BRISTOL MYERS SQUIBB CO Form 8-K May 10, 2004

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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): April 27, 2004

BRISTOL-MYERS SOUIBB COMPANY (Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction (Commission File (IRS Employer of Incorporation) Number) Identification Number)

1-1136

22-079-0350

345 Park Avenue New York, NY 10154 (Address of Principal Executive Office) Registrant's telephone number, including area code: (212) 546-4000

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Item 5. OTHER EVENTS

On April 27, 2004, the Company entered into a collaboration agreement with Merck & Co., Inc. for worldwide co-development and co-promotion for muraglitazar, the Company's dual PPAR (peroxisome proliferator activated receptor) agonist, currently in Phase III clinical development for use in treating Type 2 diabetes. Under the terms of the agreement, the Company received a \$100 million upfront payment in May 2004, and is entitled to receive \$275 million in additional payments upon the achievement of certain regulatory milestones. The Company and Merck will jointly develop the clinical and marketing strategy for muraglitazar, share equally in future development and commercialization costs and co-promote the product to physicians on a global basis, with Merck to receive payments based on net sales levels. As announced previously, an NDA for muraglitazar is expected to be submitted to the FDA within the next nine to twelve months for U.S. regulatory approval. In addition, the collaboration includes a back-up compound to muraglitazar, with

the same mechanism of action (PPAR), which is anticipated to enter Phase II clinical trials for the treatment of Type 2 diabetes this year.

The agreement will expire on a product-by-product and country-by-country basis upon the latest of (i) the expiration of the last to expire Bristol-Myers Squibb patent or patent that is jointly funded in each case with respect to the applicable product in the applicable country, (ii) the expiration of any additional statutory or administrative protections that grant exclusivity with respect to the applicable product in the applicable country, and (iii) the cessation of the sale of the applicable product in the applicable country following first commercial sale of that product in that country. The basic composition of matter patent for muraglitazar in the United States expires in 2020. Patent applications in various countries in the European Union are pending. The Company also may be entitled to additional statutory or administrative protections in the United States and the European Union that would grant exclusivity with respect to muraglitazar beyond 2020. It is not possible to predict the length of market exclusivity for any of the Company's products, including muraglitazar, with certainty because of the complex interaction between patent and regulatory forms of exclusivity, and inherent uncertainties about the enforceability of certain intellectual property rights. Accordingly, the agreement could terminate with respect to muraglitazar prior to the current patent expiration date. In addition, due to the inclusion in the collaboration of the back-up compound and the possibility that the back-up compound will be developed to the point of being a commercially marketed product, the term of the agreement could possibly extend beyond the patent expiration date and exclusivity period relating to muraglitazar.

In addition to customary termination provisions for cause, Merck also has the right to terminate the agreement for any reason upon not less than six months prior written notice to the Company. However, this right of termination can be exercised by Merck with respect to any product only during the period between the completion of Phase III clinical trials relating to such product and the time the NDA for such product is filed with the FDA. This right also can be exercised by Merck after the second anniversary of the date of filing of the NDA for such product with the FDA if the product has not been commercially launched in the United States at such time, or, if commercially launched in the United States, after the second anniversary of the commercial launch of such product in the United States. With respect to the European Union, Merck can exercise this right of termination after the second anniversary of the commercial launch of such product in the European Union or, if not commercially launched in the European Union, the third anniversary of the commercial launch of the product in the

United States. Upon any early termination, the Company will retain control of all rights to muraglitazar.

The agreement also provides that, except as described below, for so long as the collaboration between the Company and Merck remains in effect with respect to at least one country in the world, each party and its affiliates will not, and will cause its affiliates not to, advise, assist or encourage others to, directly or indirectly, without the consent of the other party: (i) acquire, announce an intention to acquire, offer or propose to acquire or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) or interest in any securities of the other party or any of its affiliates that are entitled to vote for the election of directors of

such party or affiliate ("Voting Securities") or direct or indirect rights, warrants or options to acquire, or securities convertible into or exchangeable for, any Voting Securities of the other party or any of its affiliates; (ii) effect or seek, initiate, offer or propose or participate in or assist any other person to effect or seek, initiate, offer or propose any (A) tender or exchange offer, merger, consolidation or other business combination involving the other party or any of its affiliates; or (B) any recapitalization, restructuring, liquidation, dissolution, sale of all or substantially all of its assets or other extraordinary transaction with respect to the other party or any of its affiliates; (iii) make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the United States Securities and Exchange Commission promulgated pursuant to Section 14 of the Exchange Act) with respect to the other party or any of its affiliates (whether or not such solicitation is subject to regulation under Regulation 14A promulgated under the Exchange Act) or otherwise solicit any consent or communicate with or seek to advise or influence any person with respect to the voting of such other party's (or its affiliates') Voting Securities; (iv) deposit any Voting Securities of the other party or any of its affiliates into a voting trust or subject any such Voting Securities to any arrangement or agreement with respect to the voting thereof; (v) initiate, propose or otherwise solicit stockholders of the other party or any of its affiliates for the approval of one or more stockholder proposals as described in Rule 14a-8under the Exchange Act with respect to the other party or any of its affiliates or their bylaws or other constituent documents, or induce or attempt to induce any other person to initiate any such stockholder proposal with respect to the other party or any of its affiliates or their bylaws or other constituent documents; (vi) seek election to or seek to place a representative on the Board of Directors of the other party or any of its affiliates or seek the removal of any member of the Board of Directors of the other party of any of its affiliates; (vii) call or seek to have called any meeting of the stockholders of the other party or any of its affiliates; (viii) request, or take any action to obtain, any list of holders of Voting Securities of the other party or any of its affiliates; (ix) form, join or in any way participate in a "group" (within the meaning of Section 13(d)(3) of the Exchange Act) with respect to any Voting Securities of the other party or any of its affiliates or direct or indirect rights, warrants or options to acquire, or securities convertible into or exchangeable for, any Voting Securities of the other party or any of its affiliates; (x) otherwise act, alone or in concert with others, to seek to control the Board of Directors or influence the management of the other party or any of its affiliates, provided that nothing in this clause (x) shall prevent such party or any affiliate of such party, either acting alone or in concert with others, from taking such action or refraining from taking such action as it believes is required of it under applicable law; or

(xi) enter into any agreements, discussions or arrangements with any person other than the Company, Merck or an affiliate of either of them with respect to any of the foregoing; or (xii) seek to waive, amend or modify any of the provisions contained herein (these provisions, collectively, the "Standstill Agreement").

The Standstill Agreement does not prohibit a party or any of its affiliates from acquiring Voting Securities of the other party or any of its affiliates by or through (i) a diversified mutual or pension fund managed by an independent investment adviser or pension plan established for the benefit of the employees of such party or its affiliates, (ii) any employee benefit plan of such party or any of its affiliates or (iii) any stock portfolios not controlled by such party or any of its affiliates that invest in the other

party or any of its affiliates among other companies; provided that such party or any of its affiliates does not, directly or indirectly, request the trustee or administrator or investment adviser of such fund, plan or portfolio to acquire such Voting Securities and provided that no such fund, plan or portfolio acquires more than five percent (5%) of any class of Voting Securities of such other party or any of its affiliates. Further, the Standstill Agreement does not prevent any party or any of its affiliates from acquiring securities of another pharmaceutical or biotechnology company or other person that beneficially owns any securities of the other party or any of its affiliates.

The provisions in the Standstill Agreement will be suspended solely to permit a party and its affiliates (collectively the "Acquiring Party") to: (i) take any of the actions described above to the extent the other party or any of its affiliates specifically invites the Acquiring Party to take such actions or (ii) to compete in an Acquisition Transaction (as defined below) with respect to the other party or any of its affiliates if such Acquisition Transaction shall have been publicly proposed by the other party or any of its affiliates or by a person unaffiliated with the Acquiring Party and accepted or approved by the other party or its affiliate, or if rejected or not approved by the other party and its affiliates, pursued on a unilateral basis pursuant to a tender or exchange offer and/or a proxy solicitation, or if the other party or its affiliate shall have entered into an agreement in principle or definitive agreement providing for such Acquisition Transaction. "Acquisition Transaction" means (A) any direct or indirect divestiture or sale by a party or any of its affiliates of assets representing thirty-five percent (35%) or more of the market capitalization of a party or of thirty-five percent (35%) or more of the Voting Securities of or equity interest in such party or any of its subsidiaries, or (B) any tender offer or exchange offer that if consummated would result in any person or group beneficially owning thirty-five percent (35%) or more of any class of Voting Securities of such party or affiliate, or (C) any merger, consolidation, business combination, recapitalization or similar transaction involving such party or any of its affiliates representing thirty-five percent (35%) or more of the market capitalization of such party or of thirty-five percent (35%) or more of the Voting Securities of or equity interest in such party or any of its subsidiaries."

Incorporated by reference in its entirety is a press release issued by the Registrant on April 28, 2004, attached as Exhibit 99, announcing the co-development and co-promotion agreement with Merck & Co., Inc.

Item 7(c). EXHIBITS

Exhibit 99 - Press release dated April 28, 2004 announcing the co-development and co-promotion agreement with Merck & Co., Inc.

#### SIGNATURE

Under the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 10, 2004

#### EXHIBIT INDEX

Exhibit Number Description

99 Press release dated April 28, 2004 regarding Registrant's
Co-Development and Co-Promotion Agreement with Merck & Co., Inc.