

CELGENE CORP /DE/
Form 8-K
December 23, 2008

**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 23, 2008

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other Jurisdiction of
Incorporation)

0-16132

(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:

- ☐ 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))

ITEM 8.01 OTHER EVENTS

On December 23, 2008, Celgene International Sàrl announced that its cancer drug, VIDAZA (azacitidine), has been granted full marketing authorization by the European Commission for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation with:

Intermediate-2 and high-risk MDS according to the IPSS, or

Chronic myelomonocytic leukaemia (CMML) with 10-29 percent marrow blasts without myeloproliferative disorder, or

AML with 20-30 percent blasts and multi-lineage dysplasia, according to WHO classification

The approval was based upon efficacy and safety data from clinical studies evaluating VIDAZA in MDS and RAEB-T patients within the AML category as defined by the WHO classification system. These pivotal efficacy and safety data were primarily provided from the VIDAZA survival trial (AZA-001), the largest, international randomized Phase III controlled study ever conducted in higher-risk MDS and WHO AML patients, demonstrating a clinically relevant increase in median survival of 9.4 months (24.4 vs. 15 months) as compared to conventional care regimens.

Attached hereto and incorporated herein by reference as Exhibit 99.1 is the Press Release announcing such information.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

Exhibit 99.1 Press Release dated December 23, 2008

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 23, 2008

By: /s/ David W. Gryska

Name: David W. Gryska
Title: Senior Vice President and Chief Financial Officer