CELGENE CORP /DE/

FORM 8-K
(Current report filing)

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Address	86 MORRIS AVENUE
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Telephone	(908)673-9000
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
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): **January 8, 2018**

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-34912**	**22-2711928**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

86 Morris Avenue, Summit, New Jersey	**07901**
(Address of principal executive offices)	(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 January 8, 2018, Celgene Corporation (the "Company") provided a business update as well as its preliminary 2017 results and financial outlook for 2018 at the 36th Annual J.P. Morgan Healthcare Conference. Certain preliminary 2017 unaudited results, non-GAAP financial measures and financial outlook are included in the attached press release, which is incorporated herein by reference. The Company expects to report its 2017 full-year financial results on Thursday, January 25, 2018.

The information in this Current Report on Form 8-K, including the exhibit attached hereto, is furnished solely pursuant to Item 2.02 of Form 8-K and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. Furthermore, the information in this Current Report on Form 8-K, including the exhibit attached hereto, shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

Exhibit 99.1 — Press Release dated January 8, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated January 8, 2018 with preliminary 2017 results and financial outlook for 2018

SIGNATURES

Pursuant to the requirements of the Securities and 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: January 8, 2018

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

Exhibit 99.1

Contact:

Patrick E. Flanigan III
Corporate VP, Investor Relations
Celgene Corporation
(908) 673-9969

Brian Gill
VP, Corporate Communications
Celgene Corporation
(908) 673-9530

CELGENE CORPORATION ANNOUNCES PRELIMINARY 2017 UNAUDITED RESULTS AND 2018 FINANCIAL GUIDANCE

- *Preliminary Q4 2017 total revenue of $3.5 billion, a 17 percent increase Y/Y*
- *Preliminary FY 2017 total revenue of $13.0 billion, a 16 percent increase Y/Y*
- *Reaffirming 2020 total revenue and adjusted diluted EPS financial targets*

SUMMIT, NJ — (January 8, 2018) — Celgene Corporation (NASDAQ: CELG) today provided a business update as well as its preliminary 2017 unaudited results and financial guidance for 2018 at the 36th Annual J.P. Morgan Healthcare Conference. Based on U.S. Generally Accepted Accounting Principles (GAAP), GAAP diluted earnings per share (EPS) for the full-year of 2017 is expected to be in the range of $3.64 to $4.19, a 57 percent year-over-year increase based on the mid-point of the range. Full year 2017 GAAP operating margin is expected to be approximately 36 percent, an increase from 28 percent in the prior year, primarily due to increased product sales. For the fourth quarter 2017, GAAP EPS is expected to be in the range of ($0.09) to $0.46, a 65 percent year-over-year decrease based on the mid-point of the range. Fourth quarter 2017 GAAP operating margin is expected to be approximately 34 percent, an increase from 31 percent in the prior year, primarily due to increased product sales.

Adjusted EPS is expected to be approximately $7.44 for the full year of 2017, a 25 percent year-over-year increase. Full year 2017 adjusted operating margin is expected to be 58.1 percent, an increase of 310 basis points (bps) year-over-year. For the fourth quarter of 2017, adjusted EPS is expected to be approximately $2.00, a 24 percent year-over-year increase. Fourth quarter 2017 adjusted operating margin is expected to be 55.3 percent, a decrease of 70 bps year-over-year.

“2017 was a strong year for Celgene as we delivered excellent top- and bottom-line growth and achieved critical milestones across our hematology, oncology, inflammation and immunology franchises,” said Mark J. Alles, Chief Executive Officer of Celgene. “We are executing on a strategy to achieve our 2020 targets, accelerate portfolio diversification and expand our pipeline of innovative therapies.”

Preliminary Q4 and FY 2017 Net Product Sales and Total Revenue are expected to be (Unaudited, in millions):

	Q4 2017	Y/Y%	FY 2017	Y/Y%
REVLIMID ®	$ 2,188	21%	$ 8,187	17%
POMALYST ® /IMNOVID ®	$ 442	17%	$ 1,614	23%
OTEZLA ®	$ 371	22%	$ 1,279	26%
ABRAXANE ®	$ 251	(6)%	$ 992	2%
Total Revenue	$ 3,483	17%	$ 13,003	16%

Certain activities involved in determining the audited results for the fiscal year ended December 31, 2017 are in-process and could result in the final reported audited results being different from the unaudited results noted in this press release. The ranges of our estimated GAAP diluted earnings per share for the quarter and year ended December 31, 2017 include an estimated financial statement impact of between approximately $800 million and approximately $1,300 million related to the Tax Cuts and Jobs Act ("Tax Act"), which was enacted on December 22, 2017. Our estimate of the impact of the Tax Act is based on currently available information and interpretation of its provisions. Our actual results may materially differ from our current estimate due to, among other things, further guidance that may be issued by U.S. tax authorities or regulatory bodies and/or changes in interpretations and assumptions we have preliminarily made. We will continue to analyze the Tax Act to finalize its financial statement impact, including the mandatory deemed repatriation of foreign earnings, re-measurement of deferred taxes and certain other provisions of the Tax Act. We anticipate finalizing our preliminary analysis and the impact on our December 31, 2017 financial statements by the time we announce our financial results currently anticipated on January 25, 2018. Additionally, please see the attached Use of Non-GAAP Financial Measures and Reconciliation of Estimated/Projected GAAP to Adjusted (Non-GAAP) Measures 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, for each of 2017 and 2018.

Celgene Expects Volume Driven Product Sales and Earnings Growth in 2018

In 2018, total revenue is expected to be approximately $14.4 billion to $14.8 billion, a 12 percent increase year-over-year, based on the mid-point of the range. Based on GAAP, EPS for the full-year 2018 is expected to be in the range of $6.58 to $6.95, excluding the impact of any strategic transactions, impairments, loss contingencies, changes in the fair value of equity investments and non-operating tax adjustments that have not yet occurred. For the full-year 2018, adjusted diluted EPS is expected to be in the range of $8.70 to $8.90, an 18 percent increase year-over-year, based on the mid-point of the range.

		Year-over-Year Change
Total Revenue	$14.4B to $14.8B	12% *
REVLIMID ® Net Product Sales	Approximately $9.4B	15%
POMALYST ® / IMNOVID ® Net Product Sales	Approximately $1.9B	18%
OTEZLA ® Net Product Sales	Approximately $1.5B	17%
ABRAXANE ® Net Product Sales	Approximately $1.0B	1%
GAAP diluted EPS	$6.58 to $6.95	N/M**
Adjusted diluted EPS	$8.70 to $8.90	18% *
GAAP operating margin	Approximately 46.5%	N/M**
Adjusted operating margin	Approximately 60.0%	~ +200bps
Weighted average diluted shares	775M	-34M
Adjusted tax rate	~18%	~ +200bps

* Year-over-year percentage change based on the mid-point of the range.
** Not meaningful as the 2018 measures exclude the impact of any strategic transactions, impairments, loss contingencies, changes in the fair value of equity investments and non-operating tax adjustments that have not yet occurred.

Reaffirming Expected 2020 Long-term Financial Targets

- 2020 total revenue range of $19.0 billion to $20.0 billion
- Adjusted Diluted EPS to exceed $12.50

2018 Expected Operational Milestones

Hematology & Oncology

Regulatory Submissions

- Submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for REVLIMID ® in combination with bortezomib and dexamethasone (RVd) in patients with newly diagnosed multiple myeloma (NDMM)
- Submission of a New Drug Application (NDA) to the FDA for fedratinib in myelofibrosis

Trial Initiations

- Initiate the pivotal program with CC-122 in non-Hodgkin lymphoma (NHL)
- Initiate the pivotal program with BGB-A317 (tislelizumab) in non-small cell lung cancer (NSCLC)
- Initiate a phase III trial with bb2121 in third-line plus multiple myeloma in collaboration with bluebird bio
- Initiate a phase III trial with JCAR017 in transplant-eligible second-line diffuse large B-cell lymphoma (DLBCL) in collaboration with Juno Therapeutics
- Initiate the phase III COMMANDS ™ trial with luspatercept in first-line, lower-risk myelodysplastic syndromes (MDS)

Clinical Data

- Data from the phase III AUGMENT ® trial with REVLIMID ® in combination with rituximab in patients with relapsed and/or refractory follicular lymphoma (FL)
- Data from the phase III ROBUST ® trial with REVLIMID ® in patients with first-line ABC-subtype DLBCL
- Data from the phase III apact ® trial with ABRAXANE ® as adjuvant therapy in patients with surgically resected pancreatic cancer
- Data from the phase III QUAZAR ® AML-001 trial with CC-486 as maintenance therapy in post-induction acute myeloid leukemia (AML)
- Data from the phase III OPTIMISMM ® trial with POMALYST ® in combination with bortezomib and dexamethasone (PVd) in second-line multiple myeloma
- Data from the phase III MEDALIST™ trial with luspatercept in patients with ring sideroblast-positive (RS+) MDS in collaboration with Acceleron Pharma
- Data from the phase III BELIEVE™ trial with luspatercept in patients with beta-thalassemia in collaboration with Acceleron Pharma
- Data from phase I/II trial with CC-220 in relapsed and/or refractory multiple myeloma (RRMM)

Trial Enrollment

- Complete enrollment in the pivotal KarMMa ™ trial with bb2121 in RRMM in collaboration with

bluebird bio

- Complete enrollment in the pivotal TRANSCEND WORLD trial with JCAR017 in third-line DLBCL in collaboration with Juno Therapeutics

Inflammation and Immunology

Regulatory Submissions/Decisions

- FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)
- FDA decision on the submission of an sNDA for OTEZLA ® once-daily formulation
- Submission of an sNDA for OTEZLA ® in Behçet's disease
- Submission of a Marketing Authorization Application (MAA) for ozanimod in RMS

Trial Initiations

- Initiate a phase III trial with OTEZLA ® in ulcerative colitis
- Initiate a phase III trial with OTEZLA ® in mild-to-moderate psoriasis
- Initiate a phase III trial with ozanimod in secondary progressive multiple sclerosis (SPMS)

Clinical Data

- Data from a phase III trial with OTEZLA ® in scalp psoriasis
- Data from a phase II trial with OTEZLA ® in ulcerative colitis to be presented at a medical meeting in the first quarter of 2018

Trial Enrollment

- Complete enrollment in the phase III TRUE NORTH trial with ozanimod in ulcerative colitis

Research and Early Development

- File at least 5 Investigational New Drug (IND) or Clinical Trial Applications (CTA) for novel assets

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.

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 operating margin
- 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. 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 financial results excluding 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 includes 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 financial results excluding 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: expenses for significant fair value adjustments to equity investments, significant litigation-related loss contingency accruals and expenses to settle other disputed matters.

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, 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.

Long-Term Targets

A reconciliation of long-term adjusted financial targets to the most comparable GAAP measures cannot be provided because we are unable to forecast with reasonable certainty many of the items necessary to calculate such comparable GAAP measures, including share-based compensation expense, collaboration-related upfront expense, research and development asset acquisition expense, acquisition-related expenses, fair value adjustments to contingent consideration, the ultimate outcome of legal proceedings and unusual gains and losses, as well as unforeseen events, risks and developments. These items are uncertain, depend on various factors, and could be material to our results computed in accordance with GAAP. We believe the inherent uncertainties in reconciling our long-term non-GAAP measures to the most comparable GAAP measures would make the forecasted comparable GAAP measures nearly impossible to predict with reasonable certainty and therefore inherently unreliable.

See the attached Reconciliation of Estimated/Projected GAAP to Adjusted (non-GAAP) Measures for explanations of the amounts excluded and included to arrive at the adjusted measures for the three- and twelve-month periods ended December 31, 2017 and for the projected amounts for the twelve-month period ending December 31, 2018.

Celgene Corporation and Subsidiaries
Reconciliation of Estimated/Projected GAAP to Adjusted (Non-GAAP) Measures
(Unaudited)

		Three Months Ended December 31, 2017 Range		Twelve Months Ended December 31, 2017 Range		Twelve Months Ending December 31, 2018 Range	
		Low	High	Low	High	Low	High
Estimated/projected diluted earnings per common share - GAAP	(1)	$ (0.09)	$ 0.46	$ 3.64	$ 4.19	$ 6.58	$ 6.95
Per share impact of excluded items before tax:							
Cost of goods sold (excluding amortization of acquired intangible assets):							
Share-based compensation expense	(2)	0.01	0.01	0.04	0.04	0.04	0.04
Research and development:							
Share-based compensation expense	(2)	0.09	0.09	0.33	0.33	0.35	0.32
Collaboration-related upfront expense	(1)(3)	0.12	0.12	0.95	0.95	—	—
Research and development asset acquisition expense	(1)(4)	—	—	0.40	0.40	1.44	1.44
IPR&D asset impairment charge	(1)(5)	2.03	2.03	2.00	2.00	—	—
Clinical trial & development activity wind-down charge	(5)	0.24	0.24	0.23	0.23	—	—
Selling, general and administrative:							
Share-based compensation expense	(2)	0.11	0.11	0.43	0.43	0.45	0.41
Litigation-related loss contingency accrual expense	(1)(6)	—	—	0.39	0.39	—	—
Amortization of acquired intangible assets	(1)(7)	0.10	0.10	0.41	0.41	0.34	0.30
Acquisition related (gains) charges, net:							
Change in fair value of contingent consideration	(1)(8)	(1.80)	(1.78)	(1.68)	(1.66)	—	—
Income tax provision:							
Estimated tax impact from above adjustments	(9)	(0.39)	(0.37)	(0.86)	(0.84)	(0.50)	(0.56)
Non-operating tax adjustments	(10)	1.58	0.99	1.16	0.57	—	—
Estimated/projected diluted earnings per common share - Adjusted		Approximately $2.00		Approximately $7.44		$ 8.70	$ 8.90
Estimated/projected diluted weighted average shares (in millions)		Approximately 797.4		Approximately 808.7		Approximately 775.0	

		Three Months Ended December 31, 2017 Range		Twelve Months Ended December 31, 2017 Range		Twelve Months Ending December 31, 2018 Range	
		Low	High	Low	High	Low	High
Operating margin percentage of revenue - GAAP	(1)	34.7%	34.3%	36.3%	36.2%	46.0%	46.9%
Plus adjustments:							
Share-based compensation expense	(2)	4.7%	4.7%	5.0%	5.0%	4.5%	4.0%
Collaboration-related upfront expense	(1)(3)	2.8%	2.8%	5.9%	5.9%	0.0%	0.0%
Research and development asset acquisition expense	(1)(4)	0.0%	0.0%	2.5%	2.5%	7.7%	7.5%
IPR&D asset impairment charge	(1)(5)	46.5%	46.5%	12.5%	12.5%	0.0%	0.0%
Clinical trial & development activity wind-down charge	(5)	5.4%	5.4%	1.4%	1.4%	0.0%	0.0%
Litigation-related loss contingency accrual expense	(1)(6)	0.0%	0.0%	2.4%	2.4%	0.0%	0.0%
Amortization of acquired intangible assets	(1)(7)	2.3%	2.3%	2.5%	2.5%	1.8%	1.6%
Change in fair value of contingent consideration	(1)(8)	-41.1%	-40.7%	-10.4%	-10.3%	0.0%	0.0%
Operating margin percentage of revenue - Adjusted		55.3%	55.3%	58.1%	58.1%	Approximately 60.0%	

Explanation of adjustments:

(1) Our projected 2018 financial measures do not include the effect of any business combinations, collaboration agreements, asset acquisitions, asset impairments, additional litigation-related loss contingency accruals, changes in the fair value of our CVRs issued as part of the acquisition of Abraxis BioScience Inc. (Abraxis), changes in the fair value of equity investments upon the adoption of 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.

(2) Exclude share-based compensation expense.

(3) Exclude upfront payment expense for research and development collaboration arrangements.

(4) Exclude research and development asset acquisition expenses; 2017 primarily relates to Delinia, Inc. and 2018 includes Impact Biomedicines, Inc.

(5) Exclude charges associated with the discontinuance of GED-0301 clinical trials in Crohn's disease (Trials), including impairment of an IPR&D asset and other one-time charges related to wind-down costs associated with discontinuing the Trials and certain development activities.

(6) Exclude loss contingency accrual expense related to a contractual dispute.

(7) Exclude amortization of intangible assets acquired in the acquisitions of Pharmion Corp., Gloucester Pharmaceuticals, Inc. (Gloucester), Abraxis, Celgene Avilomics Research, Inc. (Avila), and Quanticel Pharmaceuticals, Inc. (Quanticel).

(8) Exclude changes in the fair value of contingent consideration related to the acquisitions of Gloucester, Abraxis, Avila, Nogra Pharma Limited (Nogra), and Quanticel, including the impact to the Nogra contingent consideration liabilities related to the discontinuance of the Trials.

(9) Exclude the estimated tax impact from the above adjustments.

(10) Exclude other non-operating tax expense items primarily related to the estimated financial statement impact of the Tax Act, excess tax benefits related to the adoption of ASU 2016-09 (Compensation-Stock Compensation) and prior year tax benefits arising from a U.S. research and development and orphan drug tax credits study.