

CELGENE CORP /DE/  
Form 10-K  
February 26, 2019

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

(Mark one)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2018

or

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

07901

(Zip Code)

(Address of principal executive offices)  
(908) 673-9000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Name of each exchange on which registered

Common Stock, par value \$.01 per share NASDAQ Global Select Market

Contingent Value Rights NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

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  No

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  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes  No

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.

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	Accelerated	Non-accelerated	Smaller reporting	Emerging growth
filer <input checked="" type="checkbox"/>	filer <input type="checkbox"/>	filer <input type="checkbox"/>	company <input type="checkbox"/>	company <input type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2018, the last business day of the registrant's most recently completed second quarter, was \$55,804,979,945 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

There were 702,164,345 shares of Common Stock outstanding as of February 21, 2019.

**Documents Incorporated by Reference**

Specified portions of the registrant's proxy statement, which will be filed with the Commission pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2018 in connection with the registrant's 2019 Annual Meeting of Stockholders, are incorporated by reference into Part III of this annual report on Form 10-K.

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

Item No.		Page
<u>Part I</u>		
<u>1.</u>	<u>Business</u>	<u>1</u>
<u>1A.</u>	<u>Risk Factors</u>	<u>16</u>
<u>1B.</u>	<u>Unresolved Staff Comments</u>	<u>32</u>
<u>2.</u>	<u>Properties</u>	<u>32</u>
<u>3.</u>	<u>Legal Proceedings</u>	<u>33</u>
<u>4.</u>	<u>Mine Safety Disclosures</u>	<u>33</u>
<u>Part II</u>		
<u>5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>34</u>
<u>6.</u>	<u>Selected Financial Data</u>	<u>35</u>
<u>7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>36</u>
<u>7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>58</u>
<u>8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>62</u>
<u>9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>135</u>
<u>9A.</u>	<u>Controls and Procedures</u>	<u>135</u>
<u>9B.</u>	<u>Other Information</u>	<u>137</u>
<u>Part III</u>		
<u>10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>137</u>
<u>11.</u>	<u>Executive Compensation</u>	<u>137</u>
<u>12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>137</u>
<u>13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>137</u>
<u>14.</u>	<u>Principal Accountant Fees and Services</u>	<u>137</u>
<u>Part IV</u>		
<u>15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>138</u>
<u>16.</u>	<u>Form 10-K Summary</u>	<u>141</u>
	<u>Signatures</u>	<u>142</u>

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.

On January 2, 2019, we entered into a definitive merger agreement with Bristol-Myers Squibb Company (Bristol-Myers Squibb) under which Bristol-Myers Squibb will acquire Celgene in a cash and stock transaction with an equity value of approximately \$74 billion, based on the closing price of Bristol-Myers Squibb shares of \$52.43 on January 2, 2019, subject to the terms and conditions set forth therein. The transaction is subject to approval by Bristol-Myers Squibb and Celgene shareholders and the satisfaction of customary closing conditions and regulatory approvals. Bristol-Myers Squibb and Celgene expect to complete the transaction in the third quarter of 2019. See Part I, Item 1A, “Risk Factors,” Part II, Item 7, “Management's Discussion and Analysis of Financial Condition and Results of Operations,” and Note 22 of the Notes to Consolidated Financial Statements included in this report for additional information regarding the transaction.

Our primary commercial stage products include REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, OTEZLA<sup>®</sup>, ABRAXANE<sup>®</sup>, and VIDAZA<sup>®</sup>.

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 product candidates. Our clinical trial activity includes trials across the disease areas of hematology, oncology, and inflammation and immunology. REVLIMID<sup>®</sup> is being evaluated in phase III trials covering a range of hematological malignancies that include lymphomas. In July 2018, the phase III trial (AUGMENT<sup>™</sup>) for REVLIMID<sup>®</sup> in combination with rituximab (R<sup>2</sup>), for the treatment of relapsed and/or refractory follicular or marginal zone lymphoma achieved its primary endpoint. In December 2018, we submitted a U.S. supplemental New Drug Application (NDA) for REVLIMID<sup>®</sup> in combination with rituximab in relapsed and/or refractory indolent non-Hodgkin lymphoma (NHL) and in January 2019 we submitted an application with the European Medicines Agency (EMA) for approval in Europe. Also, within hematological malignancies, POMALYST<sup>®</sup> is in phase III and post-approval trials for relapsed and/or refractory multiple myeloma (RRMM). In solid tumors, ABRAXANE<sup>®</sup> is currently being investigated in pancreatic cancer, breast and non-small cell lung cancers. In inflammation and immunology in 2018, we submitted a U.S. supplemental NDA and Japan NDA for OTEZLA<sup>®</sup> in Behçet's disease following positive results from the phase III trial (RELIEF<sup>™</sup>). Patients with active Behçet's disease showed statistically significant reductions in oral ulcers with OTEZLA<sup>®</sup> when compared to placebo. Also in 2018, the phase IIIb study (STYLE<sup>™</sup>) for OTEZLA<sup>®</sup> in patients with moderate to severe scalp psoriasis showed statistically significant improvement of the Scalp Physician's Global Assessment (ScPGA) response compared with placebo. OTEZLA<sup>®</sup> is also being evaluated in a phase III trial in pediatric psoriasis (SPROUT<sup>®</sup>), while continuing to be studied in psoriatic arthritis and plaque psoriasis.

We also have a growing number of potential products in phase III trials or that have completed phase III across multiple diseases. In the inflammation and immunology therapeutic area, we completed two phase III trials (RADIANCE<sup>™</sup> and SUNBEAM<sup>™</sup>) for ozanimod in relapsing multiple sclerosis (RMS). Both RADIANCE<sup>™</sup> and SUNBEAM<sup>™</sup> achieved their primary endpoints in reducing the annualized relapse rate in patients with RMS. Enrollment is currently ongoing for the phase III TRUENORTH<sup>™</sup> trial in ulcerative colitis (UC) and the phase III YELLOWSTONE<sup>™</sup> trial in Crohn's Disease (CD). In hematology, we submitted a U.S. NDA for fedratinib for the treatment of patients with myelofibrosis in January 2019. In June and July 2018, Celgene and Acceleron Pharma, Inc. (Acceleron) announced that luspatcept achieved all primary and key secondary endpoints in the phase III

MEDALIST™ and BELIEVE™ trials in patients with low-to-intermediate risk myelodysplastic syndromes (MDS) and transfusion-dependent beta-thalassemia, respectively. In collaboration with bluebird bio, the pivotal study (KarMMa™) evaluating bb2121 in RRMM is ongoing and enrollment was completed in the fourth quarter. The clinical program evaluating bb2121 in earlier lines of multiple myeloma (MM) is also advancing. In the second quarter of 2018 we initiated the pivotal TRANSCEND WORLD trial evaluating liso-cel (lisocabtagene maraleucel) (JCAR017) in relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL). Phase III trials are also underway for CC-486 in MDS, acute myeloid leukemia (AML), and angioimmunoblastic T-Cell lymphoma (AITL). In solid tumors, we are supporting a phase III study of marizomib in newly diagnosed glioblastoma, sponsored by the European Organization for Research and the Treatment of Cancer (EORTC) in collaboration with the Canadian Cancer Trials Group (CCTG). In 2018, our partner BeiGene, Ltd. (BeiGene) initiated phase III trials for tislelizumab (BGB-A317) in 1L hepatocellular carcinoma, 2L/3L hepatocellular carcinoma, and 2L/3L non-small cell lung cancer.

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



POMALYST®/IMNOVID® (pomalidomide)<sup>1</sup>: 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
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	- European Union - Other international markets
RRMM for patients who have received REVLIMID® and bortezomib	- Japan

<sup>1</sup> 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	- United States - Japan - Other international markets
Adult patients with active psoriatic arthritis	- European Union
Adult patients with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy	- European Union
Psoriasis	- United States - Other international markets
Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	- European Union
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	- United States
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.	- 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)	- United States
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	- European Union
NSCLC	- Other international markets
Pancreatic Cancer	- Japan
Metastatic adenocarcinoma of the pancreas, a form of pancreatic cancer, as first line treatment in combination with gemcitabine	- United States
Unresectable pancreatic cancer	- European Union
Gastric Cancer	- Other international markets
	- Japan
	- Japan

VIDAZA® (azacitidine for injection): VIDAZA® is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. 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
Intermediate-2 and high-risk MDS	- European Union
MDS	- Other international markets
Chronic myelomonocytic leukemia with 10% to 29% marrow blasts without myeloproliferative disorder	- Japan
	- European Union
	- Other

AML with 20% to 30% blasts and multi-lineage dysplasia

international  
markets  
- European Union  
- Other  
international  
markets

Acute myeloid leukemia with >30% bone marrow blasts according to the World Health Organization (WHO) classification in patients aged 65 years or older who are not eligible for haematopoietic stem cell transplantation

- European Union

REVLIMID® and POMALYST® are distributed in the United States primarily through contracted pharmacies under the REVLIMID® Risk Evaluation and Mitigation Strategy (REMS) and POMALYST REMS® programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID® and POMALYST®. Internationally, REVLIMID® 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<sup>®</sup>, ABRAXANE<sup>®</sup> and VIDAZA<sup>®</sup> are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>.

## PRECLINICAL AND CLINICAL-STAGE PIPELINE

Our preclinical and clinical-stage pipeline of new product candidates includes small molecules, biologics and cell therapies. These product candidates are at various stages of preclinical and clinical development. Below we describe our significant clinical programs for new indications for our existing products, as well as new product candidates.

**Immune-Inflammatory Diseases:** OTEZLA<sup>®</sup> (apremilast) a novel PDE4 inhibitor, was submitted for approval to the U.S. Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for the treatment of oral ulcers associated with Behçet's disease, and is being studied in phase III trials for pediatric psoriasis and mild to moderate plaque psoriasis, phase IIIb trials in scalp psoriasis and moderate to severe genital psoriasis and continues to be studied in phase IV trials in psoriatic arthritis and plaque psoriasis. 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 phase III trials in UC and CD. Other potential oral therapies include iberdomide (CC-220), a CELMoD<sup>®</sup> in development for systemic lupus erythematosus (SLE) and CC-90001, a JNK inhibitor in development for idiopathic pulmonary fibrosis. Additionally, we are evaluating RPC4046, a monoclonal antibody against IL-13 in eosinophilic esophagitis.

A phase Ib trial in psoriasis patients is underway with CC-90006, an injectable PD-1 agonist antibody for autoimmune disorders. In Inflammation and Immunology, phase I trials were initiated evaluating CC-92252 an IL-2 mutein Fc protein and CC-99677 an MK2 inhibitor.

**Myeloid Diseases:** In collaboration with Acceleron, we are developing luspatercept for patients with myeloid diseases. In June and July 2018, Celgene and Acceleron announced that luspatercept achieved all primary and key secondary endpoints in the phase III MEDALIST<sup>™</sup> and BELIEVE<sup>™</sup> trials in patients with low-to-intermediate risk MDS and transfusion-dependent beta-thalassemia, respectively. In addition, the phase III COMMANDS<sup>™</sup> front-line trial evaluating luspatercept in erythropoiesis-stimulating agent (ESA)-naïve, very low, low or intermediate risk MDS patients initiated in the third quarter. The phase II BEYOND<sup>™</sup> trial in non-transfusion dependent beta-thalassemia and the phase II trial in myelofibrosis are currently enrolling.

**Epigenetics:** The current insights into molecular regulation of genetic information (Epigenetics) have the potential to transform human diseases. We currently market three epigenetic modifiers, VIDAZA<sup>®</sup>, ISTODAX<sup>®</sup> and IDHIFA<sup>®</sup>. 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<sup>®</sup> combined with standard induction chemotherapy (7+3 regimen) in patients with newly diagnosed AML with an isocitrate dehydrogenase (IDH)-1 or IDH-2 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 Therapeutics, Inc. (FORMA), are in phase I dose escalation trials under investigation in NHL, solid tumors and acute leukemia indications.

**Protein Homeostasis:** We are currently developing novel CELMoD<sup>®</sup> compounds to address unmet needs in myeloma, AML, lymphoma and lupus. These assets have been developed based on our scientific understanding of Cereblon-mediated protein homeostasis and are differentiated from previous compounds (such as thalidomide, lenalidomide and pomalidomide) based on their enhanced speed and efficiency of degrading critical substrate proteins

using Cereblon as a tool to achieve this degradation. Iberdomide (CC-220) is a CELMoD<sup>®</sup> compound currently being evaluated in a phase I/II trial in patients with RRMM and a phase II trial in patients with SLE. CC-90009, whose activity is related to the depletion of the novel substrate GSPT1 is currently in phase I in patients with relapsed or refractory AML. CC-92480 is a novel CELMoD<sup>®</sup> with a differentiated preclinical profile, currently being investigated in a phase I trial in patients with RRMM. In addition, an Investigational New Drug (IND) application and a Clinical Trial Application (CTA) were submitted in December 2018 for a novel CELMoD<sup>®</sup> in development for NHL.

Immuno-Oncology: bb2121, a B-cell maturation antigen (BCMA) chimeric antigen receptor (CAR) T cell therapy, is being developed in collaboration with bluebird bio. The pivotal KarMMa<sup>™</sup> study in RRMM is currently ongoing. Also in collaboration with bluebird bio, bb21217, a second anti-BCMA CAR T cell therapy, is currently in phase I development in RRMM. JCARH125, a BCMA CAR T cell therapy, being developed by Juno Therapeutics, a Celgene Company, is in a phase I trial (EVOLVE) in patients with RRMM. Liso-cel (JCAR017), an anti-CD19 CAR T cell therapy is being developed in patients with NHL, including the ongoing pivotal TRANSCEND trial in 3L DLBCL and the TRANSFORM trial in patients with 2L transplant-eligible DLBCL. In addition, the pivotal phase II portion of the phase I/II trial (TRANSCEND CLL-004) in patients with relapsed or refractory chronic lymphocytic leukemia initiated in January 2019.

In addition to the BCMA-targeted CAR T cell therapies in development, our BCMA campaign in MM includes CC-93269, a T cell engager currently in a phase I trial in RRMM and an antibody drug conjugate (ADC) in collaboration with Sutro Biopharma.

Our anti-CD47 antibody targeting macrophage activity, CC-90002, is currently in phase I trials being evaluated for the treatment of NHL and we are initiating a phase I study in solid tumors with CC-95251, a monoclonal antibody directed against SIRP in the macrophage activity pathway.

A number of additional programs from our collaboration partners are in phase I clinical testing in multiple solid tumor indications, including JTX-2011, an ICOS-agonist, (Jounce Therapeutics, Inc), AG-270, a MAT2a inhibitor (Agiros), GEM-333, a bispecific antibody directed against CD33 (GEMoAB), Etigilmab (OncoMed), an anti-TIGIT antibody and MSC-1, a leukemia factor inhibitor (Northern Biologics). TRPH-222 (Triphase), a CD-22 ADC, is also being investigated in a phase I study in NHL.

## PRODUCT DEVELOPMENT

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

### Phase I Clinical Trials

Phase I clinical trials begin when regulatory agencies allow initiation of clinical investigation of a new drug or product candidate and usually involve up to 80 healthy volunteers or subjects. These trials study a drug's safety profile and may include a preliminary determination of a drug or product candidate's safe dosage range. The phase I clinical trial also determines how a drug is absorbed, distributed, metabolized and excreted by the body, and therefore the potential duration of its action. Phase I clinical trials generally take from one to three years to complete.

### Phase II Clinical Trials

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

### Phase III Clinical Trials

Phase III clinical trials are typically controlled multi-center trials that involve a larger target patient population that normally consists of 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 (EU), 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 product candidates in various areas of research are outlined in the following table:

Area of Research		Status <sup>1</sup>	Entered Current Status
<b>Multiple Myeloma (MM)</b>			
IMiD: REVLIMID <sup>®</sup>	RRMM	Post-approval research	2006
	Newly diagnosed transplant ineligible	Post-approval research	2015
	Newly diagnosed multiple myeloma (NDMM) post-ASCT maintenance	Post-approval research	2017
IMiD: POMALYST <sup>®</sup> /IMNOVID <sup>®</sup>	RRMM	Post-approval research	2013
IMiD: THALOMID <sup>®</sup> /Thalidomide Celgene <sup>®</sup>	NDMM	Post-approval research	2006
BCMA CAR T: (bb2121) <sup>3</sup>	RRMM	Phase II/Pivotal	2017
BCMA CAR T: (bb21217) <sup>3</sup>	RRMM	Phase I	2017
BCMA CAR T: (JCARH125)	RRMM	Phase I	Q1 2018
CELMoD <sup>®</sup> : CC-220	RRMM	Phase I/II	2016
CELMoD <sup>®</sup> : CC-92480	RRMM	Phase I	2017
BCMA TCE: CC-93269	RRMM	Phase I	Q2 2018
<b>Myelodysplastic Syndromes (MDS)</b>			
DNMT inhibitor: VIDAZA <sup>®</sup>	MDS	Post-approval research	2004
IMiD: REVLIMID <sup>®</sup>	Deletion 5q	Post-approval research	2005
DNMT inhibitor: CC-486	Lower-risk	Phase III	2013
	Post hypomethylating agent (HMA) failure	Phase II	2015
BET inhibitor: FT-1101	MDS	Phase I	2015
TGF- inhibitor: luspatercept (ACE-536) <sup>4</sup>	MDS	Phase III	2016
<b>Acute Myeloid Leukemia (AML)</b>			
DNMT inhibitor: VIDAZA <sup>®</sup>	AML (20%-30% blasts) (EU)	Post-approval research	2008
	AML (>30% blasts) (EU)	Post-approval research	2015
BET inhibitor: FT-1101	AML	Phase I	2015
IDH2 inhibitor: IDHIFA <sup>®</sup>	AML	Post-approval research	2017
CELMoD <sup>®</sup> : CC-90009	Relapsed refractory AML	Phase I	2016
DNMT inhibitor: CC-486	Post-induction AML maintenance	Phase III	2013
CD3xCD33: GEM333	AML	Phase I	Q2 2018
<b>Lymphoma</b>			
IMiD: REVLIMID <sup>®</sup>	Mantle cell lymphoma: Relapsed and/or refractory (US)	Post-approval research	2013 2016

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Mantle cell lymphoma: Relapsed and/or refractory (EU)	Post-approval research	
Diffuse large B-cell (ABC-subtype): first line	Phase III	2015
Indolent lymphoma: Relapsed and/or refractory	Regulatory submission	Q4 2018
Adult T-cell leukemia-lymphoma (Japan)	Post-approval research	2017

7

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Area of Research		Status <sup>1</sup>	Entered Current Status
HDAC inhibitor: ISTODAX <sup>®</sup>	Cutaneous T-cell lymphoma (US) <sup>5</sup>	Post-approval research	2009
	Peripheral T-cell lymphoma: Relapsed and/or refractory (US) <sup>5</sup>	Post-approval research	2011
	Peripheral T-cell lymphoma: Relapsed and/or refractory (Japan)	Post-approval research	2017
	Peripheral T-cell lymphoma: first-line	Phase III	2013
CELMoD <sup>®</sup> : avadomide (CC-122)	Diffuse large B-cell lymphoma	Phase I	2014
	Indolent lymphoma: Relapsed and/or refractory	Phase I	2014
DNMT inhibitor: CC-486	Diffuse large B-cell lymphoma	Phase I	2015
	AITL	Phase III	Q4 2018
Liso-cel (CD19 CAR T) JCAR017	Aggressive large B-cell lymphoma: Relapsed and/or refractory	Phase I/II Pivotal	2015
Anti-CD47 antibody: CC-90002	NHL	Phase I	2015
BET inhibitor: CC-90010	NHL	Phase I	2017
Chronic Lymphocytic Leukemia (CLL)			
Liso-cel (CD19 CAR T) JCAR017	Relapsed and/or refractory CLL	Phase I/II	Q1 2018
Beta Thalassemia			
TGF- inhibitor: luspatercept (ACE-536) <sup>4</sup>	Beta-thalassemia	Phase III	2016
Myelofibrosis			
TGF- inhibitor: luspatercept (ACE-536) <sup>4</sup>	Myelofibrosis	Phase II	2017
JAK2 kinase inhibitor: fedratinib	Myelofibrosis	Regulatory submission	Q1 2019
Solid Tumors			
nab-paclitaxel: ABRAXANE <sup>®</sup>	Breast: Metastatic	Post-approval research	2005
	Non-small cell lung: Advanced (first-line)	Post-approval research	2012
	Pancreatic: Metastatic (first-line)	Post-approval research	2013
	Pancreatic: Adjuvant	Phase III	2014
	Gastric: Metastatic (Japan) <sup>6</sup>	Post-approval research	2013
Proteasome inhibitor: Marizomib	Glioblastoma	Phase III	Q3 2018
Anti-CD47 Antibody: CC-90002	Solid tumors	Phase I	2015
LSD1 Inhibitor: CC-90011	Solid tumors	Phase I	2016

BET Inhibitor: CC-90010	Glioblastoma	Phase I	2017
Anti-PD-1: Tislelizumab (BGB-A317)	Hepatocellular carcinoma (HCC)	Phase III	Q1 2018
	Non-small cell lung cancer (NSCLC)	Phase III	Q1 2018

Inflammation and Immunology

8

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Area of Research		Status <sup>1</sup>	Entered Current Status
PDE4 inhibitor: OTEZLA® (apremilast)	Psoriatic arthritis	Post-approval research	2014
	Plaque psoriasis	Post-approval research	2014
	Behçet's disease	Regulatory submission	Q3 2018
	Scalp psoriasis	Phase IIIb	2017
	Pediatric psoriasis	Phase III	Q4 2018
S1P1/5 agonist: ozanimod	Relapsing multiple sclerosis	Regulatory submission <sup>2</sup>	Q1 2018
	Ulcerative colitis	Phase III	2015
	Crohn's disease	Phase III	Q2 2018
MK2 inhibitor: CC-99677	Inflammation	Phase Ib	Q2 2018
IL-2 mutein: CC-92252	Inflammation	Phase Ib	Q3 2018
Anti-IL-13: RPC-4046	Eosinophilic esophagitis	Phase II	2014
CELMoD®: CC-220	SLE	Phase IIb	2017
JNK inhibitor: CC-90001	Idiopathic pulmonary fibrosis (IPF)	Phase II	2017
Anti-PD-1 agonist: CC-90006	Psoriasis	Phase I	2016

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

<sup>2</sup> Initial regulatory submission in Q4 2017; received Refusal to File from FDA in Q1 2018. Anticipating regulatory resubmission in Q1 2019.

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

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

<sup>5</sup> Regulatory approval based on pivotal phase II data.

<sup>6</sup> Trial conducted by licensee partner, Taiho Pharmaceuticals Co. Ltd.

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

<sup>1</sup> The patents covering these drugs include patents listed in the U.S. Orange Book.

In December 2015, we announced the settlement of litigations with Natco Pharma Ltd. (Natco) 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 (ANDA). See Note 19 of Notes to Consolidated Financial Statements contained elsewhere in this report. In June 2018, we announced the settlement of litigations with Accord Healthcare Ltd. (Accord) relating to patents for REVLIMID®. As part of the settlement, we granted Accord the ability to market a generic lenalidomide product for certain conditions prior to expiry of Celgene's patent and supplementary protection certificate (SPC) rights in the U.K. beginning on January 18, 2022, and in various other European countries where Celgene's SPC is in force beginning on February 18, 2022. In addition, subject of ongoing European Patent Office (EPO) opposition proceedings. See Note 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

<sup>4</sup> Based on ten years regulatory exclusivity.

<sup>5</sup> 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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

Subject of ongoing 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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report for more information.

<sup>7</sup> 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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

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 18 of Notes to Consolidated Financial Statements contained elsewhere in this report.

## MANUFACTURING

We own and operate a manufacturing facility in Zofingen, Switzerland which produces the active pharmaceutical ingredient (API) for OTEZLA<sup>®</sup>, REVLIMID<sup>®</sup> and THALOMID<sup>®</sup>. In addition, we contract with several third-party organizations to provide back-up API manufacturing services 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 for ABRAXANE<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, IDHIFA<sup>®</sup>, ISTODAX<sup>®</sup> and VIDAZA<sup>®</sup> (azacitidine for injection).

Manufacturing for REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, THALOMID<sup>®</sup> and OTEZLA<sup>®</sup> which consists of bulk production, packaging, warehousing and distribution, is performed at our facilities in Boudry, Switzerland and Couvet, Switzerland. Manufacturing for ABRAXANE<sup>®</sup>, which consists of bulk production, packaging, warehousing and distribution, is performed at our facility in Phoenix, Arizona, U.S. In addition, we have contracted with several third-party drug product manufacturing and packaging organizations to provide back-up sources for these products.

We have established primary and back-up manufacturing sites for late-phase development programs. For luspatercept, we have contracted third-party manufacturing organizations to supply drug substance and drug product manufacturing and packaging services. We are leveraging a combination of Celgene-owned and third-party manufacturing organizations for fedratinib, CC-486 and ozanimod. We have invested in our own manufacturing network, including facilities in Bothell, Washington and Summit, New Jersey, as well as contracted with third-party organizations, for cellular therapy product candidates, including bb2121 and liso-cel (JCAR017).

All of our owned manufacturing facilities and third-party organizations that manufacture Celgene products are approved by the regulatory authorities for the geographies that they serve.

## 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<sup>®</sup>, 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<sup>®</sup> and Otezla SupportPlus<sup>®</sup> to serve as dedicated, central points of contact for patients and healthcare professionals who use or prescribe our products. Celgene Patient Support<sup>®</sup> and Otezla SupportPlus<sup>®</sup> 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 regions, particularly in some countries in Latin America, we partner with third-party distributors. Generally, we distribute our products through commonly used channels in local markets. However, certain of our products, including REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, 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, 2018, we had 8,852 full-time employees, of whom 3,990 were engaged primarily in research and development activities, 2,497 were engaged primarily in sales and commercialization activities, 742 were engaged primarily in manufacturing, and the remaining 1,623 were engaged primarily in management and general and administrative activities. The number of full-time employees in our international operations has grown from 3,091 at the end of 2017 to 3,212 at the end of 2018. 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 (70 percent beginning in 2019). 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 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 2018 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:

- the proposed transaction with Bristol-Myers Squibb;
- 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.

### Risks Related to our Business

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" contained elsewhere in this report.

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

Our business is largely dependent on the commercial success of REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, OTEZLA<sup>®</sup>, ABRAXANE<sup>®</sup>, and VIDAZA<sup>®</sup>. REVLIMID<sup>®</sup> currently accounts for over half of our total revenue. As new products, such as POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and OTEZLA<sup>®</sup>, have obtained regulatory approval and gained market acceptance, our dependence on REVLIMID<sup>®</sup> has decreased, a trend that we expect to continue. A significant decline in REVLIMID<sup>®</sup> 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<sup>®</sup> is known to be toxic to the human fetus and exposure to the drug during pregnancy could result in significant deformities. REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> 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<sup>®</sup>, REVLIMID<sup>®</sup>, and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, 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;
- Delays in the acceptance, review and approval of products by the FDA may result from government shutdowns due to the failure by Congress to enact regular appropriations;
- 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.

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 (e.g., the President's American Patients First Blueprint and related regulatory proposals) 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, or the ACA, were signed into law in March 2010, and are referred to collectively as the Healthcare Reform Acts. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, in December 2018, a U.S. district court held that the ACA was unconstitutional, although the ruling is stayed pending the appeals process. In addition, the Tax Cuts and Jobs Act of 2017, which includes a provision that entered into effect on January 1, 2019, that repeals the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Since the enactment of the Tax Cuts and Jobs Act of 2017, there have been additional amendments to certain provisions of the ACA, and we expect the Trump Administration and Congress may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. It is uncertain the extent to which any such changes may impact our business or financial condition.

Moreover, changes could be made to governmental healthcare and insurance reimbursement programs that could significantly impact the profitability of our products. Building from the President's American Patients First Blueprint, the Centers for Medicare & Medicaid Services (CMS) released an Advanced Notice of Proposed Rulemaking in October 2018, seeking comments on possible changes to certain Medicare Part B reimbursement mechanisms. Notably, one such proposal would introduce international reference pricing for pharmaceuticals in setting reimbursement for those medicines. As these proposals are just at the beginning of the regulatory process, we cannot predict what the final rules (if any) will be, or the impacts on 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. In January 2019, as part of an inquiry sent to twelve companies representing many of the most significant Part D drugs, we received a letter from the House Oversight and Government Reform Committee ("Committee") inquiring into certain matters relating to the pricing and commercialization practices for REVLIMID®, as well as other information relating to company operations. We are cooperating with the Committee to respond; however, at this time, we cannot predict the impact of this request or the increased policy focus on the pricing or reimbursement of our products or pharmaceutical products generally. Other committees in the House or Senate have held hearings or announced plans to consider a variety of legislative initiatives relating to pricing and access for pharmaceutical products.

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.

Furthermore, the Trump Administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to, among other things, allow some states to exclude coverage for some prescription drugs under Medicaid. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures could be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

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. The effective date of this regulation was January 1, 2019. Following the effective date, manufacturers who are found to have knowingly and intentionally overcharged 340B covered entities could be subject to significant monetary penalties. Such findings could also result in negative publicity that could harm the manufacturer’s reputation or cause business disruption.

Over the course of the past few years, we have received inquiries 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 those inquiries and believe that we have complied with applicable legal requirements.

If we are ultimately required to change our sales or pricing practices with regard to the distribution of these drugs under the 340B program, or if we were required to pay penalties under the applicable regulations, 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 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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report. 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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

Upon the expiration or loss of patent protection for a product, or upon the "at-risk" launch 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, as additional competitors enter the market, our patented products may face increased competition or pricing pressure.

Orphan exclusivity and regulatory data protection for REVLIMID®'s multiple myeloma indication in Europe expired in June 2017. The regulatory marketing protection for REVLIMID® in Europe expired in June 2018. Notwithstanding that our intellectual property rights for REVLIMID® in the major European markets are due to remain in force through at least 2022, we expect that some generic drug companies may attempt to market a generic version of REVLIMID® in such European markets before this time. We have recently been made aware of various generic drug manufacturers receiving regulatory clearance for generic versions of REVLIMID® in some European countries. Although we are confident in the strength of our intellectual property rights, it may be possible for generic drug companies to successfully challenge our rights and launch their generic versions of REVLIMID® into the market prior to the expiration of our intellectual property rights in Europe for REVLIMID®.

Certain novel approaches to the treatment of diseases, such as CAR T cell therapy, may present significant challenges and risks for us.

The development of novel approaches for the treatment of diseases, such as our acquisition in the first quarter of 2018 of Juno's CAR T cell immunotherapy and related technologies, presents many new challenges and risks due to the unique nature of genetic modification of patient cells ex vivo using certain viruses to reengineer these cells to ultimately treat diseases, including obtaining regulatory approval from the FDA and other regulatory agencies that have very limited experience with the development of cellular therapies involving genetic modification of patient cells; developing and deploying consistent and reliable processes, while limiting contamination, for engineering a patient's cells ex vivo and infusing genetically modified cells back into the patient; developing processes for the safe administration of cellular therapies, including long-term follow-up for patients receiving cellular therapies; and sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process our potential CAR T products. The use of reengineered cells as a potential cancer treatment is a recent development and may not be broadly accepted by the regulatory, patient or medical communities. Further, we may not be able to satisfactorily establish the safety and efficacy or the reliability of these therapies or demonstrate the potential advantages and side effects compared to existing and future cellular therapies. Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For instance, in February 2019, CMS issued a proposed coverage decision memo on CAR T cells that would apply to the entire Medicare program that, if finalized as drafted, includes requirements such as patient enrollment in a registry and certain capabilities required of the site to be eligible for Medicare payment for CAR T cell therapy. Furthermore, certain payment models could impact the interest of appropriate treatment sites in administering CAR T cell therapies, thereby limiting patient access. The CMS has opened a national coverage analysis on CAR T cells and may impose coverage limitations on such cellular therapies. These coverage limitations would apply to the entire Medicare program and could include, among other things, a requirement for patients to be enrolled in a registry in order for the provider to be paid for CAR T cell therapy. To date, only a few products that involve the genetic modification of patient cells have been approved for commercial sale. Moreover, the safety profiles of cellular therapies may adversely influence public perception and may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians and payors to subscribe to these novel treatment approaches. If we fail to overcome these and other challenges, or if significant adverse events are reported from similar therapies, our development of these novel treatment approaches may be hampered or delayed, which could adversely affect our future anticipated revenues and/or profitability related to this therapeutic program.

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" contained elsewhere in this report.

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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

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.

We have limited experience manufacturing CAR T cell immunotherapies, and our processes may be more difficult or more expensive than the approaches taken by our current and future competitors. We cannot be sure that the manufacturing processes employed by us will result in CAR T cell immunotherapies that will be safe and effective. Our ability to source supplies for materials used to manufacture our CAR T cell immunotherapies and to develop consistent and reliable manufacturing processes and distribution networks with an attractive cost of goods could impact future anticipated revenue and gross profit for our CAR T cell immunotherapies. In addition, we may face challenges with sourcing supplies for clinical and, if approved commercial manufacturing. Logistical and shipment delays and other factors not in our control could prevent or delay the delivery of our product candidates to patients. Additionally, we are required to maintain a complex chain of identity and custody with respect to patient material as such material moves through the manufacturing process, and failure to maintain such chain of identity and custody could result in adverse patient outcomes, loss of product or regulatory remedial action, which could adversely affect our future anticipated revenues and/or profitability related to this therapeutic program.

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 acquisitions of Impact Biomedicines, Inc. and Juno Therapeutics, Inc. in the first quarter of 2018, 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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

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 contra-indications, warnings or precautions, which would have a material

adverse effect on sales of such product. We have historically purchased product liability coverage from third-party carriers for a portion of our potential liability. Such insurance has become increasingly difficult and costly to obtain. In this context and in light of the strength of our balance sheet we now self-insure these risks beginning in 2016. Product liability claims, regardless of their merits or ultimate outcome, are costly, divert management's attention, may harm our reputation and can impact the demand for our products. There can be no assurance that we will be able to recover under any existing third-party insurance policy or that such coverage will be adequate to fully cover all risks or damage awards or settlements. Additionally, if we are unable to meet our self-insurance obligations for claims that are more than we estimated or reserved for that require substantial expenditures, there could be a material adverse effect on our financial statements and results of operations.

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

We are subject to income taxes in both the United States and various foreign jurisdictions and our domestic and international tax liabilities are largely dependent upon the distribution of income among these different jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include interpretations of existing tax laws, the

accounting for stock options and other share-based compensation, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of examinations by the U.S. Internal Revenue Service and other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. See 'Liquidity and Capital Resources' within Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as Note 17 of Notes to Consolidated Financial Statements contained elsewhere in this report.

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 6 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;
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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;

27

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- 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 (Abraxis CVRs) were issued entitling each holder of an Abraxis 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, Abraxis CVR holders are subject to additional risks, including:

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

#### Risks Related to our Proposed Acquisition by Bristol-Myers Squibb

Our proposed acquisition by Bristol-Myers Squibb is subject to various closing conditions, including regulatory and stockholder approvals as well as other uncertainties, and there can be no assurances as to whether and when it may be completed.

On January 2, 2019, we entered into an Agreement and Plan of Merger (which we refer to as the "merger agreement"), with Bristol-Myers Squibb and a wholly owned subsidiary of Bristol-Myers Squibb (which we refer to as the "merger sub"). Under the terms and subject to the conditions set forth in the merger agreement, merger sub will merge with and

into Celgene (the “merger”) and Celgene will become a wholly-owned subsidiary of Bristol-Myers Squibb. Upon completion of the merger, each outstanding share of Celgene common stock, other than excluded stock or dissenting stock, will automatically be canceled and converted into the right to receive (i) \$50.00 in cash without interest thereon, (ii) one share of Bristol-Myers Squibb common stock, and (iii) one Contingent Value Right (Bristol-Myers Squibb CVR), which will entitle the holder to receive a payment for the achievement of future regulatory milestones.

Completion of the merger is subject to customary closing conditions, a number of which are not within our or Bristol-Myers Squibb's control, and it is possible that such conditions may prevent, delay or otherwise materially adversely affect the completion of the merger. These conditions include, among other things: (i) adoption of the merger agreement by our stockholders, (ii) approval of the stock issuance by the stockholders of Bristol-Myers Squibb, (iii) approval for the listing on the New York Stock Exchange (NYSE) of the shares of Bristol-Myers Squibb common stock and Bristol-Myers Squibb CVRs to be issued in the merger, (iv) absence of any injunction or order that prohibits completion of the transaction, (v) accuracy of the representations and warranties made in the merger agreement by the other party, subject to certain materiality qualifications, (vi) performance in all material respects by the other party of the material obligations required to be performed by it at or prior to completion of the merger and (vii) no stop order suspending the effectiveness of the registration statement and no proceedings for such purpose are pending before the SEC.

In addition, completion of the merger is conditioned upon the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the receipt of approvals under the antitrust laws of certain specified foreign jurisdictions. The governmental authorities from which these authorizations are required have broad discretion in administering the governing laws and regulations, and may take into account various facts and circumstances in their consideration of the merger, including other potential transactions in the health care industry or other industries. These governmental authorities may initiate proceedings seeking to prevent, or otherwise seek to prevent, the merger. As a condition to authorization of the merger or related transactions, these governmental authorities also may impose requirements, limitations or costs, require divestitures or place restrictions on the conduct of Bristol-Myers Squibb's business after completion of the merger. Under the terms of the merger agreement, Bristol-Myers Squibb is not required, and we are not permitted without Bristol-Myers Squibb's consent, to take any actions or agree to any terms or conditions that would have, or would reasonably be expected to have, individually or in the aggregate, a material adverse effect on the financial condition, business or results of operations of Celgene, Bristol-Myers Squibb and their respective subsidiaries, taken as a whole, after giving effect to the completion of the merger.

We can provide no assurance that all required consents and approvals will be obtained or that all closing conditions will otherwise be satisfied (or waived, if applicable), and, if all required consents and approvals are obtained and all closing conditions are satisfied (or waived, if applicable), we can provide no assurance as to the terms, conditions and timing of such consents and approvals or the timing of the completion of the merger. Many of the conditions to completion of the merger are not within either our or Bristol-Myers Squibb's control, and neither company can predict when or if these conditions will be satisfied (or waived, if applicable). Any delay in completing the merger could cause us not to realize some or all of the benefits that we expect to achieve if the merger is successfully completed within its expected timeframe.

Failure to complete the merger could negatively impact our stock price and future business and financial results. If the merger is not completed for any reason, including as a result of our stockholders failing to adopt the merger agreement or Bristol-Myers Squibb stockholders failing to approve the stock issuance, we will remain an independent public company. Our ongoing business may be materially and adversely affected and we would be subject to a number of risks, including the following:

- we may experience negative reactions from the financial markets, including negative impacts on trading prices of our common stock and other securities, and from our customers, collaborators, suppliers, regulators and employees;

- we may be required to pay Bristol-Myers Squibb a termination fee of \$2.2 billion if the merger agreement is terminated under certain circumstances;

- we will be required to pay certain transaction expenses and other costs incurred in connection with the merger, whether or not the merger is completed, including certain fees and expenses of Bristol-Myers Squibb, subject to a cap of \$40 million, in connection with our fee reimbursement obligation;

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the merger agreement places certain restrictions on the conduct of our business prior to completion of the merger, and such restrictions, the waiver of which is subject to the consent of Bristol-Myers Squibb, may prevent us from making certain acquisitions, taking certain other specified actions or otherwise pursuing business opportunities during the pendency of the merger that we would have made, taken or pursued if these restrictions were not in place; and

matters relating to the merger (including integration planning) will require substantial commitments of time and resources by our management and the expenditure of significant funds in the form of fees and expenses, which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us as an independent company.

In addition, we could be subject to litigation related to any failure to complete the merger or related to any proceeding to specifically enforce our performance obligations under the merger agreement.

If any of these risks materialize, they may materially and adversely affect our business, financial condition, financial results, ratings, stock prices and/or note prices.

If the merger agreement is terminated, we may, under certain circumstances, be obligated to pay a termination fee to Bristol-Myers Squibb.

If the merger agreement is terminated, in certain circumstances, we would be required to pay a termination fee of \$2.2 billion and certain expenses to Bristol-Myers Squibb. If the merger agreement is terminated under such circumstances, the termination fee we may be required to pay under the merger agreement may require us to use available cash that would have otherwise been available for general corporate purposes and other uses. For these and other reasons, termination of the merger agreement could materially adversely affect our business operations and financial results, which in turn would materially and adversely affect the price of our common stock.

Because the exchange ratio is fixed and the market price of shares of Bristol-Myers Squibb common stock has fluctuated and will continue to fluctuate, and because of the uncertainty of the fair market value of, and the ultimate realization on, the Bristol-Myers Squibb CVRs, our stockholders cannot be sure of the value of the merger consideration they will receive in the merger.

Upon completion of the merger, each share of our common stock outstanding immediately prior to the effective time of the merger will be converted into the right to receive \$50.00 in cash without interest thereon, one share of Bristol-Myers Squibb common stock and one Bristol-Myers Squibb CVR. Because the exchange ratio of one share of Bristol-Myers Squibb common stock is fixed, the value of the share consideration will depend on the market price of shares of Bristol-Myers Squibb common stock at the time the merger is completed. The market price of shares of Bristol-Myers Squibb common stock has fluctuated since the date of the announcement of the merger agreement and will continue to fluctuate from the date of this report until the date the merger is completed, which could occur a considerable amount of time after the date hereof. There is also uncertainty regarding the fair market value of the Bristol-Myers Squibb CVRs and whether any payment will ultimately be realized on the Bristol-Myers Squibb CVRs. Stock price changes may result from a variety of factors, including, among others, general market and economic conditions, changes in Bristol-Myers Squibb's and Celgene's respective businesses, operations and prospects, risks inherent in their respective businesses, changes in market assessments of the likelihood that the merger will be completed and/or the value that may be generated by the merger, and changes with respect to expectations regarding the timing of the merger and regulatory considerations. Many of these factors are beyond our control.

While the merger is pending, we are subject to business uncertainties and contractual restrictions that could materially adversely affect our operating results, financial position and/or cash flows or result in a loss of employees, customers, collaborators or suppliers.

The definitive merger agreement includes restrictions on the conduct of our business prior to the completion of the merger or termination of the merger agreement, generally requiring us to conduct our business in the ordinary course consistent with past practice. Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions. Unless we obtain Bristol-Myers Squibb's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the merger agreement, (ii) as required by applicable law or (iii) as set forth in the confidential disclosure schedule delivered by Celgene to Bristol-Myers Squibb, we may not, among other things, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property (subject to certain exceptions, including without limitation, acquisitions up to a specified individual amount and an aggregate limitation), dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures. We may find that these and other contractual restrictions in the merger agreement delay or prevent us from responding, or limit our ability to respond, effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management believes they may be advisable. The pendency of the proposed merger may also divert management's attention and our resources from ongoing business and operations.

Our employees, customers, collaborators and suppliers may experience uncertainties about the effects of the merger. In connection with the pending merger, it is possible that some customers, collaborators, suppliers and other parties with whom we have a business relationship may delay or defer certain business decisions or might decide to seek to terminate, change or renegotiate their relationship with us as a result of the merger. Similarly, current and prospective employees may experience uncertainty about their future roles with us following completion of the merger, which may materially adversely affect our ability to attract and retain key employees. If any of these effects were to occur, it could materially and adversely impact our operating results, financial position and/or cash flows and/or our stock price.

31

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Lawsuits have been filed against us and Bristol-Myers Squibb and other lawsuits may be filed against us and/or Bristol-Myers Squibb challenging the transactions contemplated by the merger agreement. An adverse ruling in any such lawsuit may delay or prevent the proposed acquisition from being completed.

Between February 4, 2019 and February 20, 2019, six putative class actions and three individual actions were filed against us, our board of directors, and in four cases, Bristol-Myers Squibb Company and/or Burgundy Merger Sub, Inc. Three complaints, *Bernstein v. Celgene Corporation, et al.*, 2:19-cv-04804; *Lowinger v. Celgene Corporation, et al.*, 2:19-cv-04752; and *Wang v. Celgene Corporation, et al.*, 2:19-cv-04865, were filed in the U.S. District Court for the District of New Jersey. Three complaints, *Gerold v. Celgene Corporation, et al.*, 1:19-cv-00233-UNA; *Sbriglio v. Celgene Corporation, et al.*, 1:19-cv-00277-UNA; and *Grayson v. Celgene Corporation, et al.*, No. 1:19-cv-00332, were filed in the U.S. District Court for the District of Delaware. Two complaints, *Rogers v. Celgene Corporation, et al.*, 1:19-cv-01275; and *Woods v. Celgene Corporation, et al.*, No. 1:19-cv-01597, were filed in the U.S. District Court for the Southern District of New York. One complaint, *Ciavarella v. Alles*, No. 2019-0133-AGB, was filed in the Court of Chancery of the State of Delaware. The federal complaints generally allege that defendants prepared and filed a false or misleading registration statement regarding the proposed merger in violation of Section 14(a) and Section 20(a) of the Exchange Act, and Rule 14a-9 promulgated under the Exchange Act. Specifically, the federal complaints allege that the registration statement misstated or omitted material information regarding the parties' financial projections and the analyses performed by the parties' financial advisors. Some of the federal complaints also allege that the registration statement misstated or omitted material information regarding potential conflicts of interest faced by Celgene directors and executives. The federal complaints further allege that our board of directors and/or Bristol-Myers Squibb are liable for these violations as "controlling persons" of Celgene under Section 20(a) of the Exchange Act. The federal complaints seek, among other relief, injunctive relief to prevent consummation of the merger until the alleged disclosure violations are cured, damages in the event the merger is consummated, and an award of attorney's fees. The *Ciavarella* complaint alleges that Celgene's directors breached their fiduciary duties by failing to maximize the value of Celgene and that Bristol-Myers Squibb aided and abetted those breaches. It seeks, among other things, injunctive relief to prevent consummation of the merger, damages in the event the merger is consummated, and an award of attorney's fees.

In addition, a complaint, *Landers, et al. v. Caforio, et al.*, No. 2019-0125-AGB, was filed in the Court of Chancery of the State of Delaware. *Landers* is styled as a putative class action on behalf of Bristol-Myers Squibb stockholders and names members of the Bristol-Myers Squibb board of directors as defendants, alleging that they breached their fiduciary duties by failing to disclose material information about the merger.

Additional lawsuits arising out of or relating to the definitive merger agreement, the registration statement and/or the proposed acquisition of us by Bristol-Myers Squibb may be filed in the future.

One of the conditions to completion of the proposed acquisition is the absence of any applicable injunction or other order being in effect that prohibits completion of the proposed acquisition. Accordingly, if a plaintiff is successful in obtaining an injunction, then such order may prevent the proposed acquisition from being completed, or from being completed within the expected timeframe.

We may have difficulty attracting, motivating and retaining executives and other key employees in light of the merger.

Uncertainty about the effect of the merger on our employees may have an adverse effect on our business. This uncertainty may impair our ability to attract, retain and motivate key personnel. Employee retention may be particularly challenging during the pendency of the merger, as our employees may experience uncertainty about their future roles in the combined business. No assurance can be given that we will be able to attract or retain key employees to the same extent that we have been able to attract or retain employees in the past.

Additional information on these risks

Additional information concerning these risks, uncertainties and assumptions can be found in the section entitled “Risk Factors” beginning on page 39 of our joint proxy statement/prospectus filed February 22, 2019 with the SEC.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

32

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**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
Phoenix, Arizona	Manufacturing and warehousing	254,000
Boudry, Switzerland	Manufacturing, administration and warehousing	253,000
Couvet, Switzerland	Manufacturing, administration and warehousing	191,000
Bothell, Washington	Manufacturing, administration and warehousing	68,000
Zofingen, Switzerland	Manufacturing	4,500

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
Seattle, Washington	Office space and research	331,400
San Diego, California	Office space and research	285,400
Warren, New Jersey	Office space and research	181,200
Cambridge, Massachusetts	Office space and research	145,300
Berkeley Heights, New Jersey	Office space	138,400
Brisbane, California	Office space and research	112,200
San Francisco, California	Office space and research	55,800
Waltham, Massachusetts	Office space and research	20,100
Overland Park, Kansas	Office space	20,000
Bothell, Washington	Warehouse	19,400
Allentown, Pennsylvania	Warehouse	15,100
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, 2018, the non-cancelable lease terms for our operating leases expire at various dates between 2019 and 2029 and in some cases include renewal options. The total amount of rent expense recorded for all leased facilities in 2018 was \$80 million.

**ITEM 3. LEGAL PROCEEDINGS**

See Note 19 of Notes to Consolidated Financial Statements contained elsewhere in this report.

**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

MARKET AND STOCKHOLDER INFORMATION

Our common stock is traded on the NASDAQ Global Select Market under the symbol "CELG." As of February 21, 2019, there were approximately 360 holders of record of our common stock.

PERFORMANCE GRAPH

The below chart sets forth a comparison of cumulative total returns per share for the periods indicated:

	Cumulative Total Return					
	12/13	12/14	12/15	12/16	12/17	12/18
Celgene Corporation	\$100.00	\$132.40	\$141.75	\$137.01	\$123.53	\$75.86
S&P 500	100.00	113.68	115.24	129.02	157.17	150.27
NASDAQ Composite	100.00	114.83	122.99	134.02	173.86	168.98
NASDAQ Biotechnology	100.00	134.40	150.22	118.15	143.74	131.00

\* \$100 Invested on 12/31/13 in Stock or Index – Including Reinvestment of Dividends, Fiscal Year Ended December 31.

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.

REPURCHASE OF EQUITY SECURITIES

From April 2009 through December 31, 2018, our Board of Directors approved purchases of up to \$28.5 billion of our common stock, including increases of \$5.0 billion and \$3.0 billion approved by our Board of Directors in February and May 2018, respectively. Approved amounts exclude share purchase transaction fees.

As part of the existing Board authorized share repurchase program, in May 2018 we entered into an Accelerated Share Repurchase (ASR) agreement with an investment bank to repurchase an aggregate of \$2.0 billion of our common stock. As part of the ASR agreement we received an initial delivery of 17,987,922 shares in May 2018 and a final delivery of 5,956,747 shares in August 2018. The total number of shares repurchased under the ASR agreement was 23,944,669 at a weighted average price of \$83.53 per share.

There were no shares repurchased during the three-month period ended December 31, 2018. As of December 31, 2018, we had a remaining purchase authorization of approximately \$2.8 billion.

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

#### ITEM 6. SELECTED FINANCIAL DATA

The following Selected Consolidated Financial Data should be read in conjunction with our Consolidated Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included in this Annual Report on Form 10-K. The data set forth below with respect to our Consolidated Statements of Income for the years ended December 31, 2018, 2017 and 2016 and the Consolidated Balance Sheet data as of December 31, 2018 and 2017 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, 2015 and 2014 and the Consolidated Balance Sheet information as of December 31, 2016, 2015 and 2014 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,				
	2018 <sup>(1)</sup>	2017 <sup>(2)</sup>	2016	2015	2014
Consolidated Statements of Income:					
Total revenue	\$15,281	\$13,003	\$11,229	\$9,256	\$7,670
Costs and operating expenses	10,090	8,296	8,063	7,001	5,151
Operating income	5,191	4,707	3,166	2,255	2,519
Interest and investment income, net	45	105	30	31	28
Interest (expense)	(741)	(522)	(500)	(311)	(176)
Other income (expense), net	337	24	(324)	48	(44)
Income before income taxes	4,832	4,314	2,372	2,023	2,327
Income tax provision	786	1,374	373	421	327
Net income	\$4,046	\$2,940	\$1,999	\$1,602	\$2,000
Net income per share:					
Basic	\$5.65	\$3.77	\$2.57	\$2.02	\$2.49
Diluted	\$5.51	\$3.64	\$2.49	\$1.94	\$2.39
Weighted average shares:					
Basic	716.3	779.2	777.2	792.2	802.7
Diluted	733.8	808.7	803.3	824.9	836.0
	As of December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheets Data:					
Cash and cash equivalents, Debt securities available-for-sale and Equity investments with readily determinable fair values <sup>(1)</sup>	\$6,042	\$12,042	\$7,970	\$6,552	\$7,547
Total assets <sup>(3)</sup>	35,480	30,141	28,086	26,964	17,291
Short-term borrowings and current portion of long-term debt	501	—	501	—	606
Long-term debt, net of discount <sup>(3)</sup>	19,769	15,838	13,789	14,161	6,217
Retained earnings	17,559	13,061	10,074	8,075	6,473
Total stockholders' equity	6,161	6,921	6,600	5,919	6,525



(1) Accounting Standards Update No. 2016-01, "Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" was effective for us on January 1, 2018. ASU 2016-01 requires changes in the fair value of equity investments with readily determinable fair values and changes in observable prices of equity investments without readily determinable fair values to be recorded in net income. For the year ended December 31, 2018, a net gain of \$317 million was recorded in Other income (expense), net. Certain prior year Consolidated Balance Sheet amounts have been reclassified to conform to the current year's presentation. See Note 1 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional information.

(2) 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 'Liquidity and Capital Resources' within Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as Note 17 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to the 2017 Tax Act.

(3) Total assets and Long-term debt, net of discount have been restated as of December 31, 2015 and 2014 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

Management's discussion and analysis of financial condition and results of operations is intended to help the reader understand our results of operations and financial condition. This discussion and analysis is provided as a supplement to, and should be read in conjunction with, our audited Consolidated Financial Statements and the accompanying Notes to Consolidated Financial Statements. Certain statements in this Item 7 of Part II of this Annual Report on Form 10-K constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors," may cause our actual results and cash generated from operations to differ materially from these forward-looking statements. Our Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and are presented in U.S. dollars.

(In all accompanying tables, amounts of dollars expressed in millions, except per share amounts, unless otherwise noted)

### 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.

### Merger Agreement with Bristol-Myers Squibb Company

On January 2, 2019 Bristol-Myers Squibb Company (Bristol-Myers Squibb) and Celgene entered into a definitive merger agreement under which Bristol-Myers Squibb will acquire Celgene in a cash and stock transaction with an equity value of approximately \$74 billion, based on the closing price of Bristol-Myers Squibb shares of \$52.43 on January 2, 2019. Under the terms of the agreement, Celgene shareholders will receive 1.0 Bristol-Myers Squibb share and \$50.00 in cash for each share of Celgene. Celgene shareholders will also receive one tradeable Bristol-Myers Squibb CVR for each share of Celgene, which will entitle the holder to receive a payment for the achievement of future regulatory milestones. The Boards of Directors of both companies have approved the merger agreement. The

definitive merger agreement includes restrictions on the conduct of our business prior to the completion of the merger or termination of the merger agreement, generally requiring us to conduct our business in the ordinary course consistent with past practice. Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions. Unless we obtain Bristol-Myers Squibb's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the merger agreement, (ii) as required by applicable law or (iii) as set forth in the confidential disclosure schedule delivered by Celgene to Bristol-Myers Squibb, we may not, among other things, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property (subject to certain exceptions, including without limitation, acquisitions up to a specified individual amount and an aggregate limitation), dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures. See Item 1A. "Risk Factors - While the merger is pending, we are subject to business uncertainties and contractual restrictions that could materially adversely affect our operating results, financial position and/or cash flows or result in a loss of employees, customers, collaborators or suppliers."

Based on the closing price of Bristol-Myers Squibb stock of \$52.43 on January 2, 2019, the cash and stock consideration to be received by Celgene shareholders at closing is valued at \$102.43 per Celgene share and one Bristol-Myers Squibb CVR. Each Bristol-Myers Squibb CVR will entitle its holder to receive a one-time potential payment of \$9.00 in cash upon U.S. Food and Drug Administration (FDA) approval of all three of ozanimod (by December 31, 2020), liso-cel (JCAR017) (by December 31, 2020) and bb2121 (by March 31, 2021), in each case for a specified indication. Upon completion of the merger, Bristol-Myers Squibb shareholders are expected to own approximately 69% of the company, and Celgene shareholders are expected to own approximately 31% based on shares outstanding for each of Bristol-Myers Squibb and Celgene.

The transaction is not subject to a financing condition. The cash portion will be funded through a combination of cash on hand and debt financing. Bristol-Myers Squibb has obtained fully committed debt financing from Morgan Stanley Senior Funding, Inc. and MUFG Bank, Ltd.

The transaction is subject to approval by Bristol-Myers Squibb and Celgene shareholders and the satisfaction of customary closing conditions and regulatory approvals. Bristol-Myers Squibb and Celgene expect to complete the transaction in the third quarter of 2019.

If the merger agreement is terminated under specified circumstances, Celgene may be required to pay Bristol-Myers Squibb a termination fee of \$2.2 billion, and if the merger agreement is terminated under certain other circumstances, Bristol-Myers Squibb may be required to pay Celgene a termination fee of \$2.2 billion.

Our primary commercial stage products include REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>, OTEZLA<sup>®</sup>, ABRAXANE<sup>®</sup>, and VIDAZA<sup>®</sup>.

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 product candidates. Our clinical trial activity includes trials across the disease areas of hematology, oncology, and inflammation and immunology. REVLIMID<sup>®</sup> is being evaluated in phase III trials covering a range of hematological malignancies that include lymphomas. In July 2018, the phase III trial (AUGMENT<sup>™</sup>) for REVLIMID<sup>®</sup> in combination with rituximab (R<sup>2</sup>), for the treatment of relapsed and/or refractory follicular or marginal zone lymphoma achieved its primary endpoint. In December 2018, we submitted a U.S. supplemental New Drug Application (NDA) for REVLIMID<sup>®</sup> in combination with rituximab in relapsed and/or refractory indolent non-Hodgkin lymphoma (NHL) and in January 2019 we submitted an application with the European Medicines Agency (EMA) for approval in Europe. Also, within hematological malignancies, POMALYST<sup>®</sup> is in phase III and post-approval trials for relapsed and/or refractory multiple myeloma (RRMM). In solid tumors, ABRAXANE<sup>®</sup> is currently being investigated in pancreatic cancer, breast and non-small cell lung cancers. In inflammation and immunology in 2018, we submitted a U.S. supplemental NDA and Japan NDA for OTEZLA<sup>®</sup> in Behçet's disease following positive results from the phase III trial (RELIEF<sup>™</sup>). Patients with active Behçet's disease showed statistically significant reductions in oral ulcers with OTEZLA<sup>®</sup> when compared to placebo. Also in 2018, the phase IIIb study (STYLE<sup>™</sup>) for OTEZLA<sup>®</sup> in patients with moderate to severe scalp psoriasis showed statistically significant improvement of the Scalp Physician's Global Assessment (ScPGA) response compared with placebo. OTEZLA<sup>®</sup> is also being evaluated in a phase III trial in pediatric psoriasis (SPROUT<sup>®</sup>), while continuing to be studied in psoriatic arthritis and plaque psoriasis.

We also have a growing number of potential products in phase III trials or that have completed phase III across multiple diseases. In the inflammation and immunology therapeutic area, we completed two phase III trials (RADIANCE<sup>™</sup> and SUNBEAM<sup>™</sup>) for ozanimod in relapsing multiple sclerosis (RMS). Both RADIANCE<sup>™</sup> and SUNBEAM<sup>™</sup> achieved their primary endpoints in reducing the annualized relapse rate in patients with RMS. Enrollment is currently ongoing for the phase III TRUENORTH<sup>™</sup> trial in ulcerative colitis (UC) and the phase III YELLOWSTONE<sup>™</sup> trial in Crohn's Disease (CD). In hematology, we submitted a U.S. NDA for fedratinib for the

treatment of patients with myelofibrosis in January 2019. In June and July 2018, Celgene and Acceleron Pharma, Inc. (Acceleron) announced that luspatercept achieved all primary and key secondary endpoints in the phase III MEDALIST™ and BELIEVE™ trials in patients with low-to-intermediate risk myelodysplastic syndromes (MDS) and transfusion-dependent beta-thalassemia, respectively. In collaboration with bluebird bio, the pivotal study (KarMMa™) evaluating bb2121 in RRMM is ongoing and enrollment was completed in the fourth quarter. The clinical program evaluating bb2121 in earlier lines of multiple myeloma (MM) is also advancing. In the second quarter of 2018 we initiated the pivotal TRANSCEND WORLD trial evaluating liso-cel (lisocabtagene maraleucel) (JCAR017) in relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL). Phase III trials are also underway for CC-486 in MDS, acute myeloid leukemia (AML), and angioimmunoblastic T-Cell lymphoma (AITL). In solid tumors, we are supporting a phase III study of marizomib in newly diagnosed glioblastoma, sponsored by the European Organization for Research and the Treatment of Cancer (EORTC) in collaboration with the Canadian Cancer Trials Group (CCTG). In 2018, our partner BeiGene initiated phase III trials for tislelizumab (BGB-A317) in 1L hepatocellular carcinoma, 2L/3L hepatocellular carcinoma, and 2L/3L non-small cell lung cancer.



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 product 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

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, 2018, 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
REVLIMID®	Relapsed and/or refractory indolent non-Hodgkin lymphoma	U.S.	FDA	Q4 2018 (submitted)
REVLIMID®	Relapsed and/or refractory indolent non-Hodgkin lymphoma	Europe	EMA	Q1 2019 (submitted)
Fedratinib	Myelofibrosis	U.S.	FDA	Q1 2019 (submitted)

#### Pivotal and Phase III Trials:

Product Candidate Trial	Disease Indication	Action
OTEZLA® CC-10004-PPSO-003 (SPROUT®)	Pediatric psoriasis	Initiated
CC-486 OR-CL-LYM - LYSARC-13134 (ORACLE)	AITL	Initiated

### Financial Update

The following table summarizes net product sales, total revenue and earnings for the years ended December 31, 2018, 2017 and 2016 (dollar amounts in millions, except per share data):

	Years Ended December 31,			% Change	
	2018	2017	2016	2018 versus 2017	2017 versus 2016
Net product sales	\$15,265	\$12,973	\$11,185	17.7%	16.0%
Total revenue	15,281	13,003	11,229	17.5%	15.8%
Net income	4,046	2,940	1,999	37.6%	47.1%
Diluted earnings per share	\$5.51	\$3.64	\$2.49	51.4%	46.2%

Total net product sales for 2018 increased by approximately \$2.3 billion, or 17.7%, to approximately \$15.3 billion compared to the year ended December 31, 2017. The increase was comprised of net volume increases of approximately \$2.0 billion, or 15.2%, and net price increases of \$369 million, or 2.9%. The increase in volume was primarily driven by increased unit sales of REVLIMID®, OTEZLA® and POMALYST®/IMNOVID®. The price impact was primarily attributable to net price increases in the U.S., which were partially offset by net price decreases in international markets. Changes in foreign currency exchange rates including the impact of foreign exchange hedging activity unfavorably impacted Net product sales by \$51 million, or 0.4%.

Total net product sales for 2017 increased by approximately \$1.8 billion, or 16.0%, to approximately \$13.0 billion compared to 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<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and OTEZLA<sup>®</sup>. The price impact was primarily attributable to price increases in the U.S., which were partially offset

38

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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 revenue increased by approximately \$2.3 billion, or 17.5%, in 2018 compared to 2017 primarily due to the continued growth in sales of REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and OTEZLA<sup>®</sup> reflecting increases of approximately \$1.7 billion, or 20.4%, in the United States and \$579 million, or 12.4%, in international markets.

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<sup>®</sup>, POMALYST<sup>®</sup>/IMNOVID<sup>®</sup> and OTEZLA<sup>®</sup> reflecting increases of approximately \$1.3 billion, or 18.7%, in the United States and \$460 million, or 10.9%, 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, 2018, 2017 and 2016 are as follows:

	Income Statement Classification	Years Ended		
		December 31,		
		2018	2017	2016
Research and development asset acquisition expenses (see Note 3*)	Research and development	\$1,125	\$325	\$893
Collaboration arrangements (see Note 18*)	Research and development	632	833	927
In-process research & development (IPR&D) asset impairment charge related to GED-0301 (see Note 5*)	Research and development	—	1,620	—
Clinical trial & development activity wind-down (income) expense related to GED-0301 (see Note 5*)	Research and development	(60 )	188	—
Litigation-related loss contingency accrual expense (see Note 19*)	Selling, general and administrative	96	315	199
Share-based compensation expense (see Notes 3 and 15*) <sup>(1)</sup>	Cost of goods sold, Research and development, and Selling, general and administrative	1,114	644	606
Amortization of acquired intangible assets (see Note 11*)	Amortization of acquired intangible assets	468	329	459
Juno Therapeutics, Inc. (Juno) acquisition costs	Acquisition related charges (gains) and restructuring, net	93	—	—
Reduction in contingent consideration liabilities related to GED-0301 (see Note 5*)	Acquisition related charges (gains) and restructuring, net	—	(1,397)	—
Fair value adjustments on equity investments (see Notes 1 and 5*)	Other income (expense), net	317	—	—
Investment impairment charges	Other income (expense), net	—	(54 )	(394 )
2017 Tax Act (see Note 17*)	Income tax provision	(43 )	1,269	—

<sup>(1)</sup> Includes share-based compensation expense related to the acquisition of Juno post-combination service period of \$320 million and \$208 million, which was recorded in Research and development and Selling, general and administrative, respectively, for the year ended December 31, 2018.

\* References to Notes in this table are to the Notes to Consolidated Financial Statements contained elsewhere in this report.



Results of Operations - Fiscal Years Ended December 31, 2018, 2017 and 2016  
Net Product Sales and Other Revenue

Net product sales and other revenue for 2018, 2017 and 2016 were as follows:

REVLIMID®

	2018	2017	2016	Percent Change	
				2018 versus 2017	2017 versus 2016
U.S.	\$6,469	\$5,426	\$4,417	19.2%	22.8%
International	3,216	2,761	2,557	16.5%	8.0%
Worldwide	\$9,685	\$8,187	\$6,974	18.3%	17.4%

REVLIMID® net sales increased by approximately \$1.5 billion, or 18.3%, to approximately \$9.7 billion for 2018 compared to 2017. Sales growth was primarily volume-driven due to global increases in treatment duration and market share. In the U.S., sales growth increased due to increases in both price and unit sales from market penetration and treatment duration of patients using REVLIMID®. International volume growth was partially offset by net price decreases.

REVLIMID® net sales increased by approximately \$1.2 billion, or 17.4%, to approximately \$8.2 billion in 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, 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.

POMALYST®/IMNOVID®

	2018	2017	2016	Percent Change	
				2018 versus 2017	2017 versus 2016
U.S.	\$1,391	\$1,008	\$778	38.0%	29.6%
International	649	606	533	7.1%	13.7%
Worldwide	\$2,040	\$1,614	\$1,311	26.4%	23.1%

POMALYST®/IMNOVID® net sales increased by \$426 million, or 26.4%, to approximately \$2.0 billion for 2018 compared to 2017, primarily due to increased sales in the U.S. market. In the U.S., sales growth increased due to both unit sales and price increases. Increases in market share and treatment duration contributed to the increase in U.S. unit sales. In addition, international unit sales increased, primarily due to sales growth in Europe as a result of increased treatment duration. International volume growth was partially offset by net price decreases.

POMALYST®/IMNOVID® net sales increased by \$303 million, or 23.1%, to approximately \$1.6 billion in 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 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.

OTEZLA®

	2018	2017	2016	Percent Change	
				2018 versus 2017	2017 versus 2016
U.S.	\$1,275	\$1,058	\$904	20.5%	17.0%
International	333	221	113	50.7%	95.6%
Worldwide	\$1,608	\$1,279	\$1,017	25.7%	25.8%

40

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OTEZLA® net sales increased by \$329 million, or 25.7%, to approximately \$1.6 billion for 2018 compared to 2017, due to increased worldwide sales. In the U.S., sales growth increased primarily due to unit sales increases as a result of managed care contracts executed in 2017 and 2018, which contributed to higher gross-to-net charges. Volume increased in all international markets led by Japan, where it was launched in 2017.

OTEZLA® net sales increased by \$262 million, or 25.8% to approximately \$1.3 billion in 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. International volume growth was partially offset by net price decreases.

#### ABRAXANE®

				Percent Change	
	2018	2017	2016	2018 versus 2017	2017 versus 2016
U.S.	\$663	\$607	\$634	9.2%	(4.3)%
International	399	385	339	3.6%	13.6%
Worldwide	\$1,062	\$992	\$973	7.1%	2.0%

ABRAXANE® net sales increased by \$70 million, or 7.1%, to approximately \$1.1 billion for 2018 compared to 2017, primarily due to unit sales and price increases in the U.S. market. International volume growth was partially offset by net price decreases.

ABRAXANE® net sales increased by \$19 million, or 2.0% to \$992 million in 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.

#### OTHER PRODUCT NET SALES

				Percent Change	
	2018	2017	2016	2018 versus 2017	2017 versus 2016
U.S.	\$217	\$211	\$248	2.8%	(14.9)%
International	653	690	662	(5.4)%	4.2%
Worldwide	\$870	\$901	\$910	(3.4)%	(1.0)%

All other product net sales, which include IDHIFA®, VIDAZA®, generic azacitidine for injection, THALOMID®, and ISTODAX®, decreased by \$31 million in 2018 compared to 2017, primarily due to decreases in net sales from VIDAZA®, THALOMID®, ISTODAX® and generic azacitidine for injection, partially offset by increased net sales from IDHIFA®, which launched in the third quarter of 2017.

All other product sales, 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.

Other Revenue: Other revenue decreased by \$14 million to \$16 million for 2018 compared to 2017. Beginning in 2018, we were no longer entitled to receive royalties from Novartis AG (Novartis) on sales of RITALIN® and FOCALIN XR®, which primarily contributed to the decrease in 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 based upon its sales of both RITALIN<sup>®</sup> and FOCALIN XR<sup>®</sup>, both of which have been unfavorably impacted by generic competition in certain markets.



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

REVLIMID<sup>®</sup> and POMALYST<sup>®</sup> are distributed in the United States primarily through contracted pharmacies under the REVLIMID REMS<sup>®</sup> and POMALYST REMS<sup>®</sup> programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>. Internationally, REVLIMID<sup>®</sup> and IMNOVID<sup>®</sup> 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<sup>®</sup>, ABRAXANE<sup>®</sup> and VIDAZA<sup>®</sup> are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>.

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 (70% beginning in 2019). 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® and POMALYST®/IMNOVID® 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, 2018, 2017 and 2016 were as follows:

	Government Rebates	Chargebacks and Distributor Service Fees	Sales Discounts	Sales Returns and Allowances	Total
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
Allowances for sales during prior periods	(38 )	4	—	—	(34 )
Allowances for sales during 2018	1,114	1,637	243	45	3,039
Credits/deductions issued for prior year sales	(355 )	(167 )	(19 )	(8 )	(549 )
Credits/deductions issued for sales during 2018	(587 )	(1,315 )	(222 )	(5 )	(2,129 )
Balance as of December 31, 2018	\$ 678	\$ 429	\$ 22	\$ 47	\$1,176

A comparison of provisions for allowances for sales within each of the four categories noted above for 2018 and 2017 follows:

2018 compared to 2017: Government rebate provisions increased by \$186 million for 2018 compared to 2017, due to a \$124 million increase in international government rebates and a \$62 million increase in the U.S. market. The increase in international government rebates was primarily driven by higher sales volumes and increased rebate rates. The increase in the U.S. market was primarily due to higher sales volumes and increased rebate rates, with \$57 million due to an increase in Medicaid rebates (primarily in the managed care channel) and \$5 million due to an increase in expense related to Medicare Part D Coverage Gap. In 2019, we expect the rebate provision for the Medicare Part D Coverage Gap to increase as a result of a planned increase in the portion manufacturers of pharmaceutical products are responsible for.

Chargebacks and distributor service fees provisions increased by \$567 million for 2018 compared to 2017. Chargebacks increased by \$245 million and distributor service fees increased by \$322 million. The increase in chargebacks was primarily due to higher sales volumes and a greater portion of sales qualifying for chargeback rebates, including a \$7 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 for OTEZLA<sup>®</sup>, which accounted for \$268 million of the increase, as well as a \$30 million increase in commercial copayment program expense and a \$16 million increase in the distributor service fee expense, both of which also were attributable to higher sales volumes.

Discount provisions increased by \$50 million for 2018 compared to 2017, primarily due to higher sales volumes. The increase was primarily comprised of an increase of \$25 million related to REVLIMID<sup>®</sup> as well as increases related to OTEZLA<sup>®</sup> and POMALYST<sup>®</sup>.

Provisions for sales returns increased by \$37 million in 2018 compared to 2017, as the current year period included a \$32 million increase in the OTEZLA<sup>®</sup> returns reserve, primarily related to \$30 million in the fourth quarter of 2018 due to an anticipated increase in returns resulting from the sales of shorter-dated inventory in early to mid 2018. In addition, the provision for ABRAXANE<sup>®</sup> returns increased by \$5 million compared to 2017.

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 in 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 in 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<sup>®</sup>, 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 in 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<sup>®</sup> as well as increases related to OTEZLA<sup>®</sup> and POMALYST<sup>®</sup>.

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

Cost of Goods Sold (excluding amortization of acquired intangible assets): Cost of goods sold and related percentages for the years ended December 31, 2018, 2017 and 2016 were as follows:

	2018	2017	2016
Cost of goods sold (excluding amortization of acquired intangible assets)	\$587	\$461	\$438
Increase from prior year	\$126	\$23	\$18
Percent increase from prior year	27.3 %	5.3 %	4.3 %
Percent of net product sales	3.8 %	3.6 %	3.9 %

Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$126 million to \$587 million in 2018 compared to 2017. The increase was primarily due to the higher level of net product sales of REVLIMID<sup>®</sup>, POMALYST<sup>®</sup> and OTEZLA<sup>®</sup>. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) increased to 3.8% for 2018 compared to 3.6% for 2017, primarily due to raw materials charges recorded during 2018.

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<sup>®</sup>, POMALYST<sup>®</sup> and OTEZLA<sup>®</sup>, which have lower cost, making up a higher percentage of net product sales, while sales of ABRAXANE<sup>®</sup>, VIDAZA<sup>®</sup> 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, 2018, 2017 and 2016 were as follows:

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	2018	2017	2016
Research and development	\$5,673	\$5,915	\$4,470
(Decrease) increase from prior year	\$(242 )	\$1,445	\$773
Percent (decrease) increase from prior year	(4.1 )%	32.3 %	20.9 %
Percent of total revenue	37.1 %	45.5 %	39.8 %

Research and development expenses decreased by \$242 million to approximately \$5.7 billion in 2018, compared to 2017. The decrease was primarily due to an IPR&D asset impairment charge in 2017 of approximately \$1,620 million as well as other one-time charges of approximately \$188 million related to estimated wind-down costs and certain development activities associated

with the discontinuation of the GED-0301 clinical trials in CD. In 2018, we recorded an adjustment of \$60 million related to the clinical trial and development activity wind-down costs associated with the discontinuation of the GED-0301 clinical trials in CD. The decrease was also attributable to a decrease of expenses related to collaboration agreements in 2018 of \$201 million. These decreases were partially offset by higher research and development asset acquisition expense related to our purchase of Impact Biomedicines, Inc. (Impact) for approximately \$1.1 billion in 2018 as compared to \$325 million for two acquisitions in 2017. Additionally, these decreases were also offset by an increase of \$967 million of incremental research and development expense related to the acquisition of Juno, including \$320 million of share-based compensation expense. See Note 5, Note 3, and Note 18 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to the discontinuation of the GED-0301 clinical trials in CD, our acquisitions, and our collaboration arrangements, respectively. 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 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 \$1,620 million 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 5 of Notes to Consolidated Financial Statements contained elsewhere in this report 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 3 of Notes to Consolidated Financial Statements contained elsewhere in this report 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.

The following table provides a breakdown of research and development expenses:

	2018	2017	2016	Increase (Decrease)	
				2018 versus 2017	2017 versus 2016
Human pharmaceutical clinical programs	\$2,087	\$1,334	\$1,136	\$753	\$198
Other pharmaceutical programs	1,102	870	824	232	46
(Benefit) charges related to GED-0301 Trials (see Note 5*)	(60 )	1,808	—	(1,868)	1,808
Drug discovery and development	787	745	690	42	55
Collaboration arrangements (see Note 18*)	632	833	927	(201 )	(94 )
Research and development asset acquisitions (see Note 3*)	1,125	325	893	800	(568 )
Total	\$5,673	\$5,915	\$4,470	\$(242)	\$1,445

\* References to Notes in this table are to the Notes to Consolidated Financial Statements contained elsewhere in this report.

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 product candidates. See Item 1. "Business" for a table summarizing the current stage of development of both our commercial stage products and new product candidates. See Note 3 and Note 18 of Notes to Consolidated Financial Statements contained elsewhere in this report 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, 2018, 2017 and 2016 were as follows:

	2018	2017	2016		
Selling, general and administrative	\$3,250	\$2,941	\$2,658		
Increase from prior year	\$309	\$283	\$353		
Percent increase from prior year	10.5	% 10.6	% 15.3	%	
Percent of total revenue	21.3	% 22.6	% 23.7	%	

Selling, general and administrative expenses increased by \$309 million to approximately \$3.3 billion for 2018 compared to 2017. The increase is primarily due to incremental expense of \$312 million related to the acquisition of Juno, including \$208 million of share-based compensation expense. The increase was also due to an increase of approximately \$160 million of marketing related expenses and an increase of \$75 million in donations to independent non-profit patient assistance organizations in the U.S. These increases were partially offset by a decrease in litigation-related loss contingency accrual expense of \$219 million primarily related to the previously disclosed resolution of the Brown Action, which was recorded in the second quarter of 2017. See Note 3 and Note 19 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to our acquisition of Juno and legal proceedings, respectively.

Selling, general and administrative expenses increased by \$283 million to approximately \$2.9 billion in 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 19 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional information related to these legal matters. 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.

#### Amortization of Acquired Intangible Assets:

	2018	2017	2016
Amortization of acquired intangible assets	\$468	\$329	\$459
Increase (decrease) from prior year	\$139	\$(130)	\$180
Percent increase (decrease) from prior year	42.2	% (28.3)	% 64.5

Amortization of intangible assets acquired as a result of business combinations is summarized below for the years ended December 31, 2018, 2017 and 2016:

	2018	2017	2016
Abraxis	\$301	\$151	\$152
Avila	—	10	139
Gloucester	23	92	92
Juno	70	—	—
Pharmion	2	4	4
Quantice	72	72	72
Total amortization	\$468	\$329	\$459

Amortization of acquired intangible assets increased by \$139 million to \$468 million in 2018 compared to 2017. Effective for the second quarter of 2018, we reduced the remaining estimated useful life of our ABRAXANE<sup>®</sup> intangible assets as a result of recent settlements of patent-related proceedings, which resulted in approximately \$150 million of accelerated amortization. Amortization expense also increased by \$70 million as a result of the technology platform asset acquired through our acquisition of Juno. These increases were partially offset by reductions in amortization expense as the Gloucester Pharmaceuticals, Inc. (Gloucester) and Avila Therapeutics, Inc. (Avila) intangible assets were fully amortized in the first quarter of 2018 and the second quarter of 2017, respectively. See Note 19 and Note 3 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional information regarding the recent settlements regarding patent litigation and our acquisition of Juno, respectively.

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.

Acquisition Related Charges (Gains) and Restructuring, net: Acquisition related charges (gains) and restructuring, net is summarized below for the years ended December 31, 2018, 2017 and 2016:

	2018	2017	2016
Acquisition related charges (gains) and restructuring, net	\$112	\$(1,350)	\$38
Increase (decrease) from prior year	\$1,462	\$(1,388)	\$(262)

Acquisition related charges (gains) and restructuring, net was a net charge of \$112 million in 2018, compared to a net gain of approximately \$1.4 billion in 2017. The net charge in 2018 primarily relates to \$93 million of acquisition and restructuring costs associated with the acquisition of Juno. In addition, the net charge in 2018 includes a charge of \$48 million related to a current period net change in fair value of legacy Juno success payment liabilities, partially offset by a gain due to the decrease in the fair value of our liability related to publicly traded Abraxis CVRs of \$23 million that were issued as part of the acquisition of Abraxis BioScience, Inc. (Abraxis). The net gain in 2017 primarily related to a decrease in the fair value of our contingent liabilities associated with the acquisition of Nogra Pharma Limited (Nogra) due to the discontinuance of the GED-0301 trials in the fourth quarter of 2017. See Note 3 and Note 5 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to our acquisition of Juno and contingent consideration liabilities, respectively.

Acquisition related charges (gains) and restructuring, net was a net gain of approximately \$1.4 billion in 2017, compared to a net charge of \$38 million in 2016. The net gain in 2017 primarily relates to an approximate \$1.3 billion net gain recorded in 2017 for the reduction of the Nogra contingent liability due to the discontinuation of the GED-0301 Trials. See Note 5 of Notes to Consolidated Financial Statements contained elsewhere in this report for details related to the change in fair value of the Nogra contingent consideration liability.

Interest and Investment Income, Net: Interest and investment income, net is summarized below for the years ended December 31, 2018, 2017 and 2016:

	2018	2017	2016
Interest and investment income, net	\$45	\$105	\$30
(Decrease) increase from prior year	\$(60)	\$75	\$(1)
Percentage (decrease) increase from prior year	(57.1)%	250.0%	(3.2)%

Interest and investment income, net which includes the net income associated with our debt securities available-for-sale, decreased by \$60 million to \$45 million in 2018 compared to 2017 primarily due to lower investment balances as compared to the prior year.

Interest and investment income, net 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 (Expense): Interest (expense) is summarized below for the years ended December 31, 2018, 2017 and 2016:

	2018	2017	2016
Interest (expense)	\$(741)	\$(522)	\$(500)
(Increase) from prior year	\$(219)	\$(22)	\$(189)
Percentage increase from prior year	42.0 %	4.4 %	60.8 %

Interest expense increased by \$219 million to \$741 million in 2018 compared to 2017 primarily due to the interest expense associated with the issuance of \$4.5 billion of senior notes during February of 2018 as well as the issuance of \$3.5 billion of senior notes during the second half of 2017. For more information related to our debt issuances, see “Liquidity and Capital Resources” and Note 12 of Notes to Consolidated Financial Statements contained elsewhere in this report.

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 \$3.0 billion of senior notes in November 2017.

Other Income (Expense), Net: Other income (expense), net is summarized below for the years ended December 31, 2018, 2017 and 2016:

	2018	2017	2016
Foreign exchange gains (losses), including foreign exchange derivative instruments not designated as hedging instruments (see Note 6*)	\$3	\$21	\$(2 )
Fair value adjustments on equity investments (see Notes 1 and 5*)	317	—	—
Investment impairment charges	—	(54 )	(394 )
Fair value adjustments of forward point amounts (see Notes 1 and 6*)	—	—	17
Gain on sale of marketable equity securities	—	44	—
Gain on sale of LifebankUSA business (see Note 3*)	—	—	38
Other gains	17	13	17
Total other income (expense), net	\$337	\$24	\$(324)
Increase (decrease) from prior year	\$313	\$348	\$(372)

\* References to Notes in this table are to the Notes to Consolidated Financial Statements contained elsewhere in this report.

**Income Tax Provision:** The income tax provision decreased by approximately \$588 million to approximately \$786 million for 2018 compared to 2017, primarily from the impact of applying the provisions of the 2017 Tax Act. The effective tax rate for 2018 was 16.3%, a decrease of 15.5 percentage points from our effective tax rate of 31.8% for 2017. The decrease in our effective tax rate was primarily due to a 30.3 percentage point decrease related to the one-time tax effects of the 2017 Tax Act and a decrease related to the reduction in the U.S. statutory tax rate from 35% to 21%, partially offset by U.S. tax on Global Intangible Low-Taxed Income (GILTI) (subject to taxation at an effective statutory tax rate of 10.5%), lower excess tax benefits from employee stock compensation deductions, non-deductible research expenses incurred in our acquisition of Impact, lower U.S. research and development and orphan drug tax credits, and a decrease in tax benefits of lower statutory tax rates on pre-tax income earned outside the U.S.

Our effective tax rate is a function of the distribution of our pre-tax income earned inside and outside of the U.S. Our pre-tax income earned in the U.S. is taxed at a U.S. statutory tax rate of 21%. Our pre-tax income earned outside the U.S. is taxed both in the U.S. at an effective federal statutory tax rate of 10.5% and in the foreign jurisdictions where we have operations at lower effective tax rates. Our global pre-tax income is also subject to taxation in most U.S. states. Our future effective tax rate can be materially impacted by shifts in the distribution of our pre-tax income among the jurisdictions where we operate, the amount of research tax credits, the amount of foreign tax credits, 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 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. This increase was partially offset by excess tax benefits from employee stock compensation deductions, higher U.S. research and development and orphan drug tax credits, 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 17 of Notes to Consolidated Financial Statements contained elsewhere in this report.



## Liquidity and Capital Resources

The following table summarizes the components of our financial condition for the years ended December 31, 2018, 2017 and 2016:

	2018	2017	2016	Increase (Decrease)	
				2018 versus 2017	2017 versus 2016
Financial assets:					
Cash and cash equivalents	\$4,234	\$7,013	\$6,170	\$(2,779)	\$843
Debt securities available-for-sale	496	3,219	909	(2,723 )	2,310
Equity investments with readily determinable fair values	1,312	1,810	891	(498 )	919
Total financial assets	\$6,042	\$12,042	\$7,970	\$(6,000)	\$4,072
Debt:					
Short-term borrowings and current portion of long-term debt	\$501	\$—	\$501	\$501	\$(501 )
Long-term debt, net of discount	19,769	15,838	13,789	3,931	2,049
Total debt	\$20,270	\$15,838	\$14,290	\$4,432	\$1,548
Working capital <sup>1</sup>	\$5,083	\$11,980	\$7,964	\$(6,897)	\$4,016

<sup>1</sup> Includes Cash and cash equivalents, Debt securities available-for-sale, Equity investments with readily determinable fair values, 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 debt securities available-for-sale 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, debt 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 pursue strategic business initiatives for the foreseeable future. The definitive merger agreement includes restrictions on the conduct of our business prior to the completion of the merger or termination of the merger agreement, generally requiring us to conduct our business in the ordinary course consistent with past practice. Without limiting the generality of the foregoing, we are subject to a variety of specified restrictions. Unless we obtain Bristol-Myers Squibb's prior written consent (which consent may not be unreasonably withheld, conditioned or delayed) and except (i) as required or expressly contemplated by the merger agreement, (ii) as required by applicable law or (iii) as set forth in the confidential disclosure schedule delivered by Celgene to Bristol-Myers Squibb, we may not, among other things, incur additional indebtedness, issue additional shares of our common stock outside of our equity incentive plans, repurchase our common stock, pay dividends, acquire assets, securities or property (subject to certain exceptions, including without limitation, acquisitions up to a specified individual amount and an aggregate limitation), dispose of businesses or assets, enter into material contracts or make certain additional capital expenditures. See Item 1A. "Risk Factors - While the merger is pending, we are subject to business uncertainties and contractual restrictions that could materially adversely affect our operating results, financial position and/or cash flows or result in a loss of employees, customers, collaborators or suppliers."

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, 2018, we held approximately \$2.8 billion of these short-term funds in foreign tax jurisdictions. As a result of the 2017 Tax Act's favorable U.S. tax treatment of repatriated foreign earnings as well as our capital contribution reserves outside the U.S., we expect to have access to our offshore earnings with minimal to no additional U.S. or foreign tax costs. 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 earnings and profit (E&P) was mandatorily deemed to be repatriated and taxed, which is also referred to as the toll charge. We have elected to pay the toll charge in annual installments over eight years through 2025.



Share Repurchase Program: In February and May 2018, our Board of Directors approved increases of \$5.0 billion and \$3.0 billion to our authorized share repurchase program, respectively, bringing the total amount authorized since April 2009 to an aggregate of up to \$28.5 billion for our common stock repurchase program of which we have approximately \$2.8 billion remaining for future share repurchases as of December 31, 2018, after deducting \$2.0 billion paid in May 2018 pursuant to an ASR agreement. During the year ended December 31, 2018, we used \$6.1 billion of cash for purchases of our common stock measured on a settlement date basis including the \$2.0 billion paid for the ASR for which we have received full delivery of shares.

#### Components of Working Capital

Cash and Cash Equivalents, Debt Securities Available-for-Sale and Equity Investments with Readily Determinable Fair Values: From time to time, 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), ultra-short income fund investments, global corporate debt securities and asset backed securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as Debt securities available-for-sale. See Note 7 of Notes to Consolidated Financial Statements contained elsewhere in this report. The approximate \$6.0 billion decrease in Cash and cash equivalents, Debt securities available-for-sale and Equity investments with readily determinable fair values as of December 31, 2018 compared to December 31, 2017 was primarily due to approximately \$8.6 billion of payments for the acquisition of Juno, net of cash acquired, and approximately \$6.1 billion of payments under our share repurchase program, partially offset by approximately \$4.5 billion in proceeds from the February 2018 issuance of senior notes and approximately \$5.2 billion of cash from operating activities.

Accounts Receivable, Net: Accounts receivable, net increased by \$145 million to approximately \$2.1 billion as of December 31, 2018 compared to December 31, 2017. 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 decreased by \$83 million to \$458 million at the end of 2018 compared to 2017 primarily due to raw materials charges recorded during 2018.

Other Current Assets: Other current assets increased by \$113 million to \$501 million at the end of 2018 compared to 2017 primarily due to increases of \$53 million in the fair value of derivative instruments, \$38 million in prepaid taxes and \$36 million earned but unbilled revenue associated with contract assets (See Note 2 of Notes to Consolidated Financial Statements contained elsewhere in this report). These increases were partially offset by \$14 million of net other decreases.

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. As of December 31, 2018, 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. During the second quarter of 2018, we amended our Credit Facility to extend the expiration date to April 25, 2023. 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, 2018, 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, 2018.

Accounts Payable, Accrued Expenses and Other Current Liabilities: Accounts payable, accrued expenses and other current liabilities increased by \$577 million to approximately \$3.4 billion at the end of 2018 compared to 2017. The increase was primarily due to increases of \$293 million for sales adjustment accruals related to government rebates and chargebacks and distributor service fees, \$113 million for accounts payable, \$70 million related to success payment obligations assumed through our acquisition of Juno, \$65 million for accrued interest expense, \$62 million related to collaboration agreement accruals, \$60 million related to the current portion of contingent consideration and success payment liabilities assumed through our acquisition of Juno, \$39 million related to accrued legal expenses, \$38 million for clinical trials and research and development expense accruals, and \$33 million for compensation related accruals. These increases were partially offset by a decrease of \$185 million associated with the payment/adjustment of clinical trial and development activity wind-down costs associated with the discontinuance of GED-0301 clinical trials in Crohn's disease which was settled.

Income Taxes Payable (Current and Non-Current): Income taxes payable decreased by \$306 million to approximately \$2.3 billion at the end of 2018 compared to 2017, primarily due to income tax payments of approximately \$1.2 billion, which were partially offset by the current provision for income taxes of \$754 million and an increase in income taxes payable related to acquisitions.

Senior Notes: We have an aggregate of \$20.350 billion principal amount of senior notes outstanding with varying maturity dates from 2019 through 2048. See Note 12 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details.

Cash flows from operating, investing and financing activities for the years ended December 31, 2018, 2017 and 2016 were as follows:

	2018	2017	2016	Variance	
				2018	2017
				versus	versus
				2017	2016
Net cash provided by operating activities	\$5,171	\$5,246	\$4,165	\$(75 )	\$1,081
Net cash used in investing activities	\$(6,418)	\$(2,891)	\$(1,002)	\$(3,527)	\$(1,889)
Net cash used in by financing activities	\$(1,540)	\$(1,584)	\$(1,834)	\$44	\$250

Operating Activities: Net cash provided by operating activities decreased by \$75 million to approximately \$5.2 billion in 2018 compared to 2017. The decrease in net cash provided by operating activities was primarily driven by the approximate \$1.1 billion initial payment made in 2018 for the acquisition of Impact compared to \$325 million for two acquisitions in 2017 as well as an increase of \$690 million in cash paid for income taxes. These decreases were partially offset by 2017 payments totaling \$315 million for litigation-related loss contingency accruals related to the previously disclosed Brown Action and a decrease of \$201 million in payments related to collaboration arrangements in 2018 as compared to 2017. See Note 3, Note 19 and Note 18 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to the Impact acquisition, legal proceedings and collaboration arrangements, respectively.

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.

Investing Activities: Net cash used in investing activities increased by approximately \$3.5 billion in 2018 compared to 2017. The increase in net cash used in investing activities was primarily due to approximately \$8.6 billion of payments for the acquisition of Juno, net of cash acquired, partially offset by approximately \$2.7 billion of net sales of

debt securities available-for-sale in 2018 compared to approximately \$2.3 billion of net purchases of debt securities available-for-sale in 2017. See Note 3 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to the Juno acquisition.

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 \$2.3 billion of net purchases of debt securities available-for-sale during 2017 compared to \$473 million of net purchases of debt securities available-for-sale during 2016.

Financing Activities: Net cash used in financing activities decreased by \$44 million in 2018 compared to 2017. This decrease in net cash used in financing activities was primarily due to proceeds from the February 2018 debt issuance, which provided approximately \$4.5 billion compared 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 which provided approximately \$1.6 billion. In

February 2018, we issued \$500 million principal amount of 2.875% senior notes due 2021, \$1.000 billion principal amount of 3.250% senior notes due 2023, \$1.500 billion principal amount of 3.900% senior notes due 2028 and \$1.500 billion principal amount of 4.550% senior notes due 2048. See Note 12 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details. This increase was partially offset by approximately \$6.1 billion of payments under our share repurchase program during 2018 compared to approximately \$3.8 billion of payments under our share repurchase program during 2017. See Note 4 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details.

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 matured in August 2018. See Note 12 of Notes to Consolidated Financial Statements contained elsewhere in this report 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.

#### Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2018:

	Payment Due By Period				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	
Senior notes	\$1,273	\$4,439	\$5,665	\$19,669	\$31,046
Operating leases	92	159	104	68	423
Other contract commitments	175	140	95	117	527
2017 Tax Act - Federal toll charge liability	—	8	412	807	1,227
Total	\$1,540	\$4,746	\$6,276	\$20,661	\$33,223

**Senior Notes:** The senior note obligation amounts include future principal of \$20.350 billion and interest payments for both current and non-current obligations as of December 31, 2018. See Note 12 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details.

**Operating Leases:** We lease office and research facilities under various operating lease agreements in the United States and various international markets as well as automobiles and certain equipment in these same markets. The non-cancelable lease terms for operating leases expire at various dates between 2019 and 2029 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. Effective January 1, 2019, these lease obligations will be discounted and presented on our Consolidated Balance Sheet as a right-of-use asset and lease liability for leases with a duration of greater than one year. See Note 1 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to this upcoming change in accounting standard. For more information on the major facilities that we occupy under lease arrangements refer to Part I, Item 2. "Properties" of this report.

Other Contract Commitments: Other contract commitments of \$527 million as of December 31, 2018 primarily included \$495 million in contractual obligations related to product supply contracts. The non-cancelable contract terms for product supply expire at various dates between 2019 and 2027 and include renewal options. In addition, we have committed to invest an aggregate \$32 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 was mandatorily deemed to be repatriated and taxed, which is also referred to as the toll charge. 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 approximately \$1.2 billion as a non-current income tax liability, included in Income taxes payable on the Consolidated Balance Sheet as of December 31, 2018.

**Collaboration Arrangements and Acquired Research and Development Assets:** We have entered into certain research and development collaboration agreements and have acquired research and development assets or rights to products and technologies from third parties with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. 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, 2018 and 2017 contained in this Annual Report on Form 10-K. Potential milestone payments (not including potential royalty payments) total approximately \$19.7 billion, including approximately \$9.2 billion contingent on the achievement of various research, development and regulatory approval milestones and approximately \$10.5 billion in sales-based milestones. These potential milestone payments relate to arrangements in which we have obtained rights, either through a license, co-development arrangement or asset acquisition, to certain programs. However, 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. For additional information regarding certain of these relationships, see Note 3 and Note 18 of Notes to Consolidated Financial Statements contained elsewhere in this report.

**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 17 of Notes to Consolidated Financial Statements contained elsewhere in this report).

#### New Accounting Standards

For a discussion of new accounting standards please see Note 1 of Notes to Consolidated Financial Statements contained elsewhere in this report.

#### 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 report, we believe the following accounting estimates and policies to be critical:

**Revenue Recognition:** Revenue from the sale of products is recognized in a manner that depicts the transfer of those promised goods to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for these goods or services. To achieve this core principle, we follow a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, we satisfy a performance obligation. In addition, we recognize revenue from other product sales and royalties based on licensees' sales of our products or products using our technologies. We do not consider royalty revenue to be a material source of our consolidated revenue.

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

REVLIMID® and POMALYST® are distributed in the United States primarily through contracted pharmacies under the REVLIMID REMS® and POMALYST REMS®, respectively. These are proprietary risk-management distribution

programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>. Internationally, REVLIMID<sup>®</sup> and IMNOVID<sup>®</sup> 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<sup>®</sup>, ABRAXANE<sup>®</sup> and VIDAZA<sup>®</sup> are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID<sup>®</sup> and POMALYST<sup>®</sup>/IMNOVID<sup>®</sup>.

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 (70% beginning in 2019). 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® and POMALYST®/IMNOVID® 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 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 matter 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, 2018, it was more likely than not that we would realize our deferred tax assets, net of valuation allowances.

We recognize the tax on GILTI as a period expense in the period the tax is incurred. Under this policy, we have not provided deferred taxes on temporary differences that upon their reversal will affect the amount of income subject to GILTI in the period.

**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 Debt Securities Available-For-Sale:** A decline in the market value of any debt security available-for-sale 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 a debt security available-for-sale 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) (OCI), 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 OCI. The amounts recorded in OCI 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.

Beginning on April 1, 2018, all new cash flow hedging relationships are accounted for using the forward method. As a result, the entire fair value of the hedging instrument is recorded in OCI as no amounts are excluded from the assessment of hedge effectiveness. In addition, the initial value of the excluded component is recognized in OCI and not in the Consolidated Statements of Income.

**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, as equity investments with readily determinable fair values, or as equity investments without readily determinable fair values. 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 in the Consolidated Statements of Income. Our equity investments with readily determinable fair values 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. Prior to Accounting Standards Update No. 2016-01, "Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU 2016-01), which we adopted on January 1, 2018, unrealized gains and losses on these investments, which were deemed to be temporary, were reported as a separate component of stockholder's equity, net of tax. Realized gains and losses as well as other-than-temporary impairment charges related to these investments were included in Other income (expense), net in the Consolidated Statements of Income. Following the adoption of ASU 2016-01, these investments are measured at fair value with changes in fair value recognized in Other income (expense), net in the Consolidated Statements of Income and are no longer subject to impairment. Also prior to the adoption of ASU 2016-01, equity investments without readily determinable fair values were recorded at cost minus other-than-temporary impairment, with other-than-temporary impairment charges included in Other income (expense), net in the Consolidated Statements of Income. Following the adoption of ASU 2016-01, these investments are measured at cost adjusted for changes in observable prices minus impairment or at net asset value (NAV), as a practical expedient, if available, with changes in measurement recognized in Other income (expense), net in the Consolidated Statements of Income. Investments in equity investments without readily determinable fair values of companies that become publicly traded and are not classified as equity method investments are accounted for as equity investments with readily determinable fair values prospectively from the date of such companies' initial public offering. Our equity method investments and equity investments without readily determinable fair values are included in Other non-current assets on the Consolidated Balance Sheets.

All equity method investments and investments without a readily determinable fair value are reviewed on a regular basis for possible impairment. If an equity method 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. Investments without a readily determinable fair value that do not qualify for the practical expedient to estimate fair value using NAV per share are written down to fair value if a qualitative assessment indicates that the investment is impaired and the fair value of the investment is less than its carrying value. Such evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value or impairment 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; a bona fide offer to purchase, an offer by the investee to sell, or a completed auction process for the same or similar security for an amount less than the carrying amount of the investment; issues that raise concerns about the investee's ability to continue as a going concern; and 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, 2018, we had recorded liabilities for three separate three-year performance cycles running concurrently and ending December 31, 2018, 2019 and 2020. 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 Abraxis 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 Pharmaceuticals, Inc. (QuanticeL). In addition, in connection with our acquisition of Juno in the first quarter of 2018, we assumed Juno's contingent consideration and success payment liabilities. The fair values of the Gloucester, Avila, Nogra, QuanticeL, and Juno 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 Abraxis CVRs. Success payment obligations assumed through our acquisition of Juno are also recorded at their estimated fair value and are revalued quarterly with changes in fair value recognized in Acquisition related charges (gains) and restructuring, net in the Consolidated Statements of Income.



**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, 2018, our market risk sensitive instruments consisted of debt securities available-for-sale and equity investments with readily determinable fair values, our long-term debt and certain derivative contracts (See Notes 7, 12 and 6 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details, respectively).

**Debt Securities Available-for-Sale**

As of December 31, 2018, the principal amounts, fair values and related weighted-average interest rates of our investments in debt securities classified as Debt securities available-for-sale were as follows (dollar amounts in millions):

	Duration			Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	
Principal amount	\$496	\$ —	\$ —	\$496
Fair value	\$496	\$ —	\$ —	\$496
Weighted average interest rate	2.7 %	—%	—%	2.7 %

**Equity Investments with Readily Determinable Fair Values**

Our Equity investments with readily determinable fair values 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. Realized and unrealized gains and losses related to such securities are included in Other income (expense), net on the Consolidated Statements of Income.

**Debt Obligations**

**Short-Term Borrowings and Current Portion of Long-Term Debt:** We had no outstanding short-term borrowing as of December 31, 2018 or December 31, 2017. The carrying value of the current portion of long-term debt outstanding as of December 31, 2018 and December 31, 2017 includes (in millions):

	2018	2017
2.250% senior notes due 2019	\$501	\$ —
Total short-term debt	\$501	\$ —

Long-Term Debt: Our outstanding senior notes with maturity dates in excess of one year after December 31, 2018 have an aggregate principal amount of \$19.850 billion with varying maturity dates and interest rates. The principal amounts and carrying values of these senior notes as of December 31, 2018 are summarized below (in millions):

	Principal Amount	Carrying Value
2.875% senior notes due 2020	\$ 1,500	\$ 1,497
3.950% senior notes due 2020	500	509
2.250% senior notes due 2021	500	498
2.875% senior notes due 2021	500	498
3.250% senior notes due 2022	1,000	1,034
3.550% senior notes due 2022	1,000	996
2.750% senior notes due 2023	750	747
3.250% senior notes due 2023	1,000	994
4.000% senior notes due 2023	700	730
3.625% senior notes due 2024	1,000	1,000
3.875% senior notes due 2025	2,500	2,478
3.450% senior notes due 2027	1,000	986
3.900% senior notes due 2028	1,500	1,490
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
4.550% senior notes due 2048	1,500	1,476
Total long-term debt	\$ 19,850	\$ 19,769

As of December 31, 2018, the fair value of our senior notes outstanding was \$19.331 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 zero-cost collars, 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, 2018 and December 31, 2017 had settlement dates within 30 months and 20 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 OCI and reclassified to the Consolidated Statements 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. 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.

Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows as of December 31, 2018 and December 31, 2017:

	Notional Amount	
Foreign Currency:	2018	2017
Australian Dollar	\$46	\$61
British Pound	82	97
Canadian Dollar	158	227
Euro	1,381	954
Japanese Yen	424	356
Total	\$2,091	\$1,695

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, 2018, 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, 2018 and December 31, 2017 were \$347 million and \$885 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, 2018 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$228 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. The premium collected from the sale of the call option is equal to the premium paid for the purchased put option, resulting in no net premium being paid. This combination of transactions is generally referred to as a “zero-cost collar.” The expiration dates and notional amounts correspond to the amount and timing of forecasted foreign currency sales. The foreign currency zero-cost collar contracts outstanding as of December 31, 2018 and December 31, 2017 had settlement dates within 24 months and 36 months, respectively. If the U.S. Dollar weakens relative to the currency of the hedged anticipated sales, the

purchased put option value reduces to zero and we benefit from the increase in the U.S. Dollar equivalent value of our anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call, which forms the upper end of the collar.

Outstanding foreign currency zero-cost collar contracts entered into to hedge forecasted revenue were as follows as of December 31, 2018 and December 31, 2017:

	Notional Amount <sup>1</sup>	
	2018	2017
Foreign currency zero-cost collar contracts designated as hedging activity:		
Purchased Put	\$ 1,933	\$ 3,319
Written Call	\$ 2,216	\$ 3,739

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

We also have entered into foreign currency purchased put option contracts to hedge forecasted revenue which were not part of a collar strategy. Such purchased put option contracts had a notional value of nil and \$258 million as of December 31, 2018 and December 31, 2017, respectively. We de-designated all of our purchased put option contracts as of December 31, 2018.

Assuming that the December 31, 2018 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts would increase by approximately \$108 million if the U.S. Dollar were to strengthen and decrease by approximately \$113 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. As of December 31, 2018 and December 31, 2017, we did not have any outstanding forward starting swaps or treasury rate locks.

**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 Statements of Income within Interest (expense) with an associated offset to the carrying value of the notes recorded on the Consolidated Balance Sheets. 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 Statements of Income within Interest (expense) with an associated offset to the derivative asset or liability on the Consolidated Balance Sheets. 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 Statements 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, 2018 and December 31, 2017:

	Notional Amount	
	2018	2017
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	450	250
3.900% senior notes due 2028	200	—
Total	\$850	\$450

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2018 and 2017, and also terminated the hedging relationship by settling certain of those swap contracts during 2018 and 2017. We settled \$250 million and \$200 million notional amount of certain swap contracts in 2018 and 2017, respectively. The settlement of swap contracts resulted in the receipt of net proceeds of \$2 million and \$3 million during the years ended December 31, 2018 and 2017, respectively, which are accounted for as a reduction of current and future interest expense associated with these notes. See Note 12 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, 2018 would have reduced the aggregate fair value of our net payable by \$1.3 billion. A one percentage point decrease as of December 31, 2018 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

	Page
Consolidated Financial Statements	
<u>Report of Independent Registered Public Accounting Firm</u>	<u>63</u>
<u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u>	<u>64</u>
<u>Consolidated Statements of Income – Years Ended December 31, 2018, 2017 and 2016</u>	<u>65</u>
<u>Consolidated Statements of Comprehensive Income – Years Ended December 31, 2018, 2017 and 2016</u>	<u>66</u>
<u>Consolidated Statements of Cash Flows – Years Ended December 31, 2018, 2017 and 2016</u>	<u>67</u>
<u>Consolidated Statements of Stockholders' Equity – Years Ended December 31, 2018, 2017 and 2016</u>	<u>69</u>
<u>Notes to Consolidated Financial Statements</u>	<u>70</u>
Financial Statement Schedule	
<u>Schedule II – Valuation and Qualifying Accounts</u>	<u>143</u>



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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, 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, 2018, 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 26, 2019 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, 2018, the Company adopted on a prospective basis FASB Accounting Standards Update No. 2016-01, "Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" and Accounting Standards Update No. 2018-03, "Technical Corrections and Improvements to Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" which requires accounting for certain equity investments and financial liabilities under the fair value option with changes in fair value recognized in Net income. The Company recognized a cumulative effect adjustment of \$731 million to Retained Earnings on January 1, 2018 due to the adoption of these new accounting standards.

#### 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 26, 2019



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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$4,234	\$7,013
Debt securities available-for-sale	496	3,219
Equity investments with readily determinable fair values	1,312	1,810
Accounts receivable, net of allowances of \$38 and \$36 as of December 31, 2018 and 2017, respectively	2,066	1,921
Inventory	458	541
Other current assets	501	388
Total current assets	9,067	14,892
Property, plant and equipment, net	1,367	1,070
Intangible assets, net	16,213	8,436
Goodwill	8,003	4,866
Other non-current assets	830	877
Total assets	\$35,480	\$30,141
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowings and current portion of long-term debt	\$501	\$—
Accounts payable	418	305
Accrued expenses and other current liabilities	2,987	2,523
Income taxes payable	78	84
Current portion of deferred revenue	73	75
Total current liabilities	4,057	2,987
Deferred revenue, net of current portion	73	34
Income taxes payable	2,190	2,490
Deferred income tax liabilities	2,753	1,327
Other non-current liabilities	477	544
Long-term debt, net of discount	19,769	15,838
Total liabilities	29,319	23,220
Commitments and Contingencies (Note 19)		
Stockholders' Equity:		
Preferred stock, \$.01 par value per share, 5.0 million shares authorized; none outstanding as of December 31, 2018 and 2017, respectively	—	—
Common stock, \$.01 par value per share, 1,150.0 million shares authorized; issued 981.5 million and 971.7 million shares as of December 31, 2018 and 2017, respectively	10	10
Common stock in treasury, at cost; 281.3 million and 212.4 million shares as of December 31, 2018 and 2017, respectively	(26,336 )	(20,243 )
Additional paid-in capital	14,978	13,806
Retained earnings	17,559	13,061
Accumulated other comprehensive (loss) income	(50 )	287
Total stockholders' equity	6,161	6,921
Total liabilities and stockholders' equity	\$35,480	\$30,141
See accompanying Notes to Consolidated Financial Statements		



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

	Years Ended December 31,		
	2018	2017	2016
Revenue:			
Net product sales	\$15,265	\$12,973	\$11,185
Other revenue	16	30	44
Total revenue	15,281	13,003	11,229
Expenses:			
Cost of goods sold (excluding amortization of acquired intangible assets)	587	461	438
Research and development	5,673	5,915	4,470
Selling, general and administrative	3,250	2,941	2,658
Amortization of acquired intangible assets	468	329	459
Acquisition related charges (gains) and restructuring, net	112	(1,350)	38
Total costs and expenses	10,090	8,296	8,063
Operating income	5,191	4,707	3,166
Other income and (expense):			
Interest and investment income, net	45	105	30
Interest (expense)	(741)	(522)	(500)
Other income (expense), net	337	24	(324)
Income before income taxes	4,832	4,314	2,372
Income tax provision	786	1,374	373
Net income	\$4,046	\$2,940	\$1,999
Net income per share:			
Basic	\$5.65	\$3.77	\$2.57
Diluted	\$5.51	\$3.64	\$2.49
Weighted average shares:			
Basic	716.3	779.2	777.2
Diluted	733.8	808.7	803.3

See accompanying Notes to Consolidated Financial Statements

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

	Years Ended December		
	31,		
	2018	2017	2016
Net income	\$4,046	\$2,940	\$1,999
Other comprehensive income (loss):			
Foreign currency translation adjustments	(28 )	70	(26 )
Pension liability adjustment	(6 )	16	(24 )
Net unrealized gains (losses) related to cash flow hedges:			
Unrealized holding gains (losses)	245	(434 )	145
Tax benefit (expense)	1	6	(13 )
Unrealized holding gains (losses), net of tax	246	(428 )	132
Reclassification adjustment for losses (gains) included in net income	7	(178 )	(300 )
Tax (benefit)	(1 )	(3 )	(3 )
Reclassification adjustment for losses (gains) included in net income, net of tax	6	(181 )	(303 )
Excluded component related to cash flow hedges:			
Amortization of excluded component (gains)	(20 )	(15 )	—
Reclassification of realized excluded component losses to net income	28	18	—
Net reclassification adjustment included in net income	8	3	—
Net unrealized (losses) gains on available for sale debt / marketable securities (see Note 1):			
Unrealized holding (losses) gains	(9 )	611	(563 )
Tax benefit (expense)	2	(216 )	203
Unrealized holding (losses) gains, net of tax	(7 )	395	(360 )
Reclassification adjustment for losses included in net income	18	37	358
Tax (benefit)	(4 )	(14 )	(126 )
Reclassification adjustment for losses included in net income, net of tax	14	23	232
Total other comprehensive income (loss)	233	(102 )	(349 )
Comprehensive income	\$4,279	\$2,838	\$1,650
See accompanying Notes to Consolidated Financial Statements			

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

	Years Ended December		
	31,		
	2018	2017	2016
Cash flows from operating activities:			
Net income	\$4,046	\$2,940	\$1,999
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	160	134	121
Amortization	475	337	384
Impairment charges	31	1,679	489
Deferred income taxes	32	(1,330)	(344)
Change in value of contingent consideration and success payments	19	(1,350)	21
Gain on sale of business	—	—	(38)
Net loss (gain) on sales of debt securities available-for-sale and equity investments	18	(61)	(7)
Fair value adjustments on equity investments	(317)	—	—
Share-based compensation expense	921	644	606
Share-based employee benefit plan expense	33	34	40
Derivative instruments	3	72	169
Other, net	(15)	(24)	(10)
Change in current assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(178)	(236)	(222)
Inventory	82	(42)	(55)
Other operating assets	(55)	(73)	94
Accounts payable and other operating liabilities	290	273	619
Income tax payable	(393)	2,229	301
Payment of contingent consideration	(22)	—	(9)
Deferred revenue	41	20	7
Net cash provided by operating activities	5,171	5,246	4,165
Cash flows from investing activities:			
Proceeds from sales of debt securities available-for-sale	3,388	5,872	633
Purchases of debt securities available-for-sale	(675)	(8,163)	(1,106)
Capital expenditures	(330)	(279)	(236)
Proceeds from sales of equity investment securities	96	116	15
Purchases of equity investment securities	(249)	(410)	(307)
Payments for acquisition of businesses, net of cash acquired	(8,648)	—	—
Other	—	(27)	(1)
Net cash used in investing activities	(6,418)	(2,891)	(1,002)
Cash flows from financing activities:			
Payment for treasury shares	(6,096)	(3,833)	(2,160)
Proceeds from short-term borrowing	5,709	—	100
Principal repayments on short-term borrowing	(5,709)	—	(100)
Proceeds from the issuance of long-term debt	4,452	3,468	—
Repayments of long-term debt	—	(1,904)	—
Net proceeds from common equity put options	—	—	8
Payment of contingent consideration	(40)	—	(41)
Net proceeds from share-based compensation arrangements	144	685	359
Net cash used in financing activities	(1,540)	(1,584)	(1,834)

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Effect of currency rate changes on cash and cash equivalents	8	72	(39 )
Net (decrease) increase in cash and cash equivalents	(2,779 )	843	1,290
Cash and cash equivalents at beginning of period	7,013	6,170	4,880
Cash and cash equivalents at end of period	\$4,234	\$7,013	\$6,170
See accompanying Notes to Consolidated Financial Statements			



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

	Years Ended December 31,		
	2018	2017	2016
Supplemental schedule of non-cash investing and financing activity:			
Change in net unrealized loss (gain) on debt securities available-for-sale/marketable securities available-for-sale	\$9	\$(611)	\$563
Investment in Human Longevity, Inc. common stock	—	—	40
Investment in Celularity, Inc. common stock	—	22	—
Supplemental disclosure of cash flow information:			
Interest paid	\$689	\$539	\$527
Income taxes paid	1,165	475	373
See accompanying Notes to Consolidated Financial Statements			

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

Years Ended December 31, 2018, 2017 and 2016	Common Stock	Treasury Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
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	—	—	—	47	(30)	17
Balances as of December 31, 2017	\$ 10	\$(20,243)	\$ 13,806	\$ 13,061	\$ 287	\$ 6,921
Net income	—	—	—	4,046	—	4,046
Other comprehensive income	—	—	—	—	233	233
Exercise of stock options and conversion of restricted stock units	—	(104)	248	—	—	144
Shares purchased under share repurchase program	—	(6,020)	—	—	—	(6,020)
Issuance of common stock for employee benefit plans	—	31	3	—	—	34
Expense related to share-based compensation	—	—	921	—	—	921
Adoption of ASU 2014-09, ASU 2016-01, ASU 2018-03, ASU 2018-02 and ASU 2016-16 (Note 1)	—	—	—	452	(570)	(118)
Balances as of December 31, 2018	\$ 10	\$(26,336)	\$ 14,978	\$ 17,559	\$ (50)	\$ 6,161

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®, and VIDAZA®. 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 one of three methods: the equity method, as an investment without a readily determinable fair value or as an investment with a readily determinable fair value.

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 product 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. During the first quarter of 2018, we adopted Accounting Standards Update No. 2016-01, “Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities” (ASU 2016-01). As such, we have recast our previously reported marketable securities available-for-sale of \$5,029 million on our Consolidated Balance Sheet as of December 31, 2017 to conform to the current year presentation as shown in the table below. There were no changes to Total current assets or Total assets as a result of this reclassification.

	December 31, 2017	
	As Reported	As Revised
Marketable securities available-for-sale	\$5,029	N/A

Debt securities available-for-sale	N/A	\$ 3,219
Equity investments with readily determinable fair values	N/A	1,810

In addition, as a result of adopting ASU 2016-01, we have also recast certain activity within our previously reported Consolidated Statement of Cash Flows for the years ended December 31, 2017 and December 31, 2016 to conform to the current year presentation as shown in the table below. There were no changes to Net cash provided by operating activities, Net cash used in investing activities and Net cash used in financing activities as a result of this reclassification.

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

	Year Ended December 31, 2017		Year Ended December 31, 2016	
	As Reported	As Revised	As Reported	As Revised
Purchases of marketable securities available for sale	\$ (8,478)	N/A	\$ (1,281)	N/A
Purchases of investment securities	(95 )	N/A	(132 )	N/A
Purchases of debt securities available-for-sale	N/A	\$ (8,163)	N/A	\$ (1,106)
Purchases of equity investment securities	N/A	(410 )	N/A	(307 )
Proceeds from sales of marketable securities available-for-sale	5,968	N/A	633	N/A
Proceeds from sales of investment securities	20	N/A	15	N/A
Proceeds from sales of debt securities available-for-sale	N/A	5,872	N/A	633
Proceeds from sales of equity investment securities	N/A	116	N/A	15

The following is a summary of our significant accounting policies.

**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 debt securities available-for-sale and equity investments with readily determinable fair values are determined through a combination of management estimates and information obtained from third parties using the latest market data. The fair value of debt securities available-for-sale and equity investments with readily determinable fair values is determined utilizing the valuation techniques appropriate to the type of security. See Note 5.

**Derivative Instruments and Hedges:** All derivative instruments are recognized on the Consolidated Balance Sheets at their fair value. Changes in the fair value of derivative instruments are recorded each period in current earnings or Other comprehensive income (loss) (OCI), 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 Accounting Standards Update No. 2017-12, "Targeted Improvements to Accounting for Hedging Activities" (ASU 2017-12), which we adopted on August 31, 2017 (Adoption Date), with an application date of January 1, 2017 (Application Date), 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 OCI. The amounts recorded in OCI 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

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

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. Beginning on April 1, 2018, all new cash flow hedging relationships are accounted for using the forward method. As a result, the entire fair value of the hedging instrument is recorded in OCI as no amounts are excluded from the assessment of hedge effectiveness. In addition, the initial value of the excluded component is recognized in OCI and not in the Consolidated Statements of Income.

In accordance with the transition provisions of ASU 2017-12, the Company is required to eliminate the separate measurement of ineffectiveness for its cash flow hedging instruments existing as of the Adoption Date through a cumulative effect adjustment to retained earnings as of the Application Date. We did not record a cumulative-effect adjustment to eliminate ineffectiveness amounts as all such amounts were not material to the Company's previously issued Consolidated Financial Statements. In addition, we did not have any ineffectiveness during fiscal year 2017.

Also in accordance with the transition provisions of ASU 2017-12, we modified the recognition model for the excluded component from a mark-to-market approach to an amortization approach for all hedges existing as of the Adoption Date with a cumulative-effect adjustment of \$30 million that reduced Accumulated other comprehensive (loss) income (AOCI) with a corresponding adjustment that increased Retained earnings as of the Application Date.

**Cash, Cash Equivalents and Debt 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), ultra-short income fund investments, global corporate debt securities and asset backed securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as debt securities available-for-sale. We determine the appropriate classification of our investments in marketable debt securities at the time of purchase.

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 debt securities available-for-sale, 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.

A decline in the market value of any debt security available-for-sale below its carrying value that is determined to be other-than-temporary would result in a charge to earnings and decrease in the debt 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 debt 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 debt securities available-for-sale 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 securities, U.S. government-sponsored agency MBS, ultra-short income fund investments, global corporate debt securities and asset backed securities (see Note 7). 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 20). While most international sales, primarily in Europe, are 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, sales in other international regions are also made to wholesalers and distributors. 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 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



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

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 excess, 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, 2018, the carrying value of pre-approval inventory was not material.

**Property, Plant and Equipment, Net:** Property, plant and equipment, net is 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. Capitalized software costs incurred in connection with developing or obtaining software are amortized over their estimated useful life from the date the systems are ready for their intended use. 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.

**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, as equity investments with readily determinable fair values, or as equity investments without readily determinable fair values. 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 in the Consolidated Statements of Income. Our

equity investments with readily determinable fair values 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. Prior to ASU 2016-01, which we adopted on January 1, 2018, unrealized gains and losses on these investments, which were deemed to be temporary, were reported as a separate component of stockholder's equity, net of tax. Realized gains and losses as well as other-than-temporary impairment charges related to these investments were included in Other income (expense), net in the Consolidated Statements of Income. Following the adoption of ASU 2016-01, these investments are measured at fair value with changes in fair value recognized in Other income (expense), net in the Consolidated Statements of Income and are no longer subject to impairment. Also prior to the adoption of ASU 2016-01, equity investments without readily determinable fair values were recorded at cost minus other-than-temporary impairment, with other-than-temporary impairment charges included in Other income (expense), net in the Consolidated Statements of Income. Following the adoption of ASU 2016-01, these investments are measured at cost adjusted for changes in observable prices minus impairment or at net asset value (NAV), as a practical expedient, if available, with changes in measurement recognized in Other income (expense), net in the Consolidated Statements of Income. Investments in equity investments without readily determinable fair values of companies that become publicly traded and are not classified as equity method investments are accounted for as equity investments with

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

readily determinable fair values prospectively from the date of such companies' initial public offering. Our equity method investments and equity investments without readily determinable fair values are included in Other non-current assets on the Consolidated Balance Sheets.

All equity method investments and investments without a readily determinable fair value are reviewed on a regular basis for possible impairment. If an equity method 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. Investments without a readily determinable fair value that do not qualify for the practical expedient to estimate fair value using NAV per share are written down to fair value if a qualitative assessment indicates that the investment is impaired and the fair value of the investment is less than its carrying value. Such evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value or impairment 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; a bona fide offer to purchase, an offer by the investee to sell, or a completed auction process for the same or similar security for an amount less than the carrying amount of the investment; issues that raise concerns about the investee's ability to continue as a going concern; and any other information that we may be aware of related to the investment.

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

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

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

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

**Contingent Consideration from Business Combinations:** Subsequent to the acquisition date, we measure contingent consideration arrangements at fair value for each period with changes in fair value recognized in income as Acquisition related charges (gains) and restructuring, net in the Consolidated Statements of Income. Changes in contingent consideration obligation values can result from movements in publicly listed prices of our Contingent Value Rights issued in connection with our acquisition of Abraxis BioScience, Inc. (Abraxis) (Abraxis CVRs),

adjustments to discount rates, updates in the assumed achievement or timing of milestones or changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval. In the absence of new information, changes in fair value reflect only the passage of time as development work towards the achievement of the milestones progresses, and is accrued based on an accretion schedule.

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

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

**Advertising Costs:** Advertising costs are expensed when incurred and are recorded in Selling, general and administrative in the Consolidated Statements of Income. Advertising costs consist of direct-to-consumer advertising and were \$174 million, \$119 million and \$95 million for the years ended December 31, 2018, 2017 and 2016, respectively.

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

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

**Revenue Recognition:** Revenue from the sale of products is recognized in a manner that depicts the transfer of those promised goods to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for these good or services. To achieve this core principle, we follow a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, we satisfy a performance obligation. In addition, we recognize revenue from other product sales and royalties based on licensees' sales of our products or products using our technologies. We do not consider royalty revenue to be a material source of our consolidated revenue.

We record gross-to-net sales accruals for government rebates, chargebacks, distributor services fees, other rebates and administrative fees, sales returns and allowances and sales discounts. See Note 2 for further detail on gross-to-net sales accruals and revenue recognition disclosures.

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

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

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

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

New accounting standards which have been adopted

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09) and has subsequently issued a number of amendments to ASU 2014-09. The new standard, as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes previous revenue recognition guidance, including industry-specific guidance. The standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASU 2014-09 includes provisions within a five step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. See Note 2 for revenue recognition disclosures.

The new standard was effective for us on January 1, 2018 and we elected to adopt it using a modified retrospective transition method, which required a cumulative effect adjustment to opening retained earnings as of January 1, 2018. The implementation of ASU 2014-09 using the modified retrospective transition method did not have a material quantitative impact on our consolidated financial statements as the timing of revenue recognition did not significantly change. We also elected the following practical expedients, which were available to us as a result of utilizing the modified retrospective transition method:

• We applied the provisions of the standard only to contracts that were not completed as of January 1, 2018; and  
• We did not retrospectively restate contracts for contract modifications executed before the beginning of the earliest period presented.

In accordance with the transition provisions of ASU 2014-09, we recorded a cumulative effect adjustment of \$4 million to increase Retained earnings (net of a \$1 million tax effect). In limited instances, the new standard permits us to recognize revenue earlier than under the previous revenue recognition guidance. Historically, we deferred certain revenue where the transaction price pursuant to the underlying customer arrangement was not fixed or determinable. Under the new standard, such customer arrangements are accounted for as variable consideration, which results in revenue being recognized earlier provided we can reliably estimate the ultimate price expected to be realized from the customer. In addition, ASU 2014-09 requires companies who elect to adopt the standard using the modified retrospective transition method to disclose within the footnotes the effects of applying the provisions of the previous standards to current year financial statements. Revenue and Net income for the year ended December 31, 2018, do not differ materially from amounts that would have resulted from application of the previous standards.

In January 2016 and February 2018, the FASB issued ASU 2016-01 and Accounting Standards Update No. 2018-03, "Technical Corrections and Improvements to Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU-2018-03), respectively. ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. ASU 2016-01 does not apply to equity investments in consolidated subsidiaries or those accounted for under the equity method of accounting. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in Net income. We have elected to measure all of our equity investments without readily determinable fair values at cost adjusted for changes in observable prices minus impairment or at NAV, as a practical expedient, if

available. Changes in measurement of equity investments without readily determinable fair values will be recognized in Net income. The guidance related to equity investments without readily determinable fair values, in which the practical expedient has not been elected, will be applied prospectively to equity investments that exist as of the date of adoption. For equity investments without a readily determinable fair value in which the NAV per share practical expedient is elected, ASU 2018-03 clarified that the transition should not be performed prospectively, but rather as a cumulative effect adjustment to opening Retained earnings as of the beginning of the fiscal year of adoption. Equity investments without readily determinable fair values are recorded within Other non-current assets on the Consolidated Balance Sheets. We have not elected the fair value option for financial liabilities with instrument-specific credit risk. Companies must assess valuation allowances for deferred tax assets related to available-for-sale debt securities in combination with their other deferred tax assets. ASU 2016-01 was effective for us on January 1, 2018 which required a cumulative effect adjustment to opening Retained earnings to be recorded for equity investments with readily determinable fair values and equity investments without readily determinable fair values in which the NAV per share practical expedient was elected. As of the adoption date, we held publicly traded equity investments with a fair value of approximately \$1.8 billion in a net unrealized gain position of \$875 million, and having an associated deferred tax liability of \$188 million. We recorded a cumulative effect adjustment of \$687 million to decrease AOCI with a corresponding increase to Retained earnings for the amount of unrealized gains or losses, net of tax as of the beginning of fiscal year 2018. In addition, we held an equity investment without a readily determinable fair value in which we elected the NAV per share practical expedient. As such, on January 1, 2018,



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

we recorded an additional cumulative effect adjustment of \$59 million to increase equity investments without readily determinable fair values as the NAV was in excess of our cost basis as of the adoption date with a corresponding increase to Retained earnings of \$44 million, net of the tax effect of \$15 million. As a result of the implementation of ASU 2016-01, effective on January 1, 2018 unrealized gains and losses in Equity investments with readily determinable fair values and equity investments without readily determinable fair values for which observable price changes for identical or similar (e.g. dividend rights, voting rights, etc.) investments occur are recorded on the Consolidated Balance Sheets within Other income (expense), net. We recorded a net gain of \$317 million in Other income (expense), net for the year ended December 31, 2018 as a result of adopting this standard. The implementation of ASU 2016-01 is expected to increase volatility in our net income as the volatility previously recorded in OCI related to changes in the fair market value of available-for-sale equity investments will now be reflected in Net income effective with the adoption date.

In February 2018, the FASB issued Accounting Standards Update No. 2018-02, "Income Statement-Reporting Comprehensive Income: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income" (ASU 2018-02). The new standard is effective on January 1, 2019 with early adoption permitted. The guidance permits a reclassification from AOCI to Retained earnings for stranded tax effects resulting from U.S. tax reform legislation enacted in December 2017 (2017 Tax Act). We elected to early adopt ASU 2018-02 on January 1, 2018. We use a specific identification approach to release the income tax effects in AOCI. We have recast our previously reported Marketable securities available-for-sale on our Consolidated Balance Sheet as of December 31, 2017 to conform to the current year presentation as outlined earlier in this Note 1. As a result of adopting this standard, we recorded a cumulative effect adjustment to increase AOCI by \$117 million with a corresponding decrease to Retained earnings. We recorded the impacts of adopting ASU 2018-02 prior to recording the impacts of adopting ASU 2016-01 and included state income tax related effects in the amounts reclassified to Retained earnings.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments" (ASU 2016-15). ASU 2016-15 clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. ASU 2016-15 was effective for us in our first quarter of fiscal 2018 and did not result in any changes to the presentation of our Consolidated Statements of Cash Flows upon adoption.

In October 2016, the FASB issued Accounting Standards Update No. 2016-16, "Intra-Entity Transfers of Assets Other Than Inventory" (ASU 2016-16). ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets other than inventory to be recognized as current period income tax expense or benefit and removes the requirement to defer and amortize the consolidated tax consequences of intra-entity transfers. The new standard was effective for us on January 1, 2018. As of the adoption date, we had net prepaid tax assets of \$166 million related to intra-entity transfers of assets other than inventory which was recorded in Other non-current assets. Using the modified retrospective approach, we recorded a cumulative effect adjustment of \$166 million to decrease Retained earnings with a corresponding decrease in prepaid tax assets as of the beginning of fiscal year 2018.

In January 2017, the FASB issued Accounting Standards Update No. 2017-01, "Business Combinations" (ASU 2017-01). ASU 2017-01 provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities (a "set") does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing

elements. The new standard was effective for us on January 1, 2018 and was adopted on a prospective basis. In the first quarter of 2018, we acquired Impact Biomedicines Inc. (Impact) and Juno Therapeutics Inc. (Juno) which were accounted for as an asset acquisition and a business combination, respectively. See Note 3 for further information on the acquisitions of Impact and Juno. We anticipate that the adoption of this standard will result in more acquisitions being accounted for as asset acquisitions.

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

The following table presents a summary of cumulative effect adjustments to Retained earnings and AOCI due to the adoption of new accounting standards on January 1, 2018 as noted above:

	Retained Earnings Increase / (Decrease)	AOCI Increase / (Decrease)
ASU 2014-09	\$ 4	\$ —
ASU 2016-01	687	(687 )
ASU 2018-03	44	—
ASU 2018-02	(117 )	117
ASU 2016-16	(166 )	—
Net cumulative effect adjustments to Retained earnings and AOCI on January 1, 2018 due to the adoption of new accounting standards	\$ 452	\$ (570 )

New accounting standards which have not yet been adopted

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, "Leases" (ASU 2016-02). ASU 2016-02 provides accounting guidance for both lessee and lessor accounting models. Among other things, lessees will recognize a right-of-use asset and a lease liability for leases with a duration of greater than one year. For income statement purposes, ASU 2016-02 will require leases to be classified as either an operating or finance lease. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. The new standard will be effective for us on January 1, 2019. In July 2018, the FASB issued Accounting Standards Update No. 2018-11, "Leases" (ASU 2018-11), which offers a transition option to entities adopting the new lease standard. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. We will adopt the standard using the modified retrospective method and intend to elect the available practical expedients on adoption. We anticipate adoption of the new standard will increase total assets by \$280 million - \$310 million, with an offsetting increase to total liabilities of \$310 million - \$340 million on our consolidated balance sheet and result in additional lease-related disclosures in the footnotes to our consolidated financial statements. Adoption of the standard has required changes to our business processes, systems and controls to comply with the provisions of the standard. We have implemented a system from a third-party service provider to assist in the adoption of the standard. We are in the process of finalizing our testing of the system. In addition, we have designed and implemented internal controls that became operational during the first quarter of 2019 to ensure our readiness.

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

In November 2018, the FASB issued Accounting Standards Update No. 2018-18, "Collaboration Arrangements: Clarifying the Interaction between Topic 808 and Topic 606" (ASU 2018-18). The issuance of ASU 2014-09 raised questions about the interaction between the guidance on collaborative arrangements and revenue recognition. ASU

2018-18 addresses this uncertainty by (1) clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASU 2014-09 when the collaboration arrangement participant is a customer, (2) adding unit of account guidance to assess whether the collaboration arrangement or a part of the arrangement is with a customer and (3) precluding a company from presenting transactions with collaboration arrangement participants that are not directly related to sales to third parties together with revenue from contracts with customers. The new standard will be effective for us on January 1, 2020 with early adoption permitted. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

## 2. Revenue

Subsequent to January 1, 2018 we account for revenue in accordance with ASU 2014-09, which we adopted using the modified retrospective method. See Note 1 for further discussion of the adoption, including the impact on our consolidated financial statements. The majority of our revenue is derived from product sales. Our primary commercial stage products include REVLIMID®, POMALYST®/IMNOVID®, OTEZLA®, ABRAXANE® and VIDAZA®. In addition, we recognize revenue from

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

other product sales and royalties based on licensees' sales of our products or products using our technologies. We do not consider royalty revenue to be a material source of our consolidated revenue. As such, the following disclosure only relates to revenue associated with net product sales.

#### Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in the current revenue standard. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied.

At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good that is distinct. When identifying our performance obligations, we consider all goods promised in the contract regardless of whether explicitly stated in the customer contract or implied by customary business practices. Generally, our contracts with customers require us to transfer an individual distinct product, which would represent a single performance obligation. In limited situations, our contracts with customers will require us to transfer two or more distinct products, which would represent multiple performance obligations for each distinct product. For contracts with multiple performance obligations, we allocate the contract's transaction price to each performance obligation on a relative standalone selling price basis. In determining our standalone selling prices for our products, we utilize observable prices for our goods sold separately in similar circumstances and to customers in the same geographical region or market. Our performance obligations with respect to our product sales are satisfied at a point in time, which transfer control upon delivery of product to our customers. We consider control to have transferred upon delivery because the customer has legal title to the asset, we have transferred physical possession of the asset, the customer has significant risks and rewards of ownership of the asset, and in most instances we have a present right to payment at that time. The aggregate dollar value of unfulfilled orders as of December 31, 2018 was not material.

#### Distribution

REVLIMID® and POMALYST® are distributed in the United States primarily through contracted pharmacies under the REVLIMID Risk Evaluation and Mitigation Strategy (REMS) and POMALYST REMS® programs, respectively. These are proprietary risk-management distribution programs tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID® and POMALYST®. Internationally, REVLIMID® 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® 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® and POMALYST®/IMNOVID®.

#### Significant Payment Terms

Our contracts with our customers state the terms of the sale including the description, quantity, and price for each product purchased as well as the payment and shipping terms. Our contractual payment terms vary by jurisdiction. In the United States, our contractual payment terms are typically due in no more than 30 days. 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. The period between when we transfer control of the promised goods to a customer and when we receive payment from such customer is expected to be one year or less. Any exceptions to this are either not

material or we collect interest from the customer for the time period between the invoice due date and the payment date. As such, we do not adjust the invoice amount for the effects of a significant financing component as the impact is not material to our consolidated financial statements.

#### Contract Balances

When the timing of our delivery of product is different from the timing of payments made by the customers, we recognize either a contract asset (performance precedes the contractual due date) or a contract liability (customer payment precedes performance). There were no significant changes in our contract asset or liability balances during the year ended December 31, 2018 other than from transactions in the ordinary course of operating activities as described above.

#### Contract Assets

In limited situations, certain customer contractual payment terms require us to bill in arrears; thus, we satisfy some or all of our performance obligations before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. We reflect these contract assets as Other current assets on the Consolidated

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

Balance Sheet. For example, certain of our contractual arrangements do not permit us to bill until the product is sold through to the end-customer. As of December 31, 2018, such contract assets were \$36 million.

#### Contract Liabilities

In other limited situations, certain customer contractual payment terms allow us to bill in advance; thus, we receive customer cash payment before satisfying some or all of its performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. We reflect these contract liabilities in Deferred revenue on our Consolidated Balance Sheet. For example, certain of our contractual arrangements provide the customer with free product after the customer has purchased a contractual minimum amount of product. We concluded the free product represents a future performance obligation in the form of a contractual material right. As such, we defer a portion of the transaction price as a contract liability upon each sale of product until the contractual minimum volume is achieved. As we satisfy our remaining performance obligations we release a portion of the deferred revenue balance. Revenue recognized for the year ended December 31, 2018 that was reflected in the deferred revenue balance at the beginning of the year was \$51 million. As of December 31, 2018, such contract liabilities were \$137 million.

#### Gross-to-Net Sales Adjustments

We record gross-to-net sales accruals for government rebates, chargebacks, distributor service fees, other rebates and administrative fees, sales returns and allowances, and sales discounts. Provisions for discounts, early payments, rebates, sales returns, distributor service fees and 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 based upon the sales terms, historical experience and trend analysis. We estimate these accruals using an expected value approach based primarily upon our historical rebate and discount payments made and the provisions included in current customer contracts and government regulations.

#### Government Rebates, including Medicaid and Medicare Rebates

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. In the U.S., we participate in state government Medicaid programs and other Federal and state government programs, which require rebates to participating government entities. 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 (70% beginning in 2019). 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.

#### Chargebacks, Distributor Service Fees, Other Rebates and Administrative Fees

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.

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 administrative 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.



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

### Returns, Refunds and Warranties

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. We do not provide warranties on our products to our customers unless the product is defective as manufactured or damaged in transit within a reasonable period of time after receipt of the product by the customer.

### Sales Discounts

Sales discounts are based on payment terms extended to customers, which are generally offered as an incentive for prompt payment. We record our best estimate of sales discounts to which customers are likely to be entitled based on both historical information and current trends.

The reconciliation of gross product sales to net product sales by each significant category of gross-to-net adjustments was as follows:

	Years Ended December 31,		
	2018	2017	2016
Gross Product Sales	\$18,270	\$15,138	\$12,787
Gross-to-Net Adjustments:			
Government Rebates	(1,076 )	(890 )	(688 )
Chargebacks and Distributor Services Fees	(1,641 )	(1,074 )	(750 )
Sales Discounts	(243 )	(193 )	(153 )
Sales Returns and Allowances	(45 )	(8 )	(11 )
Total Gross-to-Net Adjustments	(3,005 )	(2,165 )	(1,602 )
Net Product Sales	\$15,265	\$12,973	\$11,185

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

Total revenues from external customers by our franchises (Hematology / Oncology and Inflammation & Immunology), product and geography for the years ended December 31, 2018, 2017 and 2016 were as follows:

	Years Ended December		
	31,		
	2018	2017	2016
Hematology / Oncology:			
REVLIMID®			
U.S.	\$6,469	\$5,426	\$4,417
International	3,216	2,761	2,557
Worldwide	9,685	8,187	6,974
POMALYST®/IMNOVID®			
U.S.	1,391	1,008	778
International	649	606	533
Worldwide	2,040	1,614	1,311
ABRAXANE®			
U.S.	663	607	634
International	399	385	339
Worldwide	1,062	992	973
VIDAZA®			
U.S.	9	8	12
International	585	620	596
Worldwide	594	628	608
All Other			
U.S.	208	203	236
International	68	70	66
Worldwide	276	273	302
Total Hematology / Oncology:			
U.S.	8,740	7,252	6,077
International	4,917	4,442	4,091
Worldwide	13,657	11,694	10,168
Inflammation & Immunology:			
OTEZLA®			
U.S.	1,275	1,058	904
International	333	221	113
Worldwide	1,608	1,279	1,017
Total net product sales			
U.S.	10,015	8,310	6,981
International	5,250	4,663	4,204
Worldwide	15,265	12,973	11,185
Other revenue			
	16	30	44
Total revenue			
	\$15,281	\$13,003	\$11,229



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

### 3. Acquisitions and Divestitures

#### Acquisitions in 2018:

**Impact Biomedicines, Inc. (Impact):** On February 12, 2018, we acquired all of the outstanding shares of Impact, a privately held biotechnology company which was developing fedratinib, a highly selective JAK2 kinase inhibitor, for myelofibrosis.

The consideration included an initial payment of approximately \$1.1 billion. In addition, the sellers of Impact are eligible to receive contingent consideration based upon regulatory approvals of up to \$1.4 billion and contingent consideration of up to \$4.5 billion based upon the achievement of sales in any four consecutive calendar quarters between \$1.0 billion and \$5.0 billion. The acquisition of Impact was concentrated in one single identifiable asset and thus, for accounting purposes, we have concluded that the acquired assets do not meet the accounting definition of a business. The initial payment was allocated primarily to fedratinib, resulting in a \$1.1 billion research and development asset acquisition expense and the balance of approximately \$7 million was allocated to the remaining net assets acquired.

**Juno Therapeutics, Inc. (Juno):** On March 6, 2018 (Acquisition Date), we acquired all of the outstanding shares of Juno, resulting in Juno becoming our wholly-owned subsidiary. Juno 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 added a novel scientific platform and scalable manufacturing capabilities including JCAR017 and JCARH125, both directed CAR T therapeutics currently in programs for relapsed and/or refractory diffuse large B-cell lymphoma and relapsed and/or refractory multiple myeloma, respectively.

Total consideration for the acquisition was approximately \$10.4 billion, consisting of \$9.1 billion for common stock outstanding, \$966 million for the fair value of our investment in Juno and \$367 million for the portion of equity compensation attributable to the pre-combination service period. In addition, the fair value of the awards attributed to post-combination service period was \$666 million, which will be recognized as compensation expense over the requisite service period in our post-combination financial statements. We recognized \$528 million of post-combination share-based compensation for the year ended December 31, 2018.

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

The total consideration for the acquisition of Juno was \$10.4 billion, which consisted of the following:

	Total Consideration
Cash paid for outstanding common stock at \$87.00 per share	\$ 9,101
Celgene investment in Juno at \$87.00 per share <sup>(1)</sup>	966
Cash for equity compensation attributable to pre-combination service <sup>(2)</sup>	367
Total consideration	\$ 10,434

<sup>(1)</sup> The Company recognized a gain of \$458 million during the first quarter of 2018, as a result of remeasuring to fair value the equity interest in Juno held by us before the business combination, which was recorded in Other income (expense), net within the Consolidated Statement of Income. See Note 1 for further information on the adoption of

ASU 2016-01.

(2) All equity compensation attributable to pre-combination service was paid during the first quarter of 2018.

83

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

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the Acquisition Date based upon their respective fair values summarized below. The determination of fair value was finalized in the fourth quarter of 2018. During the second and fourth quarters of 2018, the Company recorded certain measurement period adjustments that were not material.

	Amounts Recognized as of the Acquisition Date
Working capital <sup>(1)</sup>	\$ 452
IPR&D	6,980
Technology platform intangible asset	1,260
Property, plant and equipment, net	144
Other non-current assets	32
Deferred tax liabilities, net	(1,530 )
Other non-current liabilities	(41 )
Total identifiable net assets	7,297
Goodwill	3,137
Total net assets acquired	\$ 10,434

<sup>(1)</sup> Includes cash and cash equivalents, debt securities available-for-sale, accounts receivable, net of allowances, other current assets, accounts payable, accrued expenses and other current liabilities (including accrued litigation). See Note 19 for litigation matters related to Juno.

The fair value assigned to acquired IPR&D was based on the present value of expected after-tax cash flows attributable to JCAR017, which is in a pivotal phase II trial and JCARH125. The present value of expected after-tax cash flows attributable to JCAR017 and JCARH125 assigned to IPR&D was determined by estimating the after-tax costs to complete development of JCAR017 and JCARH125 into commercially viable products, estimating future revenue and ongoing expenses to produce, support and sell JCAR017 and JCARH125, on an after-tax basis, and discounting the resulting net cash flows to present value. The revenue and costs projections used were reduced based on the probability that products at similar stages of development will become commercially viable products. The rate utilized to discount the net cash flows to their present value reflects the risk associated with the intangible asset and is benchmarked to the cost of equity. Acquired IPR&D will be accounted for as indefinite-lived intangible assets until regulatory approvals for JCAR017 and JCARH125 in a major market or discontinuation of development.

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

The excess of purchase price over the fair value amounts assigned to identifiable assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill recorded as part of the acquisition is primarily attributable to the broadening of our product portfolio and research capabilities in the hematology and oncology therapeutic area, the assembled workforce and the deferred tax consequences of the IPR&D

asset recorded for financial statement purposes. We do not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition has been recorded as a non-current asset in our Consolidated Balance Sheets and is not amortized, but is subject to review for impairment annually.

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

Juno actual results from the Acquisition Date through December 31, 2018, which are included in the Consolidated Statements of Income are as follows:

Classification in the Consolidated Statements of Income	Acquisition Date Through December 31, 2018
Other revenue	\$ 2
Research and development <sup>(1)</sup>	967
Selling, general and administrative <sup>(1)</sup>	312
Amortization of acquired intangible assets	70
Acquisition related charges (gains) and restructuring, net <sup>(2)</sup>	98
Interest and investment income, net	5
Other income (expense), net	10
Income tax provision	(260 )
Total	\$ (1,170 )

<sup>(1)</sup> Includes share-based compensation expense related to the post-combination service period of \$320 million and \$208 million, which was recorded in Research and development and Selling, general and administrative, respectively, for the period from the Acquisition Date through December 31, 2018.

<sup>(2)</sup> Consists of acquisition related compensation expense, transaction costs and the change in fair value of contingent consideration and success payment liabilities. In addition, we incurred incremental acquisition costs related to Juno of \$41 million for the year ended December 31, 2018.

Pro Forma Financial Information:

The following table provides unaudited pro forma financial information for the years ended December 31, 2018 and 2017 as if the acquisition of Juno had occurred on January 1, 2017.

	Years Ended December 31,	
	2018	2017
Total revenue	\$15,291	\$13,029
Net income	4,058	2,151
Net income per common share: basic	\$5.67	\$2.76
Net income per common share: diluted	\$5.53	\$2.66

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of Celgene and Juno. The supplemental pro forma financial information reflects primarily the following pro forma adjustments:

• Elimination of research related cost sharing transactions between Celgene and Juno;

• The pro forma financial information assumes that the acquisition related transaction fees and costs, including post combination share-based compensation related to the acquisition, were removed from the year ended December 31, 2018 and were assumed to have been incurred during the first quarter of 2017;

• The pro forma financial information assumes that the gain recognized as a result of remeasuring to fair value the equity interest we held in Juno prior to the business combination was removed from the year ended December 31,



2018 and was assumed to have been recognized during the first quarter of 2017;  
• Additional interest expense and amortization of debt issuance costs for a portion of the \$4.5 billion of debt that was issued in February 2018 to partially finance the acquisition;  
• Additional amortization expense on the acquired technology platform asset; and  
• Statutory tax rates were applied, as appropriate, to each pro forma adjustment based on the jurisdiction in which the adjustment occurred.

The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings that may result from the combined operations of Celgene and Juno. Accordingly, these unaudited pro forma results are presented for illustrative purposes and are not intended to represent or be indicative of the actual results of operations of the combined company that would have been achieved

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

had the acquisition occurred at the beginning of the periods presented, nor are they intended to represent or be indicative of future results of operations.

Acquisitions in 2017:

Delinia, Inc. (Delinia): On February 3, 2017, we acquired all of the outstanding shares of Delinia, a privately held biotechnology company focused on developing novel therapeutics for the treatment of autoimmune diseases. The transaction expands our Inflammation and Immunology pipeline primarily through the acquisition of Delinia's lead program, DEL-106, as well as related second generation programs. DEL-106 is a novel IL-2 mutein Fc fusion protein designed to preferentially upregulate regulatory T cells (Tregs), immune cells that are critical to maintaining natural self-tolerance and immune system homeostasis.

The consideration included an initial payment of \$302 million. In addition, the sellers of Delinia are eligible to receive up to \$475 million in contingent development, regulatory and commercial milestones. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The initial payment was allocated primarily to the DEL-106 program, resulting in a \$300 million research and development asset acquisition expense and approximately \$2 million of net assets acquired.

Other acquisitions: In addition, during the first quarter of 2017, we acquired all of the outstanding shares of a privately held biotechnology company for total initial consideration of \$26 million. The sellers are also eligible to receive up to \$210 million in contingent development and regulatory approval milestones. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The consideration transferred resulted in a \$25 million research and development asset acquisition expense and \$1 million of net assets acquired.

Divestitures in 2017:

Celgene Pharmaceutical (Shanghai) Co. Ltd. (Celgene China): On August 31, 2017, we completed the sale of our Celgene commercial operations in China to BeiGene, Ltd. (BeiGene). The transaction resulted in an immaterial loss on disposal that was recorded on our Consolidated Statement of Income in Other income (expense), net during the third quarter of 2017. In conjunction with the sale, we contemporaneously entered into both a product supply agreement and strategic collaboration arrangement with BeiGene. See Note 18 for additional details related to the collaboration arrangement with BeiGene.

Acquisitions in 2016:

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

The consideration included an initial payment of approximately 607 million Swiss Francs (CHF) (approximately \$625 million at the time of acquisition), contingent development and regulatory milestones of up to CHF 150 million (approximately \$155 million at the time of the acquisition) and contingent commercial milestones of up to CHF 2.3 billion (approximately \$2.3 billion at the time of the acquisition) based on cumulative sales levels of between \$1 billion and \$40 billion. The acquisition of EngMab did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The initial payment

was allocated primarily to the EM901 molecule and another early stage program, resulting in a \$623 million research and development asset acquisition expense and \$2 million of net working capital acquired.

Acetylon Pharmaceuticals, Inc. (Acetylon): On December 16, 2016, we acquired all of the remaining outstanding equity interests we did not already own (approximately 86%) in Acetylon, a privately held biotechnology company focused on developing next-generation selective small molecule histone deacetylase (HDAC) inhibitors, which allow for epigenetic regulation of gene and protein function. Acetylon's lead molecule, ACY-241 is a HDAC6 inhibitor in phase I trials for relapsed and/or refractory multiple myeloma. The acquisition also included another early stage molecule. Prior to the acquisition, we had an equity interest equal to approximately 14% of Acetylon's total capital stock with a carrying value of approximately \$30 million.

The consideration transferred included an initial payment of approximately \$196 million. In addition, the sellers of Acetylon are eligible to receive contingent regulatory milestones of up to \$375 million per eligible product, contingent commercial milestones of up to \$1.5 billion based on achieving annual net sales in excess of \$1 billion and tiered royalties on annual net sales of eligible products. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The initial payment and carrying value of our previous equity interest were allocated primarily to ACY-241 and another early stage molecule, resulting in a \$226 million research and development asset acquisition expense.

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

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

The consideration transferred was valued at approximately \$42 million including the value of the exercised option of \$18 million. In addition, the sellers are eligible to receive contingent development and regulatory milestones of up to \$125 million, contingent commercial milestones of up to \$300 million based on achieving annual net sales equal in excess of \$1 billion and royalties on annual net sales. The acquisition did not include any significant processes and thus, for accounting purposes, we have concluded that the acquired assets did not meet the definition of a business. The consideration transferred was allocated primarily to the marizomib asset, resulting in a \$44 million research and development asset acquisition expense and \$1 million of net liabilities acquired.

Divestitures in 2016:

LifebankUSA: In February 2016, we completed the sale of certain assets of Celgene Cellular Therapeutics (CCT) comprising CCT's biobanking business known as LifebankUSA, CCT's biomaterials portfolio of assets, including Biovance®, and CCT's rights to PSC-100, a placental stem cell program, to Human Longevity, Inc. (HLI), a genomics and cell therapy-based diagnostic and therapeutic company based in San Diego, California. We received 3.4 million shares of HLI Class A common stock with a fair value of approximately \$40 million as consideration in the transaction. The fair value of the shares common stock we received was determined based on the most recent preferred share offering and reduced for the estimated value of the liquidation preference not offered to common share-holders. The transaction generated a \$38 million gain that was recorded on our Consolidated Statements of Income in Other income (expense), net. As of December 31, 2018, our total investment in HLI represents approximately 14% of HLI's outstanding capital stock.

4. Earnings Per Share

(Amounts in millions, except per share)

	2018	2017	2016
Net income	\$4,046	\$2,940	\$1,999
Weighted-average shares:			
Basic	716.3	779.2	777.2
Effect of dilutive securities:			
Options, RSUs, PSUs, warrants and other	17.5	29.5	26.1
Diluted	733.8	808.7	803.3
Net income per share:			
Basic	\$5.65	\$3.77	\$2.57
Diluted	\$5.51	\$3.64	\$2.49

The total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 44.8 million in 2018, 24.5 million in 2017 and 23.8 million in 2016.

Share Repurchase Program: In February and May 2018, our Board of Directors approved increases of \$5.0 billion and \$3.0 billion, respectively to our authorized share repurchase program, bringing the total amount authorized since April

2009 to \$28.5 billion of our common stock. As part of the existing Board authorized share repurchase program, in May 2018, we entered into an Accelerated Share Repurchase (ASR) agreement with a bank to repurchase an aggregate of \$2.0 billion of our common stock. As part of the ASR agreement, we received an initial delivery of approximately 18.0 million shares in May 2018 and a final delivery of approximately 6.0 million shares in August 2018. The total number of shares repurchased under the ASR agreement was approximately 24.0 million shares at a weighted average price of \$83.53 per share.

As part of the management of our share repurchase program, we may, from time to time, sell put options on our common stock with strike prices that we believe represent an attractive price to purchase our shares. If the trading price of our shares exceeds the strike price of the put option at the time the option expires, we will have economically reduced the cost of our share repurchase program by the amount of the premium we received from the sale of the put option. If the trading price of our stock is below the strike price of the put option at the time the option expires, we would purchase the shares covered by the option at the strike price

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

of the put option. During 2018 and 2017, we did not sell any put options on our common stock. During 2016, we recorded net gains of \$8 million from selling put options on our common stock on the Consolidated Statements of Income in Other income (expense), net. As of December 31, 2018 and 2017, we had no outstanding put options.

We repurchased 67.8 million shares of common stock under the share repurchase program from all sources during 2018 at a total cost of \$6.0 billion. As of December 31, 2018, we had a remaining share repurchase authorization of approximately \$2.8 billion.

5. Financial Instruments and Fair Value Measurement

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2018 and 2017, and the valuation techniques we utilized to determine such fair value.

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Our level 1 assets consist of equity investments with readily determinable fair values. Our level 1 liability relates to our publicly traded Abraxis CVRs. See Note 19 for a description of the Abraxis CVRs.

Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. From time to time, our level 2 assets consist primarily of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency MBS, global corporate debt securities, asset backed securities, ultra short income fund investments, time deposits and repurchase agreements with original maturities of greater than three months. We also have derivative instruments including foreign currency forward contracts, purchased currency options, zero-cost collar currency contracts and interest rate swap contracts, which may be in an asset or liability position.

Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. We do not have any level 3 assets. Our level 3 liabilities consist of contingent consideration related to undeveloped product rights and technology platforms resulting from the acquisitions of Gloucester Pharmaceuticals, Inc. (Gloucester), Nogra Pharma Limited (Nogra), Avila Therapeutics, Inc. (Avila) and QuanticeL Pharmaceuticals, Inc. (QuanticeL). In addition, in connection with our acquisition of Juno in the first quarter of 2018, we assumed Juno's contingent consideration and success payment liabilities.

Our contingent consideration obligations are recorded at their estimated fair values and we revalue these obligations each reporting period until the related contingencies are resolved. The fair value measurements are estimated using probability-weighted discounted cash flow approaches that are based on significant unobservable inputs related to product candidates acquired in business combinations and are reviewed quarterly. These inputs include, as applicable, estimated probabilities and timing of achieving specified development and regulatory milestones, estimated annual sales and the discount rate used to calculate the present value of estimated future payments. Significant changes which increase or decrease the probabilities of achieving the related development and regulatory events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of these obligations. The fair value of our contingent consideration as of December 31, 2018 and December 31, 2017 was calculated using the following significant unobservable inputs:

	Ranges (weighted average) utilized as of:	
Inputs	December 31, 2018	December 31, 2017
Discount rate		

	3.6 to 4.8%	2.7% to 12.0%
	(4.3%)	(3.5%)
Probability of payment	0% to 68% (5%)	0% to 20% (4%)
Projected year of payment for development and regulatory milestones	2020 to 2029 (2024)	2020 to 2029 (2024)
Projected year of payment for sales-based milestones and other amounts calculated as a percentage of annual sales	N/A	2024 to 2030 (2028)

The maximum remaining potential payments related to the contingent consideration from the acquisitions of Gloucester, Avila, QuanticeL and those assumed in our acquisition of Juno are estimated to be \$120 million, \$475 million, \$214 million, and \$286 million, respectively, and \$1.8 billion plus other amounts calculated as a percentage of annual sales pursuant to the license agreement with Nogra.

Success payment obligations assumed through our acquisition of Juno are also recorded at their estimated fair values and are revalued quarterly. Changes in the fair value of contingent consideration and success payment obligations are recognized in Acquisition related charges (gains) and restructuring, net in the Consolidated Statements of Income.

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

Effective January 1, 2018, we adopted ASU 2016-01. Among other provisions, the new standard required modifications to existing presentation and disclosure requirements on a prospective basis. Certain disclosures as of December 31, 2017 below conform to the disclosure requirements of ASU 2016-01. See Note 1 for additional information related to the adoption of ASU 2016-01.

The following tables present the Company's hierarchy for its assets and liabilities measured at fair value on a recurring basis as of December 31, 2018 and 2017:

	Balance at December 31, 2018	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt securities available-for-sale	\$ 496	\$—	\$ 496	\$ —
Equity investments with readily determinable fair values	1,312	1,312	—	—
Forward currency contracts	78	—	78	—
Total assets	\$ 1,886	\$ 1,312	\$ 574	\$ —
<b>Liabilities:</b>				
Contingent value rights	\$ (19 )	\$ (19 )	\$ —	\$ —
Interest rate swaps	(10 )	—	(10 )	—
Zero-cost collar currency contracts	(1 )	—	(1 )	—
Other acquisition related contingent consideration and success payments	(163 )	—	—	(163 )
Total liabilities	\$ (193 )	\$ (19 )	\$ (11 )	\$ (163 )
	Balance at December 31, 2017	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Debt securities available-for-sale	\$ 3,219	\$—	\$ 3,219	\$ —
Equity investments with readily determinable fair values	1,810	1,810	—	—
Total assets	\$ 5,029	\$ 1,810	\$ 3,219	\$ —
<b>Liabilities:</b>				
Contingent value rights	\$ (42 )	\$ (42 )	\$ —	\$ —
Forward currency contracts	(42 )	—	(42 )	—
Interest rate swaps	(7 )	—	(7 )	—
Zero-cost collar currency contracts	(136 )	—	(136 )	—
Other acquisition related contingent consideration	(80 )	—	—	(80 )
Total liabilities	\$ (307 )	\$ (42 )	\$ (185 )	\$ (80 )



As a result of the implementation of ASU 2016-01 and ASU 2018-03, effective on January 1, 2018, we measure equity investments without a readily determinable fair value at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer or at NAV, as a practical expedient, if available. We record upward adjustments and downward adjustments and impairments of equity investments without readily determinable fair values within Other income (expense), net on the Consolidated Statements of Income. The following table represents a roll-forward of equity investments without readily determinable fair values:

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

	Year Ended December 31, 2018
Balance as of December 31, 2017	\$ 513
Cumulative effect adjustment for the adoption of ASU 2018-03 (See Note 1)	59
Purchases	105
Upward adjustments	66
Sales	(23 )
Downward adjustments and impairments	(134 )
Transfer to readily determinable fair value	(41 )
Balance as of December 31, 2018	\$ 545

For equity investments with and without readily determinable fair values held as of December 31, 2018, we recorded a net unrealized loss of \$201 million within Other income (expense), net on the Consolidated Statements of Income for the year ended December 31, 2018.

There were no security transfers between levels 1, 2 and 3 during the years ended December 31, 2018 and 2017. The following tables represent a roll-forward of the fair value of level 3 instruments:

	Year Ended December 31, 2018
Liabilities:	
Balance as of December 31, 2017	\$ (80 )
Amounts acquired from Juno, including measurement period adjustments	(116 )
Net change in fair value	(39 )
Settlements, including transfers to Accrued expenses and other current liabilities	72
Balance as of December 31, 2018	\$ (163 )

	Year Ended December 31, 2017
Liabilities:	
Balance as of December 31, 2016	\$ (1,490 )
Net change in fair value	1,348
Settlements, including transfers to Accrued expenses and other current liabilities	62
Balance as of December 31, 2017	\$ (80 )

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 Crohn's disease (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 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;
- 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.

During 2018, we recorded an adjustment related to the clinical trial and development activity wind-down costs which resulted in a benefit of \$60 million being recorded in Research and development within the Consolidated Statement of Income. In addition, all of these wind-down costs have been paid.

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

## 6. Derivative Instruments and Hedging Activities

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 zero-cost collars, 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, 2018 and December 31, 2017 had settlement dates within 30 months and 20 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 OCI and reclassified to the Consolidated Statements 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. 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.

Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows as of December 31, 2018 and December 31, 2017:

Notional  
 Amount

Foreign Currency:	2018	2017
Australian Dollar	\$46	\$61
British Pound	82	97
Canadian Dollar	158	227
Euro	1,381	954
Japanese Yen	424	356
Total	\$2,091	\$1,695

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, 2018, 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

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

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, 2018 and December 31, 2017 were \$347 million and \$885 million, respectively.

**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. The premium collected from the sale of the call option is equal to the premium paid for the purchased put option, resulting in no net premium being paid. This combination of transactions is generally referred to as a “zero-cost collar.” The expiration dates and notional amounts correspond to the amount and timing of forecasted foreign currency sales. The foreign currency zero-cost collar contracts outstanding as of December 31, 2018 and December 31, 2017 had settlement dates within 24 months and 36 months, respectively. If the U.S. Dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. Dollar equivalent value of our anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call, which forms the upper end of the collar.

Outstanding foreign currency zero-cost collar contracts entered into to hedge forecasted revenue were as follows as of December 31, 2018 and December 31, 2017:

	Notional Amount <sup>1</sup>	
	2018	2017
Foreign currency zero-cost collar contracts designated as hedging activity:		
Purchased Put	\$ 1,933	\$ 3,319
Written Call	2,216	3,739

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

We also have entered into foreign currency purchased put option contracts to hedge forecasted revenue which were not part of a collar strategy. Such purchased put option contracts had a notional value of nil and \$258 million as of December 31, 2018 and December 31, 2017, respectively. We de-designated all of our purchased put option contracts prior to December 31, 2018.

#### 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. As of December 31, 2018 and December 31, 2017, we did not have any outstanding forward starting swaps or treasury rate locks.

**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 Statements of Income within Interest (expense) with an associated offset to the carrying value of the notes recorded on the Consolidated Balance Sheets. 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 Statements of Income within Interest (expense) with an associated offset to the derivative asset or liability on the Consolidated Balance Sheets. 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 Statements 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.

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

The following table summarizes the notional amounts of our outstanding interest rate swap contracts as of December 31, 2018 and December 31, 2017:

	Notional Amount	
	2018	2017
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	450	250
3.900% senior notes due 2028	200	—
Total	\$850	\$450

We have entered into swap contracts that were designated as hedges of certain of our fixed rate notes in 2018 and 2017, and also terminated the hedging relationship by settling certain of those swap contracts during 2018 and 2017. We settled \$250 million and \$200 million notional amount of certain swap contracts in 2018 and 2017, respectively. The settlement of swap contracts resulted in the receipt of net proceeds of \$2 million and \$3 million during the years ended December 31, 2018 and 2017, respectively, which are accounted for as a reduction of current and future interest expense associated with these notes. See Note 12 for additional details related to reductions of current and future interest expense.

The following table summarizes the fair value and presentation in the Consolidated Balance Sheets for derivative instruments as of December 31, 2018 and 2017:

Instrument	Balance Sheet Location	December 31, 2018	
		Asset	Liability
		Derivatives	Derivatives
Derivatives designated as hedging instruments:			
Foreign exchange contracts <sup>1</sup>	Other current assets	\$ 63	\$ 18
	Other non-current assets	45	16
	Other non-current liabilities	12	15
Interest rate swap agreements	Other current assets	7	—
	Other non-current assets	1	—
	Other non-current liabilities	1	19
Derivatives not designated as hedging instruments:			
Foreign exchange contracts <sup>1</sup>	Other current assets	21	5
	Accrued expenses and other current liabilities	2	12
Interest rate swap agreements	Other current assets	2	3
	Other non-current assets	5	4
Total		\$ 159	\$ 92

<sup>1</sup> Derivative instruments in this category are subject to master netting arrangements and are presented on a net basis on the Consolidated Balance Sheets in accordance with Accounting Standards Codification (ASC) 210-20.



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

Instrument	Balance Sheet Location	December 31, 2017	
		Fair Value Asset	Fair Value Liability
Derivatives designated as hedging instruments:			
Foreign exchange contracts <sup>1</sup>	Other current assets	\$ 5	\$ 1
	Accrued expenses and other current liabilities	30	79
	Other non-current assets	1	—
	Other non-current liabilities	36	159
Interest rate swap agreements	Other current assets	3	—
	Other non-current liabilities	—	11
Derivatives not designated as hedging instruments:			
Foreign exchange contracts <sup>1</sup>	Other current assets	8	1
	Accrued expenses and other current liabilities	4	22
Interest rate swap agreements	Other current assets	2	2
	Other non-current assets	4	3
Total		\$ 93	\$ 278

<sup>1</sup> Derivative instruments in this category are subject to master netting arrangements and are presented on a net basis in the Consolidated Balance Sheets in accordance with ASC 210-20.

As of December 31, 2018 and December 31, 2017, the following amounts were recorded on the Consolidated Balance Sheets related to cumulative basis adjustments for fair value hedges:

Consolidated Balance Sheet Classification in Which the Hedged Item Is Included	Carrying Amount of the Hedged Liability		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability	
	December 31, 2018 <sup>(1)</sup>	December 31, 2017 <sup>(1)</sup>	December 31, 2018 <sup>(2)</sup>	December 31, 2017 <sup>(2)</sup>
Current portion of long-term debt, net of discount	\$ 501	\$ —	\$ 2	\$ —
Long-term debt, net of discount	8,227	7,270	90	128

(1) The current portion of long-term debt, net of discount includes \$501 million of carrying value with discontinued hedging relationships as of December 31, 2018. The long-term debt, net of discount includes approximately \$3.3 billion and \$3.8 billion of carrying value with discontinued hedging relationships as of December 31, 2018 and December 31, 2017, respectively.

(2) The current portion of long-term debt, net of discount includes \$2 million of hedging adjustments on discontinued hedging relationships as of December 31, 2018. The long-term debt, net of discount includes \$107 million and \$139 million of hedging adjustment on discontinued hedging relationships on long-term debt as of December 31, 2018 and December 31, 2017, respectively.



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

The following tables summarizes the effect of derivative instruments designated as cash-flow hedging instruments in AOCI for the years ended December 31, 2018 and 2017:

2018

Instrument	Amount of Gain/(Loss) Recognized in OCI on Derivative <sup>(1)</sup>	Amount of Gain/(Loss) Recognized in OCI	Classification of Gain/(Loss) Recognized in OCI	Amount Excluded from Income Related to Effectiveness Testing	Amount of Gain/(Loss) Recognized in Income on Derivative Related to Amount Excluded from Effectiveness Testing
Foreign exchange contracts					