

CELGENE CORP /DE/  
Form 8-K  
January 24, 2008



## **ITEM 8.01 OTHER EVENTS**

On January 24, 2008, Celgene International Sarl announced the results of regulatory actions regarding REVLIMID® (lenalidomide) in Australia, Canada and the European Union. In Australia, REVLIMID® received marketing authorization approval from the Australian Therapeutic Goods Administration for use in combination with dexamethasone as a treatment for patients with multiple myeloma whose disease has progressed after one therapy. In Canada, REVLIMID® received conditional marketing authorization approval from the Canadian Therapeutic Products Directorate for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

In the European Union, the European Medicines Agency's, or EMEA, Committee for Medicinal Products for Human Use, or CHMP, issued a negative opinion on the Company's Marketing Application for Lenalidomide – Celgene Europe for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. The CHMP concluded that lenalidomide is efficacious in patients suffering from deletion 5q MDS. Based on information available to the CHMP from the uncontrolled, open-label, 148-patient Phase II study (MDS-003), the CHMP was not convinced the data were sufficient to assure safety. Celgene intends to apply for a re-examination of the CHMP opinion in accordance with relevant EMEA procedures.

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.**

(d) Exhibit 99.1 – Press Release dated January 24, 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: January 24, 2008

By: /s/ David W. Gryska

Name: David W. Gryska

Title: Sr. Vice President and Chief Financial Officer