

Edgar Filing: CELGENE CORP /DE/ - Form 8-K

CELGENE CORP /DE/  
Form 8-K  
December 13, 2006

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): December 13, 2006

CELGENE CORPORATION  
(Exact name of registrant as specified in its charter)

Delaware

0-16132

22-2711928

-----  
(State or other jurisdiction of (Commission File Number) (IRS Employer  
incorporation) 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))

Edgar Filing: CELGENE CORP /DE/ - Form 8-K

ITEM 8.01 OTHER EVENTS.

On December 13, 2006, Celgene Corporation, or the Company, announced that it has been notified of an Abbreviated New Drug Application (ANDA) filed with the U.S. Food and Drug Administration (FDA), with a Paragraph IV certification, by Barr Pharmaceuticals, Inc. This applicant is seeking authorization to market a generic version of thalidomide 200 mg tablets in the United States for the acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

The Company intends to file a complaint alleging infringement of Celgene patents, within the required forty-five day response period. By bringing suit, Celgene is entitled to up to a 30-month injunction against the applicant's marketing of generic thalidomide. The Company has seven issued patents which cover methods of more safely administering thalidomide through S.T.E.P.S.(R), an integral part of the FDA approved THALOMID(R) labeling and additional broad patents protecting methods of using thalidomide in the treatment of hematological and solid tumor cancers.

Attached hereto as Exhibit 99.1 is the Press Release announcing this event.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

Exhibit 99.1 Press Release dated December 13, 2006 announcing the notification of an ANDA filing for thalidomide.

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: December 13, 2006

By: /s/ Robert J. Hugin

-----  
Name: Robert J. Hugin  
Title: President and  
Chief Operating Officer

EXHIBIT INDEX

EXHIBIT NO.                    DESCRIPTION  
-----                        -----

Exhibit 99.1    Press Release dated December 13, 2006 announcing the notification of an ANDA filing for thalidomide.

