

CELGENE CORP /DE/

FORM 8-K (Current report filing)

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Address	86 MORRIS AVENUE SUMMIT, NJ, 07901
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Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **May 4, 2018**

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

001-34912

(Commission File Number)

22-2711928

(IRS Employer Identification No.)

86 Morris Avenue, Summit, New Jersey

(Address of principal executive offices)

07901

(Zip Code)

Registrant's telephone number, including area code: **(908) 673-9000**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On May 4, 2018, Celgene Corporation issued a press release announcing its financial results for its fiscal quarter ended March 31, 2018. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, that is furnished pursuant to this Item 2.02 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibit 99.1 Press Release dated May 4, 2018 announcing results for the quarter ended March 31, 2018.

This exhibit is furnished pursuant to Item 2.02 and shall not be deemed to be “filed.”

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release dated May 4, 2018 announcing results for the quarter ended March 31, 2018.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELGENE CORPORATION

Date: May 4, 2018

By: /s/ Peter N. Kellogg
Peter N. Kellogg
Executive Vice President
Chief Financial Officer
(principal financial and accounting officer)



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**CELGENE REPORTS FIRST QUARTER 2018
 OPERATING AND FINANCIAL RESULTS**

- *Q1:18 total net product sales of \$3,531 million increased 20% Y/Y*
- *Raising full-year 2018 revenue guidance to high end of previous range*
- *Completion of Juno Therapeutics & Impact Biomedicines acquisitions will strengthen pipeline and capabilities*
 - *Submission of NDA and MAA for ozanimod in relapsing multiple sclerosis expected in Q1:19*

SUMMIT, NJ — (May 4, 2018) — Celgene Corporation (NASDAQ: CELG) reported net product sales of \$3,531 million for the first quarter of 2018, a 20 percent increase from the same period in 2017. Celgene reported first quarter 2018 total revenue of \$3,538 million, a 19 percent increase compared to \$2,962 million in the first quarter of 2017.

Based on U.S. GAAP (Generally Accepted Accounting Principles), Celgene reported net income of \$846 million and diluted earnings per share (EPS) of \$1.10 for the first quarter of 2018. For the first quarter of 2017, GAAP net income was \$932 million and diluted EPS was \$1.15.

Adjusted net income for the first quarter of 2018 increased 16 percent to \$1,572 million compared to \$1,355 million in the first quarter of 2017. For the same period, adjusted diluted EPS increased 23 percent to \$2.05 (inclusive of approximately \$0.05 dilution from the Juno acquisition) from \$1.67.

“Strong global demand and excellent commercial execution drove our exceptional first quarter results, leading to improvement in our 2018 financial guidance,” said Mark J. Alles, Chairman and Chief Executive Officer of Celgene Corporation. “With multiple catalysts for growth expected over the next 12 to 18 months, we are reaffirming our 2020 outlook.”

First Quarter 2018 Financial Highlights

Unless otherwise stated, all comparisons are for the first quarter of 2018 compared to the first quarter of 2017. The adjusted operating expense categories presented below exclude share-based employee compensation expense, research and development asset acquisition expense, collaboration-related upfront expense and a benefit associated with the adjustment to clinical trial and development activity wind-down costs. Please see the attached Use of Non-GAAP Financial Measures and Reconciliation of GAAP to Adjusted Net Income for further information relevant to the interpretation of adjusted financial measures and reconciliations of these adjusted financial measures to the most comparable GAAP measures, respectively.

Net Product Sales Performance

- REVLIMID[®] sales for the first quarter increased 19 percent to \$2,234 million. Sales growth was primarily volume-driven due to increases in treatment duration and market share. U.S. sales of \$1,487 million and international sales of \$747 million increased 21 percent and 15 percent year-over-year, respectively.
- POMALYST[®]/IMNOVID[®] sales for the first quarter were \$453 million, an increase of 24 percent year-over-year. U.S. sales were \$300 million and international sales were \$153 million, an increase of 39 percent and 3 percent year-over-year, respectively. POMALYST[®]/IMNOVID[®] sales growth was primarily volume-driven due to increases in treatment duration and market share.
- OTEZLA[®] sales for the first quarter were \$353 million, a 46 percent increase year-over-year. First quarter U.S. sales of \$276 million and international sales of \$77 million increased 39 percent and 79 percent, year-over-year, respectively. OTEZLA[®] sales in the U.S. were primarily volume-driven due to increasing demand and improved access pull-through in contracted health plans. OTEZLA[®] international sales growth was driven primarily by increasing adoption in key ex-U.S. markets.
- ABRAXANE[®] sales for the first quarter were \$262 million, an 11 percent increase year-over-year. U.S. sales were \$159 million and international sales were \$103 million, an increase of 12 percent and 10 percent, year-over-year, respectively. ABRAXANE[®] sales were positively impacted by buying patterns. Growth in Europe was driven by market share gains for ABRAXANE[®] in pancreatic cancer.
- In the first quarter, all other product sales, which include IDHIFA[®], THALOMID[®], ISTODAX[®], VIDAZA[®] and an authorized generic version of VIDAZA[®] drug product primarily sold in the U.S., were \$229 million compared to \$226 million in the first quarter of 2017.

Research and Development (R&D)

On a GAAP basis, R&D expenses were \$2,203 million for the first quarter of 2018 versus \$995 million for the same period in 2017. The first quarter increase was primarily due to an increase in research and development asset acquisition expense relating to our acquisition of Impact Biomedicines, Inc. (Impact), an increase in share-based compensation expense related to our acquisition of Juno Therapeutics, Inc. (Juno), and increased spending related to clinical trial and other R&D activity, partially offset by a reduction of one-time charges related to wind-

down costs associated with the GED-0301 clinical trials in Crohn's disease and certain development activities.

Adjusted R&D expenses were \$694 million for the first quarter of 2018 compared to \$595 million for the first quarter of 2017. The first quarter increase was primarily due to increased spending related to clinical trial and other R&D activities.

Selling, General, and Administrative (SG&A)

On a GAAP basis, SG&A expenses were \$864 million for the first quarter of 2018 compared to \$620 million for the same period in 2017. The first quarter increase was primarily due to an increase in share-based compensation expense related to our acquisition of Juno and an increase in promotional activities and legal expenses.

Adjusted SG&A expenses were \$671 million for the first quarter of 2018 compared to \$539 million for the first quarter of 2017. The first quarter increase was primarily due to an increase in promotional activities and legal expenses.

Cash, Cash Equivalents, Marketable Debt Securities and Publicly-Traded Equity Securities

Operating cash flow was \$(325) million in the first quarter of 2018, compared to \$853 million for the first quarter of 2017, which was primarily impacted by the \$1.1 billion upfront cash payment to acquire Impact Biomedicines (fedratinib).

In the first quarter, Celgene completed two strategic acquisitions for over \$10 billion. We repurchased approximately 29.0 million shares at a total cost of approximately \$2.7 billion. Celgene raised \$4.5 billion in a debt offering to finance a portion of the acquisition of Juno. Celgene ended the quarter with approximately \$4.7 billion in cash, cash equivalents, marketable debt securities and publicly-traded equity securities.

Celgene Expects Volume-Driven Product Sales and Earnings Growth in 2018

	Previous 2018 Guidance*	Updated without dilution from Juno	Updated with dilution from Juno
Total Revenue	\$14.4B to \$14.8B	~\$14.8B	~\$14.8B
REVLIMID [®] Net Product Sales	~ \$9.4B	~ \$9.5B	~ \$9.5B
POMALYST [®] /IMNOVID [®] Net Product Sales	~ \$1.9B	~ \$2.0B	~ \$2.0B
OTEZLA [®] Net Product Sales	~ \$1.5B	Unchanged	Unchanged
ABRAXANE [®] Net Product Sales	~ \$1.0B	Unchanged	Unchanged
GAAP Operating Margin	~ 46.5%	~ 45%	~ 38%
GAAP Diluted EPS	\$7.26 to \$7.66	~\$7.36	~\$6.31
Adjusted Operating Margin	~ 60.0%	Unchanged	~56.0%
Adjusted Diluted EPS	\$8.70 to \$8.90	~\$8.95	~\$8.45
Adjusted Tax Rate	~18%	~ 17.5%	~17%
Weighted Average Diluted Shares	~ 775M	~755M	~755M

* Previous 2018 guidance did not include the impact of our acquisition of Juno, which was expected to be dilutive to adjusted diluted EPS in 2018 by approximately \$0.50.

Product and Pipeline Updates

Hematology & Oncology

- At the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in June, data presentations are expected to include:
 - Updated durability and safety data from the pivotal TRANSCEND NHL-001 trial evaluating liso-cel (JCAR017) in patients with relapsed or refractory aggressive non-Hodgkin lymphoma (NHL). In addition, the pivotal TRANSCEND NHL-001 trial completed enrollment in April.
 - In collaboration with partner bluebird bio, updated data from the CRB-401 phase I trial evaluating bb2121 in patients with relapsed and/or refractory multiple myeloma (RRMM).
 - Results from the phase III OPTIMISMM[®] trial evaluating POMALYST[®] in combination with bortezomib and dexamethasone (PvD) in patients with second-line multiple myeloma.
 - Results from the phase III RELEVANCE[®] trial with REVLIMID[®] in combination with rituximab (R²) in patients with previously untreated follicular lymphoma (FL).
 - Primary progression-free survival (PFS) and safety analysis from the Genentech-sponsored phase III IMpower131 trial evaluating atezolizumab plus chemotherapy (carboplatin and ABRAXANE[®]) as first-line treatment in patients with advanced squamous non-small cell lung cancer (NSCLC).
- In April, Celgene initiated the pivotal TRANSCEND WORLD trial evaluating liso-cel in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in the EU and Japan. These data are expected to support international registration submissions for liso-cel in DLBCL.
- The phase I TRANSCEND CLL-004 trial evaluating liso-cel in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) initiated in the first quarter.
- The phase I EVOLVE trial evaluating JCARH125, a chimeric antigen receptor (CAR) T cell therapy targeting B-cell maturation antigen (BCMA), in patients with RRMM initiated in the first quarter.
- Celgene's partner BeiGene initiated the phase III trial evaluating BGB-A317 (tislelizumab) versus sorafenib in patients with previously untreated advanced hepatocellular carcinoma (HCC) in the first quarter. In addition, a phase II trial evaluating tislelizumab in patients with previously treated advanced HCC was initiated.

Inflammation & Immunology

- In February, Celgene announced it received a Refusal To File (RTF) letter from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for
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ozanimod in relapsing multiple sclerosis (RMS). Following a Type A meeting with the FDA in early April, Celgene expects to resubmit the NDA in the first quarter of 2019.

- Following a meeting with European regulatory authorities, Celgene expects to submit a Marketing Authorization Application (MAA) for ozanimod in RMS in the first quarter of 2019.
- At the 2018 American Academy of Neurology (AAN) Annual meeting in April, data from new analyses of both pivotal phase III SUNBEAM™ and RADIANCE™ Part B trials evaluating ozanimod in RMS were presented. These new analyses show dose-dependent effects of ozanimod on annualized relapse rate (ARR) versus interferon beta-1a (Avonex®) across subgroups, including baseline disability and prior exposure to disease-modifying therapies, that were consistent with the overall ARR primary endpoint. In addition, data presentations of exploratory endpoints showed reductions in cortical grey matter and thalamic volume loss consistent with the reductions in whole brain volume loss seen in SUNBEAM™ at one year and RADIANCE™ Part B at two years for ozanimod compared with Avonex®. The overall safety and tolerability profile for ozanimod has been consistent across the RADIANCE™ Part A, SUNBEAM™ and RADIANCE™ Part B studies.
- In February, data from the phase II randomized, double-blind, placebo-controlled proof of concept study evaluating OTEZLA® in patients with ulcerative colitis (UC) were presented at the 13th Congress of the European Crohn's and Colitis Organization (ECCO). In addition, these phase II data have also been accepted for an encore presentation at the Digestive Disease Week® (DDW) meeting in June. Celgene plans to initiate the pivotal program with OTEZLA® in UC in 2018.

Business Updates

- In March, Celgene announced that it completed the acquisition of Juno, a biopharmaceutical company focused on developing innovative cellular immunotherapies for the treatment of cancer. The Juno acquisition positions Celgene as a global cellular immunotherapy company by adding a novel scientific platform and scalable manufacturing capabilities, in addition to liso-cel, an investigational CD19-directed CAR T currently in a clinical development program for relapsed and/or refractory DLBCL.

Celgene acquired all the outstanding shares of common stock of Juno through a tender offer for \$87 per share in cash, or an aggregate of approximately \$9.1 billion. The transaction was funded through a combination of existing cash, cash equivalents, debt securities available-for-sale and new debt.

- In February, Celgene completed the acquisition of Impact, a privately-held biotechnology company developing fedratinib, a highly selective Janus kinase 2 (JAK2) inhibitor, for myelofibrosis. This acquisition strengthens Celgene's commitment to myelofibrosis, a disease with high unmet medical need, and expands strategic development options within Celgene's myeloid portfolio of assets.
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Under the terms of the agreement, Celgene paid approximately \$1.1 billion upfront, contingent consideration based upon regulatory approvals of up to \$1.4 billion (including \$1.25 billion for myelofibrosis), 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.

- In March, Celgene and Prothena Corporation (Prothena) announced a global collaboration to develop new therapies for a broad range of neurodegenerative diseases. The multi-year research and development collaboration is focused on three proteins implicated in the pathogenesis of several neurodegenerative diseases, including tau, TDP-43 and an undisclosed target. For each of the programs, Celgene has an exclusive right to license clinical candidates in the U.S. at Investigational New Drug (IND) filing, and if exercised, would also have a right to expand the license to global rights at the completion of phase I.

Under the terms of the collaboration, Prothena received a \$150 million upfront payment (which includes an equity investment) plus future potential exercise payments and regulatory and commercial milestones for each licensed program. Prothena will also receive additional royalties on net sales of any resulting marketed products.

- In March, Celgene and Vividion Therapeutics Inc. (Vividion), announced a multi-year strategic research collaboration focused on the identification and development of unique small molecules against targets for a range of oncology, inflammatory and neurodegenerative indications. The collaboration utilizes Vividion's platform to identify ligands and discover drug candidates against a selected list of high-value, difficult-to-drug targets.

Under the terms of the collaboration, Vividion received an upfront payment of \$101 million (which includes an equity investment). Celgene will have the right to opt in to programs at IND acceptance and Celgene will receive exclusive worldwide rights for certain programs, including the first program. In addition, other programs will allow for Celgene and Vividion to share equally either U.S. or worldwide development costs and commercialization profits and losses.

- In early March, Celgene's partner bluebird bio opted in on their right to co-develop and co-promote bb2121, an investigational anti-BCMA CAR T cell therapy for the treatment of patients with RRMM in the United States. The companies originally entered into a broad, global strategic research collaboration in 2013 to discover, develop and commercialize novel therapies in oncology, which included bb2121. Celgene and bluebird bio amended and restated the collaboration agreement in 2015 to focus on developing product candidates targeting BCMA.

Organizational Updates

- Celgene recently announced the election of Hans Bishop, Patricia "Pat" Hemingway Hall and John Weiland to the Board of Directors.
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Mr. Bishop is a 30-year industry veteran and pioneer in the field of cellular immunotherapy whose expertise will help Celgene lead in this extremely promising area of science. He was most recently President and CEO of Juno, a cellular immunotherapy company that he co-founded in 2013 and led until Juno was acquired by Celgene in March 2018.

Ms. Hemingway Hall has more than 30 years of experience with a focus on the U.S. health insurance market and deep understanding of the U.S. market access landscape which will help to shape Celgene's strategy in an increasingly complex environment. She most recently was CEO of Health Care Service Corporation (HCSC), the nation's largest mutual health insurance company, which operates as Blue Cross and Blue Shield in Illinois, Montana, New Mexico, Oklahoma and Texas, from 2008 until her retirement in 2015.

Mr. Weiland has over 30 years in the healthcare industry with significant expertise and experience across therapeutic areas and geographies. His leadership and insight will help to inform and direct Celgene's long-term growth strategy. He was most recently the President and Chief Operating Officer of C. R. Bard, Inc. (Bard), with worldwide responsibility for all of Bard's business operations prior to it being acquired by Becton, Dickinson and Company (BD) in December 2017.

First Quarter 2018 Conference Call and Webcast Information

Celgene will host a conference call to discuss the first quarter of 2018 operational and financial performance on Friday, May 4, 2018, at 9 a.m. ET. The conference call will be available by webcast at www.celgene.com. An audio replay of the call will be available from noon May 4, 2018, until midnight ET May 11, 2018. To access the replay in the U.S., dial (855) 859-2056; outside the U.S. dial (404) 537-3406. The participant passcode is 6196716.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, 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. For more information, please visit www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

About REVLIMID®

In the U.S., REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma. REVLIMID® as a single agent is also indicated as a maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplant. REVLIMID® is indicated for patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. REVLIMID® is approved in the U.S. for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. Limitations of Use: REVLIMID® is not indicated and is not recommended for the treatment of chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

About ABRAXANE[®]

In the U.S., ABRAXANE[®] for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) is indicated for the treatment of 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. ABRAXANE[®] is indicated for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. ABRAXANE[®] is also indicated for the first-line treatment of metastatic adenocarcinoma of the pancreas in combination with gemcitabine.

About POMALYST[®]

In the U.S., POMALYST[®] (pomalidomide) is indicated for patients with multiple myeloma 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.

About OTEZLA[®]

In the U.S., OTEZLA[®] (apremilast) is indicated for the treatment of adult patients with active psoriatic arthritis. OTEZLA[®] is indicated in the U.S. for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Forward-Looking Statement

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans,” “will,” “outlook” and similar expressions. Forward-looking statements are based on management’s current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

Hyperlinks are provided as a convenience and for informational purposes only. Celgene bears no responsibility for the security or content of external websites.

Use of Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this document also contains certain non-GAAP financial measures based on management's view of performance including:

- Adjusted research and development expense
- Adjusted selling, general and administrative expense
- Adjusted operating margin
- Adjusted net income
- Adjusted earnings per share

Management uses such measures internally for planning and forecasting purposes and to measure the performance of the Company. We believe these adjusted financial measures provide useful and meaningful information to us and investors because they enhance investors' understanding of the continuing operating performance of our business and facilitate the comparison of performance between past and future periods. These adjusted financial measures are non-GAAP measures and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. When preparing these supplemental non-GAAP financial measures we typically exclude certain GAAP items that management does not consider to be normal, recurring, cash operating expenses but that may not meet the definition of unusual or non-recurring items. Other companies may define these measures in different ways. The following categories of items are excluded from adjusted financial results:

Acquisition and Divestiture-Related Costs: We exclude the impact of certain amounts recorded in connection with business combinations and divestitures from our adjusted financial results that are either non-cash or not normal, recurring operating expenses due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing. These amounts may include non-cash items such as the amortization of acquired intangible assets, amortization of purchase accounting adjustments to inventories, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of contingent consideration and success payments. We also exclude transaction and certain other cash costs associated with business acquisitions and divestitures that are not normal recurring operating expenses, including severance costs which are not part of a formal restructuring program.

Share-based Compensation Expense: We exclude share-based compensation from our adjusted financial results because share-based compensation expense, which is non-cash, fluctuates from period to period based on factors that are not within our control, such as our stock price on the dates share-based grants are issued.

Collaboration-related Upfront Expenses: We exclude collaboration-related upfront expenses from our adjusted financial results because we do not consider them to be normal, recurring operating expenses due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing. Upfront payments to collaboration partners are made at the commencement of a relationship anticipated to continue for a multi-year period and provide us with intellectual property rights, option rights and other rights with respect to particular programs. The variability of amounts and lack of predictability of collaboration-related upfront expenses makes the identification of trends in our ongoing research and development activities more difficult. We believe the presentation of adjusted research and development, which does not include collaboration-related upfront expenses, provides useful and meaningful information about our ongoing research and development activities by enhancing investors' understanding of our normal, recurring operating research and development expenses and facilitates comparisons between periods and with respect to projected performance. All expenses incurred subsequent to the initiation of the collaboration arrangement, such as research and development cost-sharing expenses/reimbursements and milestone payments up to the point of regulatory approval are considered to be normal, recurring operating expenses and are included in our adjusted financial results.

Research and Development Asset Acquisition Expense: We exclude costs associated with acquiring rights to pre-commercial compounds because we do not consider such costs to be normal, recurring operating expenses

due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing. Research and development asset acquisition expenses include 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. The variability of amounts and lack of predictability of research and development asset acquisition expenses makes the identification of trends in our ongoing research and development activities more difficult. We believe the presentation of adjusted research and development, which does not include research and development asset acquisition expenses, provides useful and meaningful information about our ongoing research and development activities by enhancing investors' understanding of our normal, recurring operating research and development expenses and facilitates comparisons between periods and with respect to projected performance.

Restructuring Costs: We exclude costs associated with restructuring initiatives from our adjusted financial results. These costs include amounts associated with facilities to be closed, employee separation costs and costs to move operations from one location to another. We do not frequently undertake restructuring initiatives and therefore do not consider such costs to be normal, recurring operating expenses.

Certain Other Items: We exclude certain other significant items that may occur occasionally and are not normal, recurring, cash operating expenses from our adjusted financial results. Such items are evaluated on an individual basis based on both the quantitative and the qualitative aspect of their nature and generally represent items that, either as a result of their nature or magnitude, we would not anticipate occurring as part of our normal business on a regular basis. While not all-inclusive, examples of certain other significant items excluded from adjusted financial results would be: significant litigation-related loss contingency accruals and expenses to settle other disputed matters and, effective for fiscal year 2018, changes in the fair value of our equity securities upon the adoption of ASU 2016-01 (Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities).

Estimated Tax Impact From Above Adjustments: We exclude the net income tax impact of the non-tax adjustments described above from our adjusted financial results. The net income tax impact of the non-tax adjustments includes the impact on both current and deferred income taxes and is based on the taxability of the adjustment under local tax law and the statutory tax rate in the tax jurisdiction where the adjustment was incurred.

Non-Operating Tax Adjustments: We exclude the net income tax impact of certain other significant income tax items, which are not associated with our normal, recurring operations ("Non-Operating Tax Items"), from our adjusted financial results. Non-Operating Tax Items include items which may occur occasionally and are not normal, recurring operating expenses (or benefits), including adjustments related to acquisitions, divestitures, collaborations, certain adjustments to the amount of unrecognized tax benefits related to prior year tax positions, the impact of tax reform legislation commonly referred to as the Tax Cuts and Jobs Act (2017 Tax Act), and other similar items. We also exclude excess tax benefits and tax deficiencies that arise upon vesting or exercise of share-based payments recognized as income tax benefits or expenses due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing.

See the attached Reconciliations of GAAP to Adjusted Net Income for explanations of the amounts excluded and included to arrive at the adjusted measures for the three-month periods ended March 31, 2018 and 2017, and for the projected amounts for the twelve-month period ending December 31, 2018.

Celgene Corporation and Subsidiaries
Condensed Consolidated Statements of Income
(Unaudited)
(In millions, except per share data)

	Three-Month Periods Ended	
	March 31,	
	2018	2017*
Net product sales	\$ 3,531	\$ 2,952
Other revenue	7	10
Total revenue	<u>3,538</u>	<u>2,962</u>
Cost of goods sold (excluding amortization of acquired intangible assets)	135	113
Research and development	2,203	995
Selling, general and administrative	864	620
Amortization of acquired intangible assets	87	82
Acquisition related charges and restructuring, net	31	39
Total costs and expenses	<u>3,320</u>	<u>1,849</u>
Operating income	218	1,113
Interest and investment income, net	13	15
Interest (expense)	(166)	(127)
Other income, net	<u>965</u>	<u>13</u>
Income before income taxes	1,030	1,014
Income tax provision	<u>184</u>	<u>82</u>
Net income	<u>\$ 846</u>	<u>\$ 932</u>
Net income per common share:		
Basic	\$ 1.13	\$ 1.20
Diluted	\$ 1.10	\$ 1.15
Weighted average shares:		
Basic	748.3	779.0
Diluted	768.3	811.2

* During the third quarter of 2017, we adopted ASU 2017-12 with an initial application date of January 1, 2017. Prior to the adoption of ASU 2017-12, we recognized all changes in the fair value of the excluded component of a hedge in Other income, net in the Consolidated Statements of Income under a mark-to-market approach. Pursuant to the provisions of ASU 2017-12, we no longer recognize the adjustments to the fair value of the excluded component in Other income, net but we instead recognize the initial value of the excluded component using an amortization approach over the life of the hedging instrument. The results for the quarterly period ended March 31, 2017 have been recast to reflect the adoption of ASU 2017-12. The three-month period ended March 31, 2017 includes the following immaterial revisions to previously issued financial results:

	Three-Month Period Ended	
	March 31, 2017	
	As Reported	As Revised
Net product sales	\$ 2,950	\$ 2,952
Other income, net	26	13
Income tax provision	84	82
Net income	941	932
Diluted net income per common share	\$ 1.16	\$ 1.15

	March 31, 2018	December 31, 2017
Balance sheet items:		
Cash, cash equivalents, debt securities available-for-sale and equity investments with readily determinable fair values	\$ 4,740	\$ 12,042
Total assets	34,556	30,141
Long-term debt, including current portion	20,271	15,838
Total stockholders' equity	5,172	6,921

Celgene Corporation and Subsidiaries
Reconciliation of GAAP to Adjusted Net Income
(In millions, except per share data)

	Three-Month Periods Ended	
	March 31,	
	2018	2017*
Net income - GAAP	\$ 846	\$ 932
Before tax adjustments:		
Cost of goods sold (excluding amortization of acquired intangible assets):		
Share-based compensation expense	(1)	9
Research and development:		
Share-based compensation expense	(1)	199
Collaboration-related upfront expense	(2)	245
Research and development asset acquisition expense	(3)	1,125
Adjustment to clinical trial and development activity wind-down charge	(4)	(60)
Selling, general and administrative:		
Share-based compensation expense	(1)	193
Amortization of acquired intangible assets	(5)	87
Acquisition related charges and restructuring, net:		
Change in fair value of contingent consideration and success payments	(6)	(30)
Acquisition related charges	(7)	61
Other income, net:		
Changes in fair value of equity investments	(8)	(959)
Income tax provision:		
Estimated tax impact from above adjustments	(9)	(133)
Non-operating tax adjustments	(10)	(11)
Net income - Adjusted	<u>\$ 1,572</u>	<u>\$ 1,355</u>
Net income per common share - Adjusted		
Basic	\$ 2.10	\$ 1.74
Diluted	\$ 2.05	\$ 1.67

Explanation of adjustments:

- (1) Exclude share-based compensation expense totaling \$401, including \$250 related to Juno Therapeutics, Inc. (Juno), for the three-month period ended March 31, 2018 and \$153 for the three-month period ended March 31, 2017.
- (2) Exclude upfront payment expense for research and development collaboration arrangements.
- (3) Exclude research and development asset acquisition expenses.
- (4) Exclude adjustment of clinical trial and development activity wind-down charge associated with the discontinuance of GED-0301 clinical trials in Crohn's disease.
- (5) Exclude amortization of intangible assets acquired in the acquisitions of Pharmion Corp., Gloucester Pharmaceuticals, Inc. (Gloucester), Abraxis BioScience, Inc. (Abraxis), Celgene Avilomics Research, Inc. (Avila), QuanticeL Pharmaceuticals, Inc. (QuanticeL) and Juno.
- (6) Exclude changes in the fair value of contingent consideration related to the acquisitions of Gloucester, Abraxis, Avila, Nogra Pharma Limited (Nogra), QuanticeL and Juno, as well as changes in the fair value of Juno's success payments.
- (7) Exclude acquisition costs related to Juno.
- (8) Exclude changes in the fair value of equity investments due to the adoption of ASU 2016-01 (Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities).
- (9) Exclude the estimated tax impact of the above adjustments.
- (10) Exclude other non-operating tax expense items. The adjustment for the three-month periods ended March 31, 2018 and March 31, 2017 is to exclude the excess tax benefits of \$11 and \$75, respectively, recorded in the Income Tax Provision as per ASU 2016-09 (Compensation-Stock Compensation).

* During the third quarter of 2017, we adopted ASU 2017-12 with an initial application date of January 1, 2017. Prior to the adoption of ASU 2017-12, we recognized all changes in the fair value of the excluded component of a hedge in Other income, net in the Consolidated Statements of Income under a mark-to-market approach. Pursuant to the provisions of ASU 2017-12, we no longer recognize the adjustments to the fair value of the excluded component in Other income, net but we instead recognize the initial value of the excluded component using an amortization approach over the life of the hedging instrument. The results for the quarterly period ended March 31, 2017 have been recast to reflect the adoption of ASU 2017-12. The three-month period ended March 31, 2017 includes the following immaterial revisions to previously issued financial results:

	Three-Month Period Ended	
	March 31, 2017	
	As Reported	As Revised
Net income - GAAP	\$ 941	\$ 932

Net income - Adjusted		1,364		1,355
Diluted net income per common share - Adjusted	\$	1.68	\$	1.67

Celgene Corporation and Subsidiaries
Reconciliation of Full-Year 2018 Projected GAAP to Adjusted Net Income
(In millions, except per share data)

		<u>Updated without Dilution from June</u>	<u>Updated with Dilution from June</u>
Projected net income - GAAP	(1)	\$ 5,556	\$ 4,767
Before tax adjustments:			
Cost of goods sold (excluding amortization of acquired intangible assets):			
Share-based compensation expense		30	30
Research and development:			
Share-based compensation expense		269	524
Collaboration-related upfront expense		257	257
Research and development asset acquisition expense		1,125	1,125
Adjustment to clinical trial and development activity wind-down charge		(60)	(60)
Selling, general and administrative:			
Share-based compensation expense		347	511
Amortization of acquired intangible assets		257	319
Acquisition related charges and restructuring, net:			
Change in fair value of contingent consideration and success payments		(30)	(16)
Acquisition related charges		—	61
Other income, net:			
Changes in fair value of equity investments		(950)	(950)
Income tax provision:			
Estimated tax impact from above adjustments		(33)	(177)
Non-operating tax adjustments		(11)	(11)
Projected net income - Adjusted		<u>\$ 6,757</u>	<u>\$ 6,380</u>
Projected net income per diluted common share - GAAP	~	\$ 7.36	\$ 6.31
Projected net income per diluted common share - Adjusted	~	\$ 8.95	\$ 8.45
Projected weighted average diluted shares		<u>755.0</u>	<u>755.0</u>

- (1) Our projected 2018 earnings do not include the effect of any business combinations, collaboration agreements, asset acquisitions, asset impairments, litigation-related loss contingency accruals, changes in the fair value of our CVRs issued as part of the acquisition of Abraxis, changes in the fair value of equity investments as per ASU 2016-01 (Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities) or non-operating tax adjustments that may occur after the day prior to the date of this press release.

Celgene Corporation and Subsidiaries
Net Product Sales
(In millions)

	Ended March 31,		Three-Month Periods			
	2018	2017	Reported	% Change		
				Operational(1)	Currency(2)	
REVLIMID®						
U.S.	\$ 1,487	\$ 1,234	20.5%	20.5%	0.0%	
International	747	650	14.9%	14.0%	0.9%	
Worldwide	2,234	1,884	18.6%	18.3%	0.3%	
POMALYST®/IMNOVID®						
U.S.	300	216	38.9%	38.9%	0.0%	
International	153	148	3.4%	3.6%	(0.2)%	
Worldwide	453	364	24.5%	24.6%	(0.1)%	
OTEZLA®						
U.S.	276	199	38.7%	38.7%	0.0%	
International	77	43	79.1%	78.5%	0.6%	
Worldwide	353	242	45.9%	45.8%	0.1%	
ABRAXANE®						
U.S.	159	142	12.0%	12.0%	0.0%	
International	103	94	9.6%	9.5%	0.1%	
Worldwide	262	236	11.0%	11.0%	0.0%	
IDHIFA® (3)						
U.S.	14	—	N/A	N/A	N/A	
International	—	—	N/A	N/A	N/A	
Worldwide	14	—	N/A	N/A	N/A	
VIDAZA®						
U.S.	2	2	0.0%	0.0%	0.0%	
International	155	156	(0.6)%	(1.0)%	0.4%	
Worldwide	157	158	(0.6)%	(1.0)%	0.4%	
azacitidine for injection						
U.S.	6	9	(33.3)%	(33.3)%	0.0%	
International	1	—	N/A	N/A	N/A	
Worldwide	7	9	(22.2)%	(22.2)%	0.0%	
THALOMID®						
U.S.	19	22	(13.6)%	(13.6)%	0.0%	
International	12	14	(14.3)%	(14.7)%	0.4%	
Worldwide	31	36	(13.9)%	(14.1)%	0.2%	
ISTODAX®						
U.S.	16	17	(5.9)%	(5.9)%	0.0%	
International	3	3	0.0%	(3.3)%	3.3%	
Worldwide	19	20	(5.0)%	(5.4)%	0.4%	
All Other						
U.S.	—	—	N/A	N/A	N/A	
International	1	3	N/A	N/A	N/A	
Worldwide	1	3	N/A	N/A	N/A	
Total Net Product Sales						
U.S.	2,279	1,841	23.8%	23.8%	0.0%	
International	1,252	1,111	12.7%	12.3%	0.4%	
Worldwide	\$ 3,531	\$ 2,952	19.6%	19.4%	0.2%	

(1) Operational includes impact from both volume and price

(2) Currency includes the impact from both foreign exchange rates and hedging activities

(3) IDHIFA® was approved in August 2017 in the U.S. for the treatment of adult patients with R/R AML with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved test.