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CELGENE CORP /DE/

FORM 8-K
(Current report filing)

Filed 02/27/18 for the Period Ending 02/26/18

Address	86 MORRIS AVENUE
	SUMMIT, NJ, 07901
Telephone	(908)673-9000
CIK	0000816284
Symbol	CELG
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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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): February 26, 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 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 8.01 OTHER EVENTS.

On February 27, 2018, Celgene Corporation (the "Company") issued a press release announcing that it received a Refusal to File letter from the U.S. Food and Drug Administration ("FDA") regarding its New Drug Application ("NDA") for ozanimod in development for the treatment of patients with relapsing forms of multiple sclerosis. Upon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review. Celgene intends to seek immediate guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

d) Exhibits

99.1 Press Release, dated February 27, 2018

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: February 27, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated February 27, 2018

Exhibit 99.1

CELGENE PROVIDES REGULATORY UPDATE ON OZANIMOD FOR THE TREATMENT OF RELAPSING MULTIPLE SCLEROSIS

Conference call scheduled for today at 5:30 p.m. ET

SUMMIT, N.J. – (February 27, 2018) – Celgene Corporation (NASDAQ:CELG) today announced that it has received a Refusal to File letter from the United States Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for ozanimod in development for the treatment of patients with relapsing forms of multiple sclerosis. Ozanimod is a novel, oral, selective sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator.

Upon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review. Celgene intends to seek immediate guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA.

"We remain confident in ozanimod's clinical profile demonstrated in the pivotal program in relapsing forms of multiple sclerosis," said Jay Backstrom, M.D., Chief Medical Officer and Head of Global Regulatory Affairs for Celgene. "We will work with the FDA to expeditiously address all outstanding items and bring this important medicine to patients."

Conference Call Information

Celgene will hold a conference call to discuss this update today at 5:30 p.m. ET. The conference call may be accessed by dialing 1-866-428-9517 for U.S. callers and 1-224-357-2194 for international callers. The passcode for the call is 9179457. The call can also be accessed via an audio webcast in the Investor Relations section of the company website at www.celgene.com . An audio replay will be available through March 6, 2018 by calling 1-855-859-2056 or 1-404-537-3406 and entering access code 9179457.

About Ozanimod

Ozanimod is a novel, oral, selective, sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator in development for immune-inflammatory indications, including relapsing multiple sclerosis, ulcerative colitis and Crohn's disease. Selective binding with S1PR1 is believed to inhibit a specific sub set of activated lymphocytes from migrating to sites of inflammation. The result is a reduction of circulating T and B lymphocytes that leads to anti-inflammatory activity. Importantly, immune surveillance is maintained.

Selective binding with S1PR5 is thought to activate specific cells within the central nervous system (CNS). This has the potential to enhance remyelination and prevent synaptic defects. Ultimately, neurological damage may be prevented.

Ozanimod is an investigational compound that is not approved for any use in any country.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global pharmaceutical 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 Statements

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 U.S. 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.

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