

BRISTOL MYERS SQUIBB CO

Form 8-K

September 03, 2004

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 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) September 3, 2004

**Bristol-Myers Squibb Company**

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(Exact Name of Registrant as Specified in Its Charter)  
Delaware

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(State or Other Jurisdiction of Incorporation)

1-1136

22-079-0350

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(Commission File Number)

(IRS Employer Identification No.)

345 Park Avenue New York, NY

10154

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(Address of Principal Executive Offices)

(212) 546-4000

(Zip Code)

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(Registrant's Telephone Number, Including Area Code)

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(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))
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Item 8.01. OTHER EVENTS

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Item 8.01. OTHER EVENTS

On August 11, 2004, Otsuka Pharmaceutical Co., Ltd. (Otsuka) filed with the United States Patent and Trademark Office (USPTO) a Request for Reexamination of the basic U.S. composition of matter patent covering Abilify (aripiprazole), an antipsychotic agent used for the treatment of schizophrenia (U.S. Patent Number No. 5,006,528, the 528 Patent ) that expires in 2009, and may be extended until 2014 if pending supplemental protection extensions are granted. Otsuka has determined that the original 528 Patent application contained an error in that the description of a prior art reference was identified by the wrong patent number. In addition, Otsuka has taken the opportunity to bring other citations to the attention of the USPTO. The Request for Reexamination, if granted by the USPTO, will allow the USPTO to consider the patentability of the patent claims in light of the corrected patent number and newly cited documents. The USPTO is expected to make a final decision on the reexamination within the next ten to fifteen months.

Bristol-Myers Squibb Company ( Company ) and Otsuka believe that the invention claimed in the 528 Patent is patentable over the prior art and expect that the USPTO will reconfirm that in the reexamination. However, there can be no guarantee as to the outcome.

Under an alliance agreement with Otsuka, the Company has the right to market Abilify in the United States and Puerto Rico until November 2012 and in countries in the European Union where the Company has an exclusive right to market Abilify until June 2014. As previously disclosed, Abilify sales are expected to contribute to the Company's growth opportunities over the next several years. If the patentability of the 528 Patent were not reconfirmed following a reexamination, there may be sooner than expected loss of market exclusivity of Abilify and the subsequent development of generic competition which would be material to the Company.

The Company is making this announcement at this time in connection with the expected effectiveness of a shelf registration statement.

SIGNATURE

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.

Dated: September 3, 2004

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ Sandra Leung

Name: Sandra Leung

Title: Corporate Secretary