and $5.0 billion. The acquisition is subject to customary closing conditions and applicable waiting period under the Hart Scott Rodino Antitrust Improvements Act. The transaction is expected to close in the first quarter of 2018. The acquisition of Impact is not anticipated to include any significant processes and thus, for accounting purposes, we have preliminary concluded that the acquired assets will not meet the accounting definition of a business. As such, the transaction will be accounted for as a research and development asset acquisition.

Juno Therapeutics, Inc. (Juno): On January 21, 2018, we entered into a merger agreement with Juno under which we will pay $87 per share in cash, or approximately $9.0 billion net of cash and marketable securities acquired and Juno shares already owned by us (approximately 9.7% of outstanding shares), which we anticipate to be accounted for as a business combination. Juno is a publicly held biotechnology company which is developing CAR (chimeric antigen receptor) T and TCR (T cell receptor) therapeutics with a broad, novel portfolio evaluating multiple targets and cancer indications. The acquisition will also add a novel scientific platform and scalable manufacturing capabilities including JCAR017, a CD19-directed CAR T currently in a program for relapsed an/or refractory diffuse large B-Cell lymphoma. The transaction has been approved by the board of directors of Celgene and Juno. We expect to complete the transaction during the first quarter of 2018, subject to customary closing conditions and the expiration of applicable waiting period under the Hart Scott Rodino Antitrust Improvements Act. The transaction is expected to be funded through a combination of existing cash, cash equivalents, marketable securities and new debt.

Financial Update

The following table summarizes net product sales, total revenue and earnings for the years ended December 31, 2017, 2016 and 2015 (dollar amounts in millions, except per share data):

	Years Ended December 31,			% Change 2017 versus 2016	% Change 2016 versus 2015
	2017	2016	2015		
Net product sales	$12,973	$11,185	$9,161	16.0%	22.1%
Total revenue	$13,003	$11,229	$9,256	15.8%	21.3%

Net income	$2,940	$1,999	$1,602	47.1%	24.8%
Diluted earnings per share	$3.64	$2.49	$1.94	46.2%	28.4%

Total net product sales for 2017 increased by approximately $1.8 billion, or 16.0%, to approximately $13.0 billion compared to the year ended December 31, 2016. The increase was comprised of net volume increases of approximately $1.5 billion, or 13.6%, and net price increases of $369 million, or 3.3%. The increase in volume was primarily driven by increased unit sales of REVLIMID®, POMALYST®/IMNOVID® and OTEZLA®. The price impact was primarily attributable to price increases in the U.S., which were partially offset by price decreases in Europe. Changes in foreign currency exchange rates, including the impact of foreign exchange hedging activity, unfavorably impacted net product sales by $98 million, or 0.9%.

Total net product sales for 2016 increased by approximately $2.0 billion, or 22.1%, to approximately $11.2 billion compared to 2015. The increase was comprised of net volume increases of $1.7 billion or 18.4% and net price increases of $415 million or 4.5%, offset in part by a $71 million, or 0.8% 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 revenue increased by approximately $1.8 billion, or 15.8%, in 2017 compared to 2016 primarily due to the continued growth in sales of REVLIMID®, POMALYST®/IMNOVID® and OTEZLA® reflecting increases of approximately $1.3 billion, or 18.7%, in the United States and $460 million, or 10.9%, in international markets.

Total revenue increased by approximately $2.0 billion, or 21.3%, in 2016 compared to 2015 primarily due to the continued growth in sales of REVLIMID®, POMALYST®/IMNOVID® and OTEZLA® reflecting increases of approximately $1.4 billion, or 25.1%, in the United States and $567 million, or 15.5%, in international markets.

In addition to the increase in total revenue discussed above, notable items impacting net income and diluted earnings per share for the years ended December 31, 2017, 2016 and 2015 are as follows (dollar amounts in millions):

		Years ended December 31,		
	Income Statement Classification	2017	2016	2015
IPR&D asset impairment charge related to GED-0301 (see Note 10*)	Research and development	$1,620	$ —	$ —
Clinical trial & development activity wind-down costs related to GED-0301 (see Note 4*)	Research and development	188	—	—
Collaboration arrangements (see Note 17*)	Research and development	833	927	1,529
Research and development asset acquisition expenses (see Note 2*)	Research and development	325	893	—
Litigation-related loss contingency accrual expense (see Note 18*)	Selling, general and administrative	315	199	—
Reduction in contingent consideration liabilities related to GED-0301 (see Note 4*)	Acquisition related (gains) charges and restructuring, net	(1,397)	—	—
Receptos acquisition charges	Acquisition related (gains) charges and restructuring, net	—	—	297
Investment impairment charges	Other income (expense), net	54	394	49
2017 Tax Act (see Note 16*)	Income tax provision	1,269	—	—

* References to Notes in this table are to the Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Results of Operations - Fiscal Years Ended December 31, 2017, 2016 and 2015
Net Product Sales and Other Revenue

Net product sales and other revenue for 2017, 2016 and 2015 were as follows (dollar amounts in millions):

REVLIMID®

			Percent Change	
2017	2016	2015	2017 versus 2016	2016 versus 2015

U.S.	$5,426	$4,417	$3,535	22.8%	25.0%
International	2,761	2,557	2,266	8.0 %	12.8%
Worldwide	$8,187	$6,974	$5,801	17.4%	20.2%

REVLIMID® net sales increased by approximately $1.2 billion, or 17.4%, to approximately $8.2 billion for 2017 compared to 2016, primarily due to increased sales in both U.S. and international markets. U.S. sales growth increased due to both price increases and, to a lesser extent, an increase in unit sales from market penetration and treatment duration of patients using REVLIMID®. In addition, unit sales increased across all international regions, primarily in Europe and Japan, driven by increased duration of use and market share gains. International volume growth was partially offset by net price decreases.

REVLIMID® net sales increased by approximately $1.2 billion, or 20.2%, to approximately $7.0 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 Newly Diagnosed Multiple Myeloma following approval in February 2015.

POMALYST®/IMNOVID®

				Percent Change	
	2017	2016	2015	2017 versus 2016	2016 versus 2015
U.S.	$1,008	$778	$592	29.6%	31.4%
International	606	533	392	13.7%	36.0%
Worldwide	$1,614	$1,311	$984	23.1%	33.2%

POMALYST®/IMNOVID® net sales increased by $303 million, or 23.1%, to approximately $1.6 billion for 2017 compared to 2016, primarily due to increased sales in the U.S. and to a lesser extent international markets. In the U.S., sales growth increased primarily due to an increase in unit sales and, to a lesser extent, price increases. In addition, unit sales increased across all international regions, primarily in Europe. Increases in market share and treatment duration contributed to the increases in U.S. and international regions. International volume growth was partially offset by net price decreases.

POMALYST®/IMNOVID® net sales increased by $327 million, or 33.2%, to approximately $1.3 billion in 2016 compared to 2015, reflecting net sales of $778 million in the U.S. and $533 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 contributed to the growth of POMALYST®/IMNOVID® net sales in international markets.

OTEZLA®

				Percent Change	
	2017	2016	2015	2017 versus 2016	2016 versus 2015
U.S.	$1,058	$904	$440	17.0%	105.5%
International	221	113	32	95.6%	253.1%
Worldwide	$1,279	$1,017	$472	25.8%	115.5%

OTEZLA® net sales increased by $262 million, or 25.8%, to approximately $1.3 billion for 2017 compared to 2016, primarily due to increased worldwide unit sales. Net sales in the U.S. were volume driven reflecting increased market share and expanding patient access. We anticipate a slowing in market growth, offset by continued market share expansion in the U.S. due to new managed care contracts, as well as increasing contributions from early launch countries in Europe, the launch in Japan, and launches subsequent to additional international approvals. International volume growth was partially offset by net price decreases.

OTEZLA® net sales increased by $545 million to approximately $1.0 billion in 2016 compared to 2015, reflecting net sales of $904 million in the U.S. and $113 million in international markets. As 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.

ABRAXANE®

				Percent Change	
	2017	2016	2015	2017 versus 2016	2016 versus 2015
U.S.	$607	$634	$653	(4.3)%	(2.9)%
International	385	339	314	13.6 %	8.0 %
Worldwide	$992	$973	$967	2.0 %	0.6 %

ABRAXANE® net sales increased by $19 million, or 2.0%, to $992 million for 2017 compared to 2016, primarily due to increases in unit sales in international markets. The increase was partially offset by decreased unit sales in the U.S. The decrease in U.S. unit sales reflects the continuing competition in breast cancer and lung cancer indications.

ABRAXANE® net sales increased by $6 million, or 0.6% to $973 million in 2016 compared to 2015. 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.

OTHER PRODUCT SALES

				Percent Change	
	2017	2016	2015	2017 versus 2016	2016 versus 2015
U.S.	$211	$248	$304	(14.9)%	(18.4)%
International	690	662	633	4.2 %	4.6 %
Worldwide	$901	$910	$937	(1.0)%	(2.9)%

All other product sales, which include IDHIFA®, VIDAZA®, azacitidine for injection, which is an authorized generic version of VIDAZA® (generic azacitidine for injection), THALOMID®, and ISTODAX®, decreased by $9 million in 2017 compared to 2016, primarily due to decreases in generic azacitidine for injection and THALOMID® net sales, which were partially offset by increases in net sales from the launch of IDHIFA® and VIDAZA® net sales.

All other product sales, decreased by $27 million in 2016 compared to 2015, primarily due to decreases in THALOMID® and generic azacitidine for injection net sales, which were partially offset by increases in VIDAZA® and ISTODAX® net sales.

Other Revenue: Other revenue decreased by $14 million to $30 million for 2017 compared to 2016. This decrease is primarily due to a reduction in royalty revenue from Novartis AG (Novartis) based upon its sales of both RITALIN® and FOCALIN XR®, both of which have been unfavorably impacted by generic competition in certain markets. Beginning in fiscal 2018, we are no longer entitled to receive royalties on RITALIN® and FOCALIN XR®.

Other revenue decreased by $51 million to $44 million for 2016 compared to 2015 primarily due to a $36 million decrease in royalty revenue from Novartis based upon its sales of both RITALIN® and FOCALIN XR®, both of which were unfavorably impacted by generic competition in certain markets.

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

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®.

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.

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

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.

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, 2017, 2016 and 2015 were as follows (in millions):

	Government Rebates	Chargebacks and Distributor Service Fees	Sales Discounts	Sales Returns and Allowances	Total
Balance as of December 31, 2014	$ 138	$ 94	$ 12	$ 10	$254
Allowances for sales during prior periods	(5)	(3)	—	1	(7)
Allowances for sales during 2015	424	542	112	15	1,093
Credits/deductions issued for prior year sales	(78)	(50)	(9)	(4)	(141)
Credits/deductions issued for sales during 2015	(254)	(441)	(103)	(5)	(803)
Balance as of December 31, 2015	$ 225	$ 142	$ 12	$ 17	$396
Allowances for sales during prior periods	20	(14)	—	(6)	—
Allowances for sales during 2016	668	764	153	17	1,602
Credits/deductions issued for prior year sales	(175)	(56)	(10)	(6)	(247)
Credits/deductions issued for sales during 2016	(367)	(646)	(139)	(4)	(1,156)
Balance as of December 31, 2016	$ 371	$ 190	$ 16	$ 18	$595
Allowances for sales during prior periods	9	(28)	—	(5)	(24)
Allowances for sales during 2017	881	1,102	193	13	2,189
Credits/deductions issued for prior year sales	(310)	(96)	(17)	(8)	(431)
Credits/deductions issued for sales during 2017	(407)	(898)	(172)	(3)	(1,480)
Balance as of December 31, 2017	$ 544	$ 270	$ 20	$ 15	$849

A comparison of provisions for allowances for sales within each of the four categories noted above for 2017 and 2016 follows:

2017 compared to 2016: Government rebate provisions increased by $202 million for 2017 compared to 2016, which was primarily due to a $122 million increase in the U.S. market and an $80 million increase in international government rebates. The increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, with $120 million due to an increase in Medicaid rebates (primarily in the managed care channel) and $2 million due to an increase in expense related to Medicare Part D Coverage Gap. The increase in international government rebates was primarily driven by higher sales volumes and increased rebate rates.

Chargebacks and distributor service fees provisions increased by $324 million for 2017 compared to 2016. Chargebacks increased by approximately $127 million and distributor service fees increased by approximately $197 million. The increase in chargebacks was primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates, including a $13 million increase related to the TRICARE program driven by higher sales volumes. The distributor service fee increase was primarily attributable to increased sales volumes and new managed care contracts effective January 1, 2017 for OTEZLA®, which accounted for $154 million of the increase, as well as a $22 million increase in commercial copayment program expense and a $14 million increase in the distributor service fee expense, both of which also were attributable to higher sales volumes.

Discount provisions increased by $40 million for 2017 compared to 2016, which was primarily due to a $37 million increase in the U.S. market and a $3 million increase in international discounts, both due to higher sales volumes. The U.S. market increase was comprised of an increase of $24 million related to REVLIMID® as well as increases related to OTEZLA® and POMALYST®.

Provisions for sales returns decreased by $3 million in 2017 compared to 2016, primarily due to a reduction in the ABRAXANE® returns reserve allowance.

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: Government rebate provisions increased by $269 million in 2016 compared to 2015, primarily due to a $121 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 million and the increase for sales of IMNOVID® in the current year due to higher rebate

rates in France was $23 million. The $148 million increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, with $108 million due to an increase in Medicaid rebates (primarily in the managed care channel) and $40 million due to an increase in expense related to Medicare Part D Coverage Gap.

Chargebacks and distributor service fees provisions increased by $211 million in 2016 compared to 2015. Chargebacks increased by approximately $140 million and distributor service fees increased by approximately $71 million. The chargeback increases were primarily due to higher sales volumes, including an $11 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 million of the increase in distributor service fees.

Discount provisions increased by $41 million in 2016 compared to 2015, primarily due to increased sales volumes. The $41 million increase consisted of a $37 million increase in the United States and a $4 million increase related to international markets. The U.S. increases included increases of $21 million for cash discounts related to REVLIMID®, $12 million related to OTEZLA® and $4 million related to POMALYST®.

Provisions for sales returns decreased by $5 million in 2016 compared to 2015, primarily due to the ABRAXANE® allowances for sales returns being $5 million higher in 2015 than in 2016 due to an increase in inventory levels held by certain distributors in 2015.

Cost of Goods Sold (excluding amortization of acquired intangible assets): Cost of goods sold and related percentages for the years ended December 31, 2017, 2016 and 2015 were as follows (dollar amounts in millions):

	2017	2016	2015
Cost of goods sold (excluding amortization of acquired intangible assets)	$461	$438	$420
Increase from prior year	$23	$18	$34
Percent increase from prior year	5.3 %	4.3 %	8.9 %
Percent of net product sales	3.6 %	3.9 %	4.6 %

Cost of goods sold (excluding amortization of acquired intangible assets) increased by $23 million to $461 million in 2017 compared to 2016. 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 3.6% for 2017 compared to 3.9% for 2016, primarily due to REVLIMID®, POMALYST® and OTEZLA®, which have lower cost, making up a higher percentage of net product sales, while sales of ABRAXANE®, VIDAZA® and generic 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 $18 million to $438 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 generic 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, 2017, 2016 and 2015 were as follows (dollar amounts in millions):

2017	2016	2015

Research and development	$5,915		$4,470		$3,697	
Increase from prior year	$1,445		$773		$1,266	
Percent increase from prior year	32.3	%	20.9	%	52.1	%
Percent of total revenue	45.5	%	39.8	%	39.9	%

Research and development expenses increased by approximately $1.4 billion to approximately $5.9 billion in 2017, compared to 2016. The increase was primarily due to an IPR&D asset impairment charge of approximately $1.6 billion as well as other one-time charges of approximately $188 million related to wind-down costs and certain development activities associated with the

discontinuation of the GED-0301 clinical trials in CD. See Note 4 of Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to the discontinuation of the Trials. In addition, there was an increase of $253 million in clinical trial and drug discovery and development activity. These increases were partially offset by a decrease of $568 million of research and development asset acquisition expenses. See Note 2 of Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to our acquisitions. Our research and development expenses may fluctuate from period-to-period based on the volume and timing of closing asset acquisitions and collaboration arrangements and associated obligations pursuant to such arrangements.

Research and development expenses increased by $773 million to $4.5 billion in 2016 compared to 2015. The increase was primarily due to $893 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 and Note 17 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to our research and development asset acquisitions and collaboration arrangements, respectively.

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

				Increase (Decrease)	
	2017	2016	2015	2017 versus 2016	2016 versus 2015
Human pharmaceutical clinical programs	$1,334	$1,136	$1,029	$198	$107
Other pharmaceutical programs	870	824	755	46	69
Charges related to GED-0301 Trials (see Note 4*)	1,808	—	—	1,808	—
Drug discovery and development	745	690	384	55	306
Collaboration arrangements (see Note 17*)	833	927	1,529	(94)	(602)
Research and development asset acquisitions (see Note 2*)	325	893	—	(568)	893
Total	$5,915	$4,470	$3,697	$1,445	$773

* References to Notes in this table are to the Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K

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 2 and 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 acquisitions and collaboration arrangements, respectively.

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.

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, 2017, 2016 and 2015 were as follows (dollar amounts in millions):

	2017		2016		2015	
Selling, general and administrative	$2,941		$2,658		$2,305	
Increase from prior year	$283		$353		$277	
Percent increase from prior year	10.6	%	15.3	%	13.7	%
Percent of total revenue	22.6	%	23.7	%	24.9	%

Selling, general and administrative expenses increased by $283 million to approximately $2.9 billion for 2017 compared to 2016. The increase was primarily due to higher litigation-related loss contingency accrual expenses incurred in 2017. During 2017, we recorded a litigation-related loss contingency accrual expense of $315 million related to the Brown Action, which represented our probable and reasonably estimable risk of loss. We reached a settlement agreement with respect to the Brown Action during the third quarter of 2017. During 2016, we recorded a $199 million litigation-related loss contingency accrual expense with respect to the lawsuit filed against us by Children's Medical Center Corporation (CMCC), which represented our probable and reasonably estimable risk of loss at that time. Subsequently, we reached a settlement agreement with CMCC during the first quarter of 2017. See Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional information related to these legal matters. Additionally, the increase was also due to an increase of $70 million in donations to independent non-profit patient assistance organizations in the U.S. and approximately a $40 million increase in selling and marketing activities.

Selling, general and administrative expenses increased by $353 million to $2.7 billion in 2016 compared to 2015. The increase was primarily due to a $199 million litigation-related loss contingency accrual expense, and approximately a $90 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.

Amortization of Acquired Intangible Assets:

	2017	2016	2015
Amortization of acquired intangible assets	$329	$459	$279
(Decrease) increase from prior year	$(130)	$180	$21
Percent increase (decrease) from prior year	(28.3)%	64.5 %	8.1 %

Amortization of intangible assets acquired as a result of business combinations is summarized below for the years ended December 31, 2017, 2016 and 2015 (in millions):

	2017	2016	2015
Avila	$10	$139	$47
Abraxis	151	152	152
Gloucester	92	92	62
Pharmion	4	4	4
Quanticel	72	72	14
Total amortization	$329	$459	$279

Amortization of acquired intangible assets decreased by $130 million to $329 million in 2017 compared to 2016. The decrease in amortization expense was primarily related to the prior year accelerated amortization expense and impairment charge to write down the technology platform asset obtained in the acquisition of Avila Therapeutics, Inc. (Avila).

Amortization of acquired intangible assets increased by $180 million to $459 million in 2016 compared to 2015. The increase in amortization expense primarily related to an $83 million impairment charge as well as $18 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.

Acquisition Related (Gains) Charges and Restructuring, net: Acquisition related charges and restructuring, net is summarized below for the years ended December 31, 2017, 2016 and 2015 (in millions):

	2017	2016	2015
Acquisition related (gains) charges, net	$(1,350)	$22	$290
Restructuring charges, net	—	16	10
Total	$(1,350)	$38	$300
Increase (decrease) from prior year	$(1,388)	$(262)	$251

Acquisition related (gains) charges and restructuring charges, net decreased by approximately $1.4 billion in 2017 to a net gain of $1,350 million. The decrease was primarily due to an approximately $1.3 billion net gain recorded in 2017 for the reduction of the Nogra Pharma Limited (Nogra) contingent liability due to the discontinuation of the GED-0301 Trials. See Note 4 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for details related to the change in fair value of the Nogra contingent consideration liability.

Acquisition related (gains) charges and restructuring, net decreased by $262 million to $38 million in 2016 compared to $300 million in 2015. The decrease was primarily due to a $297 million reduction in costs related to the acquisition of Receptos, Inc. which occurred in August 2015 and a $61 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 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 million increase in expense related to our contingent liabilities for the Quanticel Pharmaceuticals, Inc. acquisition, and a $6 million increase in restructuring charges in 2016 related to our relocation of certain operations into our two Summit, NJ locations as well as costs associated with certain headcount reductions.

Interest and Investment Income, Net: Interest and investment income, net is summarized below for the years ended December 31, 2017, 2016 and 2015 (dollar amounts in millions):

	2017	2016	2015
Interest and investment income, net	$105	$30	$31
Increase (decrease) from prior year	$75	$(1)	$3
Percentage increase (decrease) from prior year	250.0%	(3.2)%	10.7%

Interest and investment income, net which includes the net income associated with our investments in available-for-sale marketable securities, increased by $75 million to $105 million in 2017 compared to 2016 primarily due to higher investment balances and higher yields compared to the prior year.

Interest and investment income, net decreased by $1 million to $30 million in 2016 compared to 2015.

Interest Expense: Interest expense is summarized below for the years ended December 31, 2017, 2016 and 2015 (dollar amounts in millions):

	2017	2016	2015
Interest expense	$522	$500	$311
Increase from prior year	$22	$189	$135
Percentage increase from prior year	4.4 %	60.8 %	76.7 %

Interest expense increased by $22 million to $522 million in 2017 compared to 2016 primarily due to interest expense associated with the issuance of $500 million of senior notes in August 2017 and $3.000 billion of senior notes in November 2017. 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 $189 million to $500 million in 2016 compared to 2015 primarily due to interest expense associated with the issuance of $8.000 billion of senior notes in August 2015.

Other Income (Expense), Net: Other income (expense), net is summarized below for the years ended December 31, 2017, 2016 and 2015 (in millions):

	2017	2016	2015
Foreign exchange gains (losses), including foreign exchange derivative instruments not designated as hedging instruments (see Note 5*)	$21	$(2)	$(12)
Fair value adjustments of forward point amounts (see Notes 1 and 5*)	—	17	23
Celgene puts sold gains (losses) (see Notes 3 and 5*)	—	8	(10)
Premium paid on equity investment (see Note 17*)	—	(6)	—
Investment impairment charges	(54)	(394)	(49)
Gain on sale of marketable equity securities	44	—	—
Gain on sale of equity investment in Flexus Biosciences, Inc.	9	7	86
Gain on sale of LifebankUSA business (see Note 2*)	—	38	—
Other gains	4	8	10
Total other income (expense), net	$24	$(324)	$48
Increase (decrease) from prior year	$348	$(372)	$92

* References to Notes in this table are to the Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Income Tax Provision: The income tax provision increased by approximately $1.0 billion to approximately $1.4 billion for 2017 compared to 2016, primarily from the impact of applying the provisions of the 2017 Tax Act. The effective tax rate for 2017 was 31.8%, an increase of 16.1 percentage points from our effective tax rate of 15.7% for 2016. The increase in our effective tax rate was primarily due to a 29.4 percentage point increase related to the one-time tax effects of the 2017 Tax Act, which was enacted on December 22, 2017. This increase was partially offset by excess tax benefits from employee stock compensation deductions, for which our 2017 effective tax rate was reduced by 6.7 percentage points (see Note 1 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K), U.S. research and development and orphan drug tax credits, for which our 2017 effective tax rate was reduced by 1.3 percentage points, and an increase in pre-tax earnings from jurisdictions with lower statutory tax rates, all of which were partially offset by a non-recurring prior year tax benefit related to a loss on our investment in Avila. The tax benefits recognized in 2017 for U.S. research and development and orphan drug tax credits were the result of a change in estimate upon completion of a comprehensive analysis (see Note 16 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K).

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. Our future effective tax rate is expected to be materially impacted by the 2017 Tax Act, which, among other changes, reduces the U.S. corporate tax rate from 35% to 21% and introduces a new U.S. tax on certain off-shore earnings referred to as GILTI at an effective tax rate of 10.5% for tax years beginning after December 31, 2017 (increasing to 13.125% for tax years beginning after December 31, 2025). See Note 16 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for further details related to the 2017 Tax Act. Our future effective tax rate can also be materially impacted by shifts in the distribution of our pre-tax income among the jurisdictions where we operate, the timing and amount of tax benefits from employee stock compensation, payments to collaboration partners, acquisitions, divestitures, changes in tax laws, audit settlements, and many other factors which are difficult to forecast.

The income tax provision decreased by $48 million to $373 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 was 15.7%. 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 was 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).

Liquidity and Capital Resources

The following table summarizes the components of our financial condition for the years ended December 31, 2017, 2016 and 2015 (in millions):

	2017	2016	2015	Increase (Decrease) 2017 versus 2016	Increase (Decrease) 2016 versus 2015
Financial assets:					
Cash and cash equivalents	$7,013	$6,170	$4,880	$843	$1,290
Marketable securities available-for-sale	5,029	1,800	1,672	3,229	128
Total financial assets	$12,042	$7,970	$6,552	$4,072	$1,418
Debt:					
Short-term borrowings and current portion of long-term debt	$—	$501	$—	$(501)	$501
Long-term debt, net of discount	15,838	13,789	14,161	2,049	(372)
Total debt	$15,838	$14,290	$14,161	$1,548	$129
Working capital[1]	$11,980	$7,964	$7,493	$4,016	$471

[1] Includes Cash and cash equivalents, Marketable securities available-for-sale, Accounts receivable, net of allowances, 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 the current portion of 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, 2017, we held approximately $6.0 billion of these short-term funds in foreign tax jurisdictions. As a result of the 2017 Tax Act and the toll charge, we expect to have access to this cash with minimal to no additional U.S. tax impact. Therefore, we no longer consider these funds permanently reinvested offshore. 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, restrictions on distributions out of foreign tax jurisdictions 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).

Under the 2017 Tax Act, a company’s post-1986 previously untaxed foreign E&P are mandatorily deemed to be repatriated and taxed, which is also referred to as the toll charge. The toll charge is assessed regardless of whether or not a company has cash in its foreign subsidiaries and irrespective of whether the company will actually bring back its accumulated undistributed foreign earnings. However, the charge can be paid in installments over eight years. During the fourth quarter of 2017, we recorded an income tax expense of $1,890 million which represents the toll charge liability for the deemed repatriation of E&P. We have elected to pay the toll charge in installments over eight years, or through 2025. However, the toll charge liability is not discounted on our financial statements. As such, we have recorded $1,732 million and $150 million as a non-current and current income tax liability, respectively, as of December 31, 2017. In prior years, we recorded U.S. deferred tax liabilities of $317 million for certain offshore earnings that were expected to be remitted to our domestic operations. These deferred tax liabilities reduced the income tax expense recorded in the fourth quarter of 2017 for the toll charge. The remaining amounts earned overseas

were expected to be permanently reinvested outside of the United States, and therefore, no accrual for U.S. taxes was provided.

Share Repurchase Program: Since April 2009, our Board of Directors has approved an aggregate $20.5 billion common stock repurchase program of which we have approximately $822 million remaining for future repurchases as of December 31, 2017. During 2017, we used $3.9 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, commercial paper, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities (MBS), an ultra short income fund, global corporate debt securities, asset backed securities and ultra-short income fund investments. 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. See Note 6 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K. The $4.1 billion increase in cash, cash equivalents and marketable securities available-for-sale as of December 31, 2017 compared to 2016 was primarily due to approximately $5.2 billion of cash from operating activities and $611 million of net unrealized holding gains on marketable securities available-for-sale, which were partially offset by approximately $1.6 billion of net cash used in financing activities.

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. For more information related to the accounting treatment, beginning in the first quarter of 2018, for our equity investments, see Note 1 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Accounts Receivable, Net: Accounts receivable, net increased by $300 million to approximately $1.9 billion as of December 31, 2017 compared to December 31, 2016. 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 hematology and oncology products directly to principally government owned or controlled hospitals, which in turn directly deliver critical care to patients. Many of 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 $43 million to $541 million at the end of 2017 compared to 2016.

Other Current Assets: Other current assets decreased by $391 million to $388 million at the end of 2017 compared to 2016 primarily due to decreases of $347 million in the fair value of derivative instruments and $112 million in prepaid taxes, which were partially offset by $68 million of net other increases.

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 $2.0 billion. As of December 31, 2017, we had available capacity to issue up to $2.0 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 $2.0 billion, which was increased from $1.8 billion in April 2016. We extended the Credit Facility in April 2017 from April 17, 2021 to April 17, 2022. 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. As of December 31, 2017, there was no outstanding borrowing against the Credit Facility.

The Credit Facility and the Revolving Credit Agreement contain affirmative and negative covenants, including certain customary financial covenants. We were in compliance with all financial covenants as of December 31, 2017.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities increased by $466 million to approximately $2.8 billion at the end of 2017 compared to 2016. The increase was primarily due to increases of $250 million for sales adjustment accruals, $188 million of one-time charges related to GED-0301 wind-down costs associated with discontinuing the Trials and certain development activities, $92 million for clinical trials and research and development expense accruals, $73 million for accounts payable and other accruals, $64 million for derivative accruals, $39 million related to collaboration agreement accruals and $15 million for contingent consideration accruals, which includes the net change in fair value (see Note 4 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K) as well as transfers from long-term liabilities. These increases were partially offset by a $199 million litigation-related loss contingency accrual recorded in 2016 (see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K) and a decrease of $56 million for compensation related accruals.

Income Taxes Payable (Current and Non-Current): Income taxes payable increased by $2.1 billion to approximately $2.6 billion at the end of 2017 compared to 2016, primarily from the current provision for income taxes of $2.7 billion, partially offset by income tax payments of $0.5 billion and income tax receivables of $0.1 billion. See Note 16 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details related to the 2017 Tax Act.

Senior Notes: We have an aggregate of $15.850 billion principal amount of senior notes outstanding with varying maturity dates from 2019 through 2047. See Note 11 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details.

Cash flows from operating, investing and financing activities for the years ended December 31, 2017, 2016 and 2015 were as follows (in millions):

				Increase (Decrease)	
	2017	2016	2015	2017 versus 2016	2016 versus 2015
Net cash provided by operating activities	$5,246	$4,165	$2,785	$1,081	$1,380
Net cash used in investing activities	$(2,891)	$(1,002)	$(6,259)	$(1,889)	$5,257
Net cash (used in) provided by financing activities	$(1,584)	$(1,834)	$4,283	$250	$(6,117)

Operating Activities: Net cash provided by operating activities increased by approximately $1.1 billion to approximately $5.2 billion in 2017 compared to 2016. The increase in net cash provided by operating activities was primarily attributable to an increase in net income of $941 million in 2017 compared to 2016.

Net cash provided by operating activities increased by approximately $1.4 billion to approximately $4.2 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 million in 2016 compared to 2015, which included a $492 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 $196 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 million increase in change in other operating assets primarily attributable to a $298 million decrease in prepaid taxes and a $92 million increase in change in accounts payable and other operating liabilities primarily attributable to an increase of $199 million of accrued expenses related to a litigation-related loss contingency accrual as well as other balance sheet fluctuations.

Investing Activities: Net cash used in investing activities increased by approximately $1.9 billion in 2017 compared to 2016. The increase in net cash used in investing activities was primarily due to the approximately $2.5 billion of net purchases of marketable securities available-for-sale during 2017 compared to $648 million of net purchases of marketable securities available-for-sale during 2016.

Net cash used in investing activities decreased by approximately $5.3 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 approximately $7.7 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 $648 million during 2016 compared to net cash proceeds of approximately $1.9 billion from net sales of marketable securities available for sale during 2015.

Financing Activities: Net cash used in financing activities decreased by $250 million in 2017 compared to 2016. The decrease in net cash used in financing activities was primarily attributable to proceeds from the August 2017 and November 2017 debt issuances partially offset by principal repayments in August 2017 and debt redemptions in December 2017. In August 2017, we issued an additional $500 million principal amount of 2.250% senior notes due 2021 and received net cash proceeds of approximately $496 million. In August 2017, we repaid the 1.900% senior notes with a principal amount of $500 million upon maturity. In November 2017, we issued an additional $3.0 billion principal amount of senior notes consisting of $750 million principal amount of 2.750% due 2023, $1.0 billion principal amount of 3.450% due 2027 and $1.250 billion principal amount of 4.350% due 2047 and received net cash proceeds of approximately $3.0 billion. In December 2017, we paid approximately $1.4 billion to redeem all of the outstanding $1.0 billion aggregate principal amount of 2.125% senior notes and $400 million aggregate principal amount of 2.300% senior notes, each maturing in August 2018. See Note 11 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details. In addition to the debt activity, net cash used in financing activities decreased due to the approximately $3.8 billion of payments under our share repurchase program during 2017 compared to approximately $2.2 billion of payments under our share repurchase program during 2016.

Net cash used in financing activities was approximately $1.8 billion in 2016 compared to net cash provided by financing activities of approximately $4.3 billion in 2015. The approximately $6.1 billion decrease in net cash provided by financing activities was primarily attributable to the 2015 issuance of long-term debt which provided approximately $7.9 billion.

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2017 (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	$605	$3,700	$3,503	$16,857	$24,665
Operating leases	56	89	57	33	235
Other contract commitments	399	159	103	134	795
2017 Tax Act - Federal toll charge liability	150	301	301	1,130	1,882
Total	$1,210	$4,249	$3,964	$18,154	$27,577

Senior Notes: The senior note obligation amounts include future principal of $15.850 billion and interest payments for both current and non-current obligations as of December 31, 2017. See Note 11 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional details.

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 2018 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 $795 million as of December 31, 2017 primarily included $748 million in contractual obligations related to product supply contracts. In addition, we have committed to invest an aggregate $47 million in investment funds, which are callable at any time.

2017 Tax Act: Under the 2017 Tax Act, a company's post-1986 previously untaxed foreign E&P are mandatorily deemed to be repatriated and taxed, which is also referred to as the toll charge. The toll charge is assessed regardless of whether or not a company has cash in its foreign subsidiaries and irrespective of whether the company will actually bring back its accumulated undistributed foreign earnings. However, the charge can be paid in installments over eight years. During the fourth quarter of 2017, we recorded an income tax expense of $1,890 million which represents the toll charge liability for the deemed repatriation of E&P. We have elected to pay the toll charge in installments over eight years, or through 2025. However, the toll charge liability is not discounted on our financial statements. As such, we have recorded $1,732 million and $150 million as a non-current and current income tax liability, respectively, as of December 31, 2017.

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 as of December 31, 2017 and 2016 contained in this Annual Report on Form 10-K. Potential milestone payments (not including potential royalty payments) total approximately $10.7 billion, including approximately $5.6 billion contingent on the achievement of various research, development and regulatory approval milestones and approximately $5.1 billion in sales-based milestones. For additional information about our acquisitions of research and development assets and collaboration arrangements, see Note 2 and Note 17, respectively, of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

Uncertain Tax Positions: We are unable to predict the timing of tax settlements related to our obligations for uncertain tax positions as tax audits can involve complex issues and the resolution of those issues may span multiple years, particularly if subject to negotiation or litigation. Accordingly, we have not included obligations for uncertain tax positions in our table of contractual obligations (see Note 16 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 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 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®, VIDAZA® and IDHIFA® 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®.

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.

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

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.

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 some portion or all of a deferred tax asset 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. As of December 31, 2017, 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 derivative instruments are highly effective in offsetting the changes in the fair value or cash flows of hedged items. 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 Other income (expense), net in our Consolidated Statements of Income. 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.

Prior to the adoption of Accounting Standards Update No. 2017-12, "Derivatives and Hedging" (ASU 2017-12), we were required to separately measure and reflect the amount by which the hedging instrument did not offset the changes in the fair value or cash flows of hedged items, which was referred to as the ineffective amount. We assessed hedge effectiveness on a quarterly basis and recorded the gain or loss related to the ineffective portion of derivative instruments, if any, in Other income (expense), net in the Consolidated Statements of Income. Pursuant to the provisions of ASU 2017-12, we are no longer required to separately measure and recognize hedge ineffectiveness. Upon adoption of ASU 2017-12, we no longer recognize hedge ineffectiveness in our Consolidated Statements of Income, but we instead recognize the entire change in the fair value of:

- cash flow hedges included in the assessment of hedge effectiveness in Other comprehensive income (loss). The amounts recorded in Other comprehensive income (loss) will subsequently be reclassified to earnings in the same line item in the Consolidated Statements of Income as impacted by the hedged item when the hedged item affects

earnings; and

- fair value hedges included in the assessment of hedge effectiveness in the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item.

Prior to the adoption of ASU 2017-12, we excluded option premiums and forward points (excluded components) from our assessment of hedge effectiveness for our foreign exchange cash flow hedges. We recognized all changes in fair value of the excluded components in Other income (expense), net in the Consolidated Statements of Income. The amendments in ASU 2017-12 continue to allow those components to be excluded from the assessment of hedge effectiveness, which we have elected to continue to apply. Pursuant to the provisions of ASU 2017-12, we no longer recognize changes in the fair value of the excluded components in Other income (expense), net, but we instead recognize the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, within the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item.

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 and are not classified as equity method investments 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. As of December 31, 2017, we had recorded liabilities for three separate three-year performance cycles running concurrently and ending December 31, 2017, 2018 and 2019. 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 IPR&D: We have recorded goodwill, acquired intangible assets and IPR&D through acquisitions accounted for as business combinations. When identifiable intangible assets, including IPR&D 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. As of December 31, 2017, 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: As of December 31, 2017, our marketable securities available-for-sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed (MBS) securities, global corporate debt securities, asset backed securities, ultra short income-fund securities, time deposits and repurchase agreements with original maturities of greater than three months and marketable equity securities. U.S. Treasury securities include government debt instruments issued by the U.S. Department of the Treasury. U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. government sponsored enterprises. 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. Ultra short income fund includes investments in certificates of deposit, repurchase agreements, commercial paper and corporate notes. Our time deposits and repurchase agreements have original maturities greater than three months. Our repurchase agreements are collateralized by U.S. government securities, cash, bonds, commercial paper and bank certificates of deposit.

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 arrangements. 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 on the Consolidated Statements of Income.

Realized gains and losses and other than temporary impairment charges related to equity securities are included in Other income (expense), net on the Consolidated Statements of Income.

As of December 31, 2017, the principal amounts, fair values and related weighted-average interest rates of our investments in debt securities classified as marketable securities available-for-sale were as follows (dollar amounts in millions):

	Duration			
	Less than 1 Year	1 to 3 Years	3 to 5 Years	Total
Principal amount	$1,867	$1,237	$28	$3,132
Fair value	$1,868	$1,233	$29	$3,130
Weighted average interest rate	1.5 %	2.1 %	2.7 %	1.7 %

Debt Obligations

Short-Term Borrowings and Current Portion of Long-Term Debt: We had no outstanding short-term borrowing as of December 31, 2017 or December 31, 2016. The carrying value of the current portion of long-term debt outstanding as of December 31, 2017 and December 31, 2016 includes (in millions):

	2017	2016
1.900% senior notes due 2017	$ —	$501
Total short-term debt	$ —	$501

Long-Term Debt: Our outstanding senior notes with maturity dates in excess of one year after December 31, 2017 have an aggregate principal amount of $15.850 billion with varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of December 31, 2017 are summarized below (in millions):

	Principal Amount	Carrying Value
2.250% senior notes due 2019	$500	$505
2.875% senior notes due 2020	1,500	1,495
3.950% senior notes due 2020	500	514
2.250% senior notes due 2021	500	497
3.250% senior notes due 2022	1,000	1,044
3.550% senior notes due 2022	1,000	994
2.750% senior notes due 2023	750	746
4.000% senior notes due 2023	700	737
3.625% senior notes due 2024	1,000	1,001
3.875% senior notes due 2025	2,500	2,478
3.450% senior notes due 2027	1,000	991
5.700% senior notes due 2040	250	247
5.250% senior notes due 2043	400	393
4.625% senior notes due 2044	1,000	987
5.000% senior notes due 2045	2,000	1,975
4.350% senior notes due 2047	1,250	1,234
Total long-term debt	$15,850	$15,838

As of December 31, 2017, the fair value of our senior notes outstanding was $16.573 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 as of December 31, 2017 and December 31, 2016 had settlement dates within 20 months and 31 months, respectively. The spot rate components of these foreign currency forward contracts are designated as cash flow hedges and any unrealized gains or losses are reported in other comprehensive income (OCI) and reclassified to the Consolidated Statement of Income 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 transactions affect earnings. Prior to the adoption of ASU 2017-12, the forward point components of these foreign currency forward contracts were excluded from assessing effectiveness of the hedging relationship and all fair value adjustments of forward point amounts were recorded on the Consolidated Statements of Income in Other income (expense), net. Upon adoption of ASU 2017-12, we recognize in earnings the initial value of the forward point components on a straight-line basis over the life of the derivative instrument within the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item. See Note 1 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K for additional information related to the adoption of ASU 2017-12.

Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows as of December 31, 2017 and December 31, 2016 (in millions):

	Notional Amount	
Foreign Currency:	2017	2016
Australian Dollar	$61	$49
British Pound	97	199

Canadian Dollar	227	193
Euro	954	1,812
Japanese Yen	356	597
Total	$1,695	$2,850

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, 2017, 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 as of December 31, 2017 and December 31, 2016 were $885 million and $934 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, 2017 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately $260 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 as of December 31, 2017 and December 31, 2016 had settlement dates within 36 months and 48 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 as of December 31, 2017 and December 31, 2016:

	Notional Amount[1]	
	2017	2016
Foreign currency option contracts designated as hedging activity:		
Purchased Put	$3,319	$1,790
Written Call	$3,739	$2,009

[1] 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.

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 $258 million and $387 million as of December 31, 2017 and December 31, 2016, respectively, and settlement dates within 12 months and 24 months, respectively. Assuming that the December 31, 2017 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts would increase by approximately $228 million if the U.S. Dollar were to strengthen and decrease by approximately $270 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.

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2017 and 2016 and also terminated the hedging relationship by settling certain of those swap contracts during 2017. During 2017, we settled $500 million notional amount of certain swap contracts, and then subsequently entered into new $500 million notional amount swap contracts.

We terminated the hedging relationship on those certain outstanding swap contracts amounting to $500 million notional amount by settling such swap contracts. The net settlement and termination of those swap contracts resulted in a net loss of approximately $4 million. See Note 11 for additional details related to reductions of current and future interest expense. Additionally, we re-designated $500 million 10-year notional amount forward starting swaps to certain of our 30-year outstanding fixed rate notes, resulting in a gain of approximately $29 million. In addition, in 2017, we entered into and then subsequently settled, $500 million notional treasury locks on 30-year debt, resulting in a loss of approximately $2 million.

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, 2017	December 31, 2016
Forward starting interest rate swap contracts:		
Forward starting swaps with effective dates in 2017	$ —	$ 500
Forward starting swaps with effective dates in 2018	—	500

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 benchmark interest rates. Gains or losses resulting from changes in fair value of the underlying debt attributable to the hedged benchmark interest rate risk are recorded on the Consolidated Statement of Income within Interest (expense) with an associated offset to the carrying value of the notes recorded on the Consolidated Balance Sheet. Since the specific terms and notional amount of the swap are intended to match those of the debt being hedged all changes in fair value of the swap are recorded on the Consolidated Statement of Income within Interest (expense) with an associated offset to the derivative asset or liability on the Consolidated Balance Sheet. Consequently, there is no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense on the Consolidated Statement of Income. 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.

The following table summarizes the notional amounts of our outstanding interest rate swap contracts as of December 31, 2017 and December 31, 2016:

	Notional Amount	
	2017	2016
Interest rate swap contracts entered into as fair value hedges of the following fixed-rate senior notes:		
3.875% senior notes due 2025	$200	$200
3.450% senior notes due 2027	250	—
Total	$450	$200

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2017 and 2016 and also terminated the hedging relationship by settling certain of those swap contracts during 2017 and 2016. In 2017, we terminated the hedging relationship on certain outstanding swap contracts amounting to $200 million notional amount by settling such swap contracts. In July 2016, we terminated the hedging relationship on all of our then outstanding swap contracts, amounting to $3.6 billion notional amount, by settling such swap contracts. The settlement of swap contracts resulted in the receipt of net proceeds of $3 million and $196 million during the years ended December 31, 2017 and 2016, respectively, which are accounted for as a reduction of current and future interest

expense associated with these notes. See Note 11 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 as of December 31, 2017 would have reduced the aggregate fair value of our net payable by $1.3 billion. A one percentage point decrease as of December 31, 2017 would have increased the aggregate fair value of our net payable by $1.5 billion.

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

Celgene Corporation:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Celgene Corporation and subsidiaries (the Company) as of December 31, 2017 and 2016, 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, 2017, the related notes, and the consolidated financial statement schedule, "Schedule II - Valuation and Qualifying Accounts" (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 7, 2018 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, on January 1, 2017 the Company has adopted on a prospective basis FASB Accounting Standards Update No. 2016-09, "Compensation-Stock Compensation," which requires that excess tax benefits and tax deficiencies that arise upon vesting or exercise of share-based payments be recognized as income tax benefits and expenses in the income statement.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 1986.

Short Hills, New Jersey

February 7, 2018

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Dollars in millions, except per share amounts)

	December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$7,013	$6,170
Marketable securities available-for-sale	5,029	1,800
Accounts receivable, net of allowances of $36 and $31 as of December 31, 2017 and 2016, respectively	1,921	1,621
Inventory	541	498
Other current assets	388	779
Total current assets	14,892	10,868
Property, plant and equipment, net	1,070	930
Intangible assets, net	8,436	10,392
Goodwill	4,866	4,866
Other non-current assets	877	1,030
Total assets	$30,141	$28,086
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowings and current portion of long-term debt	$—	$501
Accounts payable	305	247
Accrued expenses and other current liabilities	2,523	2,115
Income taxes payable	84	41
Current portion of deferred revenue	75	55
Total current liabilities	2,987	2,959
Deferred revenue, net of current portion	34	28
Income taxes payable	2,490	420
Deferred income tax liabilities	1,327	—
Other non-current tax liabilities	—	2,519
Other non-current liabilities	544	1,771
Long-term debt, net of discount	15,838	13,789
Total liabilities	23,220	21,486
Commitments and Contingencies (Note 18)		
Stockholders' Equity:		
Preferred stock, $.01 par value per share, 5.0 million shares authorized; none outstanding as of December 31, 2017 and 2016, respectively	—	—
Common stock, $.01 par value per share, 1,150.0 million shares authorized; issued 971.7 million and 954.1 million shares as of December 31, 2017 and 2016, respectively	10	10
Common stock in treasury, at cost; 212.4 million and 175.5 million shares as of December 31, 2017 and 2016, respectively	(20,243)	(16,281)
Additional paid-in capital	13,806	12,378
Retained earnings	13,061	10,074
Accumulated other comprehensive income	287	419
Total stockholders' equity	6,921	6,600
Total liabilities and stockholders' equity	$30,141	$28,086

See accompanying Notes to Consolidated Financial Statements

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CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(In millions, except per share amounts)

	Years Ended December 31,		
	2017	2016	2015
Revenue:			
Net product sales	$12,973	$11,185	$9,161
Other revenue	30	44	95
Total revenue	13,003	11,229	9,256
Expenses:			
Cost of goods sold (excluding amortization of acquired intangible assets)	461	438	420
Research and development	5,915	4,470	3,697
Selling, general and administrative	2,941	2,658	2,305
Amortization of acquired intangible assets	329	459	279
Acquisition related (gains) charges and restructuring, net	(1,350)	38	300
Total costs and expenses	8,296	8,063	7,001
Operating income	4,707	3,166	2,255
Other income and (expense):			
Interest and investment income, net	105	30	31
Interest (expense)	(522)	(500)	(311)
Other income (expense), net	24	(324)	48
Income before income taxes	4,314	2,372	2,023
Income tax provision	1,374	373	421
Net income	$2,940	$1,999	$1,602
Net income per share:			
Basic	$3.77	$2.57	$2.02
Diluted	$3.64	$2.49	$1.94
Weighted average shares:			
Basic	779.2	777.2	792.2
Diluted	808.7	803.3	824.9

See accompanying Notes to Consolidated Financial Statements

CELGENE CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Dollars in millions)

	Years Ended December 31,		
	2017	2016	2015
Net income	$ 2,940	$ 1,999	$ 1,602
Other comprehensive income (loss):			
Foreign currency translation adjustments	70	(26)	(26)
Pension liability adjustment	16	(24)	2
Net unrealized (losses) gains related to cash flow hedges:			
Unrealized holding (losses) gains	(434)	145	411
Tax benefit (expense)	6	(13)	7
Unrealized holding (losses) gains, net of tax	(428)	132	418
Reclassification adjustment for (gains) included in net income	(178)	(300)	(349)
Tax (benefit)	(3)	(3)	(2)
Reclassification adjustment for (gains) included in net income, net of tax	(181)	(303)	(351)
Excluded component related to cash flow hedges:			
Amortization of excluded component (losses)	(15)	—	—
Reclassification of realized excluded component losses to net income	18	—	—
	3	—	—

Reclassification adjustment for losses included in net income			
Net unrealized gains (losses) on marketable securities available for sale:			
Unrealized holding gains (losses)	611	(563)	(315)
Tax (expense) benefit	(216)	203	110
Unrealized holding gains (losses), net of tax	395	(360)	(205)
Reclassification adjustment for losses included in net income	37	358	23
Tax (benefit)	(14)	(126)	(8)
Reclassification adjustment for losses included in net income, net of tax	23	232	15
Total other comprehensive (loss)	(102)	(349)	(147)
Comprehensive income	$ 2,838	$ 1,650	$ 1,455

See accompanying Notes to Consolidated Financial Statements

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

	Years Ended December 31,		
	2017	2016	2015
Cash flows from operating activities:			
Net income	$2,940	$1,999	$1,602
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	134	121	115
Amortization	337	384	287
Deferred income taxes	(1,330)	(344)	(33)
Impairment charges	1,679	489	49
Change in value of contingent consideration	(1,350)	21	(8)
(Gain) on sale of business	—	(38)	—
Net (gain) on sale of investments	(61)	(7)	(84)
Share-based compensation expense	644	606	577
Share-based employee benefit plan expense	34	40	35
Derivative instruments	72	169	(25)
Other, net	(24)	(10)	26
Change in current assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(236)	(222)	(305)
Inventory	(42)	(55)	(51)
Other operating assets	(73)	94	(326)
Accounts payable and other operating liabilities	273	619	527
Payment of contingent consideration	—	(9)	—
Income tax payable	2,229	301	362
Deferred revenue	20	7	37
Net cash provided by operating activities	5,246	4,165	2,785
Cash flows from investing activities:			
Proceeds from sales of marketable securities available for sale	5,968	633	3,800
Purchases of marketable securities available for sale	(8,478)	(1,281)	(1,889)
Payments for acquisition of businesses, net of cash acquired	—	—	(7,695)
Capital expenditures	(279)	(236)	(286)
Proceeds from sales of investment securities	20	15	92
Purchases of investment securities	(95)	(132)	(273)
Other investing activities	(27)	(1)	(8)
Net cash used in investing activities	(2,891)	(1,002)	(6,259)
Cash flows from financing activities:			
Payment for treasury shares	(3,833)	(2,160)	(3,257)
Proceeds from short-term borrowing	—	100	6,111
Principal repayments on short-term borrowing	—	(100)	(6,213)
Proceeds from the issuance of long-term debt	3,468	—	7,913
Repayments of long-term debt	(1,904)	—	(514)
Net proceeds (payments) from common equity put options	—	8	(9)
Payment of contingent consideration	—	(41)	—
Net proceeds from share-based compensation arrangements	685	359	252
Net cash (used in) provided by financing activities	(1,584)	(1,834)	4,283
Effect of currency rate changes on cash and cash equivalents	72	(39)	(51)

Net increase in cash and cash equivalents	843	1,290	758
Cash and cash equivalents at beginning of period	6,170	4,880	4,122
Cash and cash equivalents at end of period	$7,013	$6,170	$4,880

See accompanying Notes to Consolidated Financial Statements

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

	Years Ended December 31,		
	2017	2016	2015
Supplemental schedule of non-cash investing and financing activity:			
Fair value of contingent consideration issued in business combinations	$—	$—	$166
Change in net unrealized (gain) loss on marketable securities available for sale	(611)	563	315
Investment in Human Longevity, Inc. common stock	—	40	—
Investment in Celularity, Inc. common stock	22	—	—
Supplemental disclosure of cash flow information:			
Interest paid	$539	$527	$243
Income taxes paid	475	373	361

See accompanying Notes to Consolidated Financial Statements

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

Years Ended December 31, 2017, 2016 and 2015	Common Stock	Treasury Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
Balances as of December 31, 2014	$ 9	$(10,699)	$ 9,827	$ 6,473	$ 915	$ 6,525
Net income				1,602		1,602
Other comprehensive (loss)					(147)	(147)
Exercise of stock options and conversion of restricted stock units	—	(135)	395			260
Shares purchased under share repurchase program		(3,257)				(3,257)
Issuance of common stock for employee benefit plans		39	18			57
Expense related to share-based compensation			577			577
Income tax benefit upon exercise of stock options			302			302
Balances as of December 31, 2015	$ 9	$(14,052)	$ 11,119	$ 8,075	$ 768	$ 5,919
Net income				1,999		1,999
Other comprehensive (loss)					(349)	(349)
Exercise of stock options and conversion of restricted stock units	1	(105)	453			349
Shares purchased under share repurchase program		(2,160)				(2,160)
Issuance of common stock for employee benefit plans		36	15			51
Expense related to share-based compensation			606			606
Income tax benefit upon exercise of stock options			185			185
Balances as of December 31, 2016	$ 10	$(16,281)	$ 12,378	$ 10,074	$ 419	$ 6,600
Net income				2,940		2,940
Other comprehensive (loss)					(102)	(102)
Exercise of stock options and conversion of restricted stock units	—	(83)	776			693
Shares purchased under share repurchase program		(3,911)				(3,911)
Issuance of common stock for employee benefit plans		32	8			40
Expense related to share-based compensation			644			644
Adoption of ASU 2016-09 and ASU 2017-12 (Note 1)				47	(30)	17
Balances as of December 31, 2017	$ 10	$(20,243)	$ 13,806	$ 13,061	$ 287	$ 6,921

See accompanying Notes to Consolidated Financial Statements

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®), THALOMID® (sold as THALOMID® or Thalidomide Celgene® outside of the U.S.) and IDHIFA®. IDHIFA® was approved by the U.S. Food and Drug Administration (FDA) in August 2017 for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) or (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved diagnostic test. We began recognizing revenue related to IDHIFA® during the third quarter of 2017. 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, 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 derivative instruments are highly effective in offsetting the changes in the fair value or cash flows of hedged items. 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 Other income (expense), net in our Consolidated Statements of Income. 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.

Prior to the adoption of Accounting Standards Update No. 2017-12, "Targeted Improvements to Accounting for Hedging Activities" (ASU 2017-12), we were required to separately measure and reflect the amount by which the hedging instrument did not offset the changes in the fair value or cash flows of hedged items, which was referred to as the ineffective amount. We assessed hedge effectiveness on a quarterly basis and recorded the gain or loss related to the ineffective portion of derivative instruments, if any, in Other income (expense), net in the Consolidated Statements of Income. Pursuant to the provisions of ASU 2017-12, we are no longer required to separately measure and recognize hedge ineffectiveness. Upon adoption of ASU 2017-12, we no longer recognize hedge ineffectiveness in our Consolidated Statements of Income, but we instead recognize the entire change in the fair value of:

- cash flow hedges included in the assessment of hedge effectiveness in Other comprehensive income (loss). The amounts recorded in Other comprehensive income (loss) will subsequently be reclassified to earnings in the same line item in the Consolidated Statements of Income as impacted by the hedged item when the hedged item affects earnings; and

- fair value hedges included in the assessment of hedge effectiveness in the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item.

Prior to the adoption of ASU 2017-12, we excluded option premiums and forward points (excluded components) from our assessment of hedge effectiveness for our foreign exchange cash flow hedges. We recognized all changes in fair value of the excluded components in Other income (expense), net in the Consolidated Statements of Income. The amendments in ASU 2017-12 continue to allow those components to be excluded from the assessment of hedge effectiveness, which we have elected to continue to apply. Pursuant to the provisions of ASU 2017-12, we no longer recognize changes in the fair value of the excluded components in Other income (expense), net, but we instead recognize the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, within the same line item in the Consolidated Statements of Income that is used to present the earnings effect of the hedged item.

Cash, Cash Equivalents and Marketable Securities Available for Sale: We invest our excess cash primarily in money market funds, repurchase agreements, time deposits, commercial paper, U.S. Treasury securities, U.S. government-sponsored agency mortgage-backed securities (MBS), an ultra short income fund, 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 in the Consolidated Statements of Income.

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, commercial paper, U.S. Treasury securities, U.S. government-sponsored agency MBS, an ultra short income fund,

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 hematology and oncology products directly to principally government owned or controlled hospitals, which in turn directly deliver critical care to patients. Many of 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 net realizable value, 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.

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. As of December 31, 2017, the carrying value of pre-approval inventory was not material.

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.