ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
August 28, 2002

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): August 27, 2002
(August 26, 2002)

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

DELAWARE	39040	13-4022871
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

100 Painters Drive
Chadds Ford, Pennsylvania 19317

(Address of principal executive offices) (Zip Code)

(610) 558-9800

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Item 5. Other Events.

Effective August 26, 2002, the Registrant's wholly owned subsidiary Endo Pharmaceuticals Inc. ("EPI") entered into an amendment agreement with Bristol-Myers Squibb Pharma Company ("BMS Pharma") amending certain of the terms and conditions of that certain Manufacturing and Supply Agreement effective August 26, 1997 by and between EPI and BMS Pharma (as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company). A copy of this amendment agreement is filed herewith as Exhibit 10.17.2 and is incorporated herein by reference.

In connection with the amendment agreement, on August 26, 2002, the Registrant issued a press release, a copy of which is filed herewith as

Exhibit 99.1 and is incorporated herein by reference.

Item 7. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

Exhibit Number	Description
10.17.2	Amendment Agreement effective August 27, 2002 by and between Endo Pharmaceuticals Inc. ("EPI") and Bristol-Myers Squibb Pharma Company as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company**
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on August 26, 2002

** Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 406 of the Securities Act of 1933.

SIGNATURES

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

ENDO PHARMACEUTICALS HOLDINGS INC.
(Registrant)

By: /s/ CAROL A. AMMON

Name: Carol A. Ammon
Title: Chairman & Chief Executive Officer

Dated: August 27, 2002

INDEX TO EXHIBITS

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Exhibit 10.17.2

AMENDMENT AGREEMENT TO THE MANUFACTURE AND SUPPLY AGREEMENT BETWEEN ENDO PHARMACEUTICALS INC. AND BRISTOL-MYERS SQUIBB PHARMA COMPANY AS SUCCESSOR-IN-INTEREST TO DUPONT PHARMACEUTICALS COMPANY

The confidential portions of this exhibit have been filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. REDACTED PORTIONS OF THIS EXHIBIT ARE MARKED BY AN ***.

THIS AMENDMENT AGREEMENT (this "Amendment") effective the 27th day of August, 2002 (the "Effective Date"), is by and between Endo Pharmaceuticals Inc. ("EPI"), having its principal offices at 100 Painters Drive, Chadds Ford, Pennsylvania, and Bristol-Myers Squibb Pharma Company as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company, having its principal offices at Longmeadow Drive, Wilmington, Delaware, and amends that certain Manufacture and Supply Agreement effective August 26, 1997 between EPI and The DuPont Merck Pharmaceutical Company, as amended by amendment effective May 7, 1999, and further amended by two amendments, both dated July 1, 1999 (collectively, the "Original Agreement").

PRELIMINARY STATEMENTS

WHEREAS, pursuant to a purchase agreement by and among Bristol-Myers Squibb Company, DuPont Pharmaceuticals Company and other DuPont entities effective October 1, 2001, Bristol-Myers Squibb Pharma Company ("BMS Pharma") became the successor-in-interest to DuPont Pharmaceuticals Company effective October 1, 2001;

WHEREAS, EPI and BMS Pharma wish to amend the Original Agreement to extend the term thereof and make certain other amendments, all upon the terms and subject to the conditions set forth in this Amendment;

NOW, THEREFORE, in consideration of the Preliminary Statements and the mutual covenants contained in this Amendment and other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree to amend the Original Agreement and be legally bound as follows:

AMENDED TERMS AND CONDITIONS

1. Parties. All references to DuPont Pharmaceuticals Company, The DuPont Merck Pharmaceutical Company, DuPont Merck Pharma and/or DuPont Pharma in the Original Agreement are hereby amended and replaced with Bristol-Myers Squibb Pharma Company or BMS Pharma.

2. Defined Terms. (a) Unless set forth herein, the capitalized terms contained in this Amendment shall have the meaning set forth in the Original Agreement.

(b) Whenever references to sections are made in this Amendment, unless another document is specifically referred to, such references shall refer to the sections in the Original Agreement.

3. Definition. (a) Section 1.2 is amended to delete in its entirety the following defined terms: "Additional Compensation Factor" and "Agreed Manufacturing Level."

(b) Section 1.2 is further amended to add the following defined term:

"'2002 Amendment' shall mean that certain amendment to this Agreement, dated as of August 27, 2002, by and between Endo Pharmaceuticals Inc. and Bristol-Myers Squibb Pharma Company."

4. Non-Exclusivity. Section 2.3 is deleted and replaced in its

entirety as follows:

"2.3 Non-Exclusivity. BMS Pharma agrees to sell to EPI all of EPI's requirements for Products for resale anywhere in the world. Except as set forth in this Agreement, including EPI's commitment set forth in Paragraph 20 of the 2002 Amendment; it is specifically agreed that EPI shall have the right to have up to 100% of its requirements for any Product to be produced by BMS Pharma or have production for such requirements transferred to a third party, at EPI's sole discretion."

5. New Products. The provisions of Section 2.4 shall continue to apply to any New Product added prior to the Effective Date, provided however, EPI shall not have any right to add any New Product on or after the Effective Date.

6. Adequate Supply - API Inventory Levels. Section 2.5(a) is deleted and replaced in its entirety as follows:

"(a) API Inventory Levels. BMS Pharma shall maintain inventory of API for each Product at levels mutually agreed upon by the parties, as may be modified from time to time through the S&OP Process (as referenced in Section 2.7(c)), or at such higher levels as may be specified by EPI pursuant to Section 5.1(b) and agreed to by BMS Pharma. BMS Pharma specifically agrees that it will not unreasonably withhold consent for EPI's requests for higher levels of inventory. In the event that BMS Pharma believes it is necessary to make changes to the inventory levels of API for a particular Product outside of the S&OP process set forth in the Agreement, EPI specifically agrees that it will not unreasonably withhold consent which could prevent BMS Pharma's compliance with Section 2.5(c); so long as (x) all Product containing such API has at least 90% of expiration dating and (y) following the termination or expiration of the Agreement, EPI shall not be obligated to pay for any API that is in BMS Pharma's inventory as a result of any such inventory level change requested by BMS Pharma.

Notwithstanding the foregoing, EPI may order from BMS Pharma up to *** kilograms of *** API and up to *** kilograms of *** API to be delivered to EPI or its designee; provided that, EPI places such orders with BMS Pharma in writing no later than 5:00 PM (EST) on ***. In the case of the *** API only, BMS Pharma shall adhere to the plan for the qualification of *** API in the product *** which plan is attached hereto as Attachment A, it being understood that in the event that BMS Pharma does not adhere to such plan, EPI may order up to *** kilograms of *** API. Each written order shall identify the API as well as the number of kilograms requested for production. BMS Pharma shall deliver such API ordered to EPI or its designee during the ***, on any particular date or dates it determines in its discretion so long as BMS Pharma provides EPI five (5) business days notice prior to such delivery. The cost of this API to be charged EPI shall be set at the 2003 Variable Standard Cost (as further described in Paragraph 16 (iii) of the 2002 Amendment). In no event shall the production and/or delivery of such quantities of API be construed as any extension of the Final Term."

7. Adequate Supply - Validation of Alternate Facility. The provisions of Section 2.5(b) shall continue to apply to any alternate facility validated prior to the Effective Date; provided however, BMS Pharma shall have no obligation to validate any alternate facility on or

after the Effective Date other than to provide the assistance and documentation as contemplated in Paragraph 14 of this Amendment.

8. Adequate Supply - Agreed Manufacturing Level. Section 2.5(c) is deleted and replaced in its entirety as follows:

"(c) Agreed Manufacturing Level. BMS Pharma agrees that it will not knowingly take on additional manufacturing responsibilities or commitments at the Facilities or otherwise knowingly take any actions that would prevent it from manufacturing Products in accordance with this Agreement."

9. Failure to Supply. Section 2.6 is deleted and replaced in its entirety as follows:

"2.6 Failure to Supply. If BMS Pharma fails to supply (a) any Product to meet EPI's requirements that has been ordered in accordance with Article 5 of this Agreement or (b) any API that has been ordered in accordance with Section 2.5(a) (other than EPI's failure to supply API sourced by EPI), in either case, for a period in excess of thirty (30) days from the agreed date of delivery, then this Agreement shall be extended, for such Product or API only, beyond the last day of the Final Term or any Extension Period, as the case may be, until such date that BMS Pharma has supplied EPI with 100% of its 2003 Forecast for Products and 100% of API ordered in accordance with Section 2.5(a), at no additional cost to EPI (other than the Variable Costs due in accordance herewith following EPI's receipt of the Product or API). Notwithstanding the foregoing, in no event shall BMS Pharma deliver any Product to EPI with expiration dating that is less than 90%."

10. Contact Persons/Teams. Section 2.7(a) is amended by substituting Umesh Dalvi in place of each of the representatives listed for the three BMS Pharma sites.

11. Term. Section 3.1 is amended to provide that the Original Agreement is renewed for an additional one-year term (the "Final Term") commencing at 12:01 a.m. (EST) on August 27, 2002 and ending at 11:59 p.m. (EST) on August 26, 2003. Unless otherwise extended as set forth in Paragraph 12 below, the Original Agreement, as hereby amended, will expire at 11:59 p.m. (EST) on August 26, 2003 and BMS Pharma's manufacture and supply of the Products (***, to the extent the manufacture and supply of such Products becomes subject to a separate agreement negotiated between the parties hereto pursuant to Paragraph 29 below) will cease on that date.

The pricing terms for the Final Term are set forth below in Paragraphs 15 and 16 of this Amendment.

12. Final Term Extension. Section 3.1 is further amended to provide that EPI may extend the Final Term one time for up to an additional four months, which extension period shall commence at 11:59 p.m. (EST) on August 26, 2003 and end no later than 11:59 p.m. (EST) on December 31, 2003 (any such period, the "Extension Period"); provided that EPI gives written notice of such extension to BMS Pharma no later than 5:00 p.m. (EST) on February 28, 2003. Such written notice of such extension shall specify the number of months (not to exceed four) the Final Term is being extended. Under no circumstances will EPI have any right to extend the Final Term beyond December 31, 2003. The pricing terms for such extension are set forth below in Paragraphs 15 and 16 of this Amendment.

13. Special Termination Provisions. Section 3.2 is deleted and

replaced in its entirety as follows:

"3.2 [deleted]"

14. Effect of Termination. Section 3.4 is deleted and replaced in its entirety as follows:

"3.4 Effect of Termination. Upon termination or expiration of this Agreement:

(a) Transfer of EPI Property. To the extent not previously transferred at Closing, BMS Pharma will transfer all NDA's, ANDA's and DMF's, all documents required to be transferred pursuant to 21 CFR 314.81 and all of EPI's Intellectual Property, technical information and other documentation with respect to the Products within sixty (60) business days of the completion of the last production to EPI or a third party designated by EPI. For the avoidance of doubt, the transfer of technical documentation shall mean the transfer of technical documentation regarding the manufacture and testing of the Products and confirmance that the technical documentation transferred is the most current and approved version thereof. BMS Pharma will also deliver all other property of EPI in its possession (including, but not limited to, equipment purchased by EPI), to EPI or a third party designated by EPI. BMS Pharma will provide such assistance with respect to such transfer or delivery as EPI reasonably requests. For the further avoidance of doubt, assistance to EPI shall mean: (i) permitting observation of BMS Pharma's commercial manufacturing and analytical procedures for the Products by EPI or by third-party representatives designated by EPI; (ii) responding to technical questions regarding such manufacturing and analytical procedures raised by EPI or such third-party representatives; (iii) supplying, upon request, analytical quantities of samples, such as API, EPI-specific reference standards and impurities, Excipients and finished product to EPI to assist in the transfer of the Products to a third-party manufacturing facility; and (iv) providing data from normal release testing of API, impurities, degradation products and finished products. For the further avoidance of doubt, BMS Pharma will not (a) perform comparative testing or additional Interlaboratory Qualification testing on any API, degradation products and finished products, (b) be obligated to train third parties, review or approve third party documents, or (c) resolve technical issues between EPI and third parties. All requests for technical information/documentation and assistance shall be made in writing with reasonable notice to BMS Pharma.

(b) Inventory. BMS Pharma shall deliver all inventory of finished Products on hand to EPI or a third party designated by EPI within forty-five (45) days of such termination or expiration so long as the amount of any such inventory is consistent with the 2003 Forecast; provided that EPI agrees to consider in good faith purchasing any inventory of finished Products in excess of the 2003 Forecast. BMS Pharma shall invoice EPI, and EPI shall make payment pursuant to the payment terms set forth in Section 6.2 for such inventory of finished Products at the applicable Variable Cost.

(c) Retained Samples.BMS Pharma shall deliver all retained quality samples of Product to EPI or a third party designated by EPI within forty-five (45) days of such termination or expiration; provided that EPI shall be solely responsible for the expense of the delivery of such retained quality samples. Upon

transfer of such retained quality samples, EPI shall assume all regulatory responsibilities with respect to such retained samples.

15. Fixed Costs During the Final Term and Any Extension. Notwithstanding anything to the contrary in this Amendment or in the Original Agreement (including Sections 4.1 and 4.2 thereof), the parties hereby agree that: (A) during the Final Term, EPI shall pay BMS Pharma a total of Five Million Dollars ($5,000,000) in respect of Fixed Costs at both the Manati Facility and the Garden City Facility, which amount shall be payable in four equal quarterly installments of One Million Two Hundred Fifty Thousand Dollars ($1,250,000) each on September 1, 2002, December 1, 2002, March 1, 2003 and June 1, 2003; (B) in the event EPI extends the Final Term pursuant to Paragraph 12 above, EPI shall pay BMS Pharma Five Hundred Thousand Dollars ($500,000) per month of the Extension Period in respect of Fixed Costs at both the Manati Facility and the Garden City Facility, payable on the 5th day of each month of the Extension Period; and (C) in the event EPI extends the Final Term pursuant to Paragraph 12 above and only requests BMS Pharma to manufacture *** and/or *** during such extension, then EPI shall only be obligated to pay BMS Pharma One Hundred Fifty Thousand Dollars ($150,000) per month of the Extension Period in respect of Fixed Costs at the Garden City Facility, payable on the 5th day of each month of the Extension Period.

16. Variable Costs During the Final Term and Any Extension. Notwithstanding anything to the contrary herein or in the Original Agreement (including Sections 4.1 and 4.2 thereof), the parties hereby agree that (i) the term "Variable Costs" (also referred to as Standard Variable Costs or Standards) for the period of August 27, 2002 through December 31, 2002 (the "2002 Stub Period") are as set forth in the electronic mail from Hal Torman dated April 3, 2002 to EPI, attached to this Amendment as Exhibit A; (ii) during the 2002 Stub Period, EPI shall pay to BMS Pharma the Variable Costs of Products manufactured by BMS Pharma, which amounts shall be invoiced as provided in Section 6.2 of the Agreement; (iii) Variable Standard Costs for the calendar year 2003 shall be adjusted to reflect expected cost increases or decreases from the Variable Standard Costs for the 2002 Stub Period; it being understood that any such adjustment will be capped at five percent (5%) of the 2002 Stub Period Variable Standard Costs; it being further understood that EPI shall have the right to ask material questions to BMS Pharma regarding the 2003 Standards and BMS Pharma shall answer such questions with reasonable diligence and in good faith; it being still further understood that EPI shall be responsible to BMS Pharma for any amounts attributable to any labor variance and any inventory or material write-offs, including without limitation, inventory build for API, resulting from EPI changing the volume forecast for the period January 1, 2003 to August 26, 2003 which was provided to BMS Pharma on June 28, 2002 and is attached to this Amendment as Exhibit B (as may be amended as a result of any Extension Period, the "2003 Forecast"); and (iv) the Variable Costs provided to EPI include (x) all direct materials (excluding API) used in the manufacture of the Products, (y) all direct labor used in the manufacture of the Products and (z) reasonable profit for BMS Pharma with respect thereto.

17. Transfer Fee. Notwithstanding anything to the contrary in this Amendment or in the Original Agreement (including Sections 4.1 and 4.2 thereof), the parties hereby agree that in consideration of BMS Pharma allowing EPI to transfer up to 100% of any EPI Product out of any BMS Pharma facility at any time, and for the assistance provided EPI by BMS Pharma as reflected in Paragraph 14 above, EPI shall make to BMS Pharma a payment of Nine Million Dollars ($9,000,000), which payment is due and payable on August 27, 2002.

18. Additional General Compensation Matters - Cash Cap Amount;

Promissory Notes Stay in Effect. Notwithstanding anything to the contrary in this Amendment or in the Original Agreement (including Sections 4.1, 4.2 and 4.3 thereof), the parties hereby agree with respect to the Final Term and any Extension Period, no Cash Cap Amount shall apply. This Amendment shall have no effect on the obligations under any promissory notes issued and/or executed under the Original Agreement.

19. Additional General Compensation Matters - Adjustment of Variable Costs. Section 4.3(c) is deleted and replaced in its entirety as follows:

"(c) [deleted]"

20. Forecasts and Orders. Notwithstanding anything to the contrary in this Amendment or in the Original Agreement (including Section 5.1 thereof), EPI hereby agrees that its actual orders during the period January 1, 2003 to August 26, 2003 shall not, in the aggregate, be less than seventy-five percent (75%) nor greater than one hundred twenty five percent (125%) of the 2003 Forecast. EPI shall update the forecast monthly on the fifth day of the month on a rolling basis, with the forecast for the most current three-month period constituting a firm order which shall state in detail the quantities of Products ordered and shall bind both parties regarding the Products to be purchased.

21. Addresses. Section 5.4 is amended to delete and replace (a) EPI's address with Endo Pharmaceuticals Inc., 100 Painters Drive, Chadds Ford, PA 19317, (b) BMS Pharma's Wilmington address and representative with Bristol-Myers Squibb Pharma Company, 1 Squibb Drive, New Brunswick, New Jersey 08903; Attention: Larry Jaffe and (c) BMS Pharma's contact person, Ilsa M. Esteves, at the Manati Facility with Luis Albors.

22. Payment Provisions - Variable Costs. Section 6.2(a) is amended to provide that Schedule H shall not apply for the Final Term or Extension Period, if any.

23. Retention Samples. Section 10.4 is deleted and replaced in its entirety as follows:

"10.4 Retained Samples. Subject to Section 3.4(c), BMS Pharma will store and maintain retention samples of raw material, API and Product from each lot to meet regulatory requirements."

24. Product Notices. Section 13.8 is amended to delete and replace (a) EPI's address with Endo Pharmaceuticals Inc., 100 Painters Drive, Chadds Ford, PA 19317 and (b) BMS Pharma's Wilmington address with Bristol-Myers Squibb Company, One Squibb Drive, New Brunswick, NJ 08903, Attention: Robert Tagliente, 732-519-2171 (Tel).

25. Notices. Section 17.1 is amended to delete and replace (a) EPI's address with Endo Pharmaceuticals Inc., 100 Painters Drive, Chadds Ford, PA 19317; Attention Carol A. Ammon, Chairman and Chief Executive Officer; Fax 610/558-9682 and (b) BMS Pharma's Wilmington address with Bristol-Myers Squibb Pharma Company, 1 Squibb Drive, New Brunswick, New Jersey 08903; Attention: William Keane, VP, Sourcing, Strategy and Operations Effectiveness and Senior Counsel, Technical Operations; Fax 732/519-1086.

26. ***. Notwithstanding anything to the contrary in this Amendment or in the Original Agreement, (a) BMS Pharma hereby agrees to validate the current process used in the manufacture of *** using *** API manufactured by BMS in accordance with the plan for the qualification of BMS *** API in the product *** which plan is attached hereto as Attachment

B and (b) once such validation is completed, EPI hereby agrees to purchase, and BMS Pharma hereby agrees to manufacture and supply, *** post-validated batches of ***, *** of which will be delivered by BMS Pharma to EPI or its designee on or about each of ***, ***, and ***; provided that each batch shall have at least sixteen (16) months of expiration dating upon delivery to Endo (or its designee); provided further that these batches shall be in addition to the batches necessary for the validation set forth in clause (a) above. BMS Pharma shall invoice EPI, and EPI shall make payment pursuant to the payment terms set forth in Section 6.2 of the Original Agreement for such inventory of finished Products at the applicable Variable Cost. To the extent a validation issue arises, the parties agree to negotiate in good faith to revise the delivery schedule set forth in the plan.

27. Assignment. Section 17.4(b) is deleted and replaced in its entirety as follows:

"(b) Assignment by BMS Pharma. BMS Pharma may not assign this Agreement, or its rights and obligations hereunder, without the prior written consent of EPI. Subject to the preceding, this Agreement will be binding upon, inure to the benefit of and be enforceable by the parties and their respective successors and assigns. Notwithstanding the foregoing:

(i) In the event of the sale or other disposition of all or substantially all of the business or assets of BMS Pharma prior to December 31, 2003, BMS Pharma may assign this Agreement, and its rights and obligations hereunder, to the successor to the business or assets of BMS Pharma provided that EPI consents to such assignment, which consent shall not be unreasonably withheld (and in determining whether to consent, EPI shall consider the pre-acquisition financial strength of the successor and if such successor has at least $250 million of tangible net worth, such amount of tangible net worth shall be prima facie evidence of the satisfactory financial strength of the successor). Notwithstanding the foregoing, in the event BMS Pharma desires such sale or disposition to occur after August 27, 2003 and on or prior to December 31, 2003, EPI agrees that it will grant its consent to such sale or disposition so long as Bristol-Myers Squibb Company guarantees the delivery of 100% of the Products set forth in the 2003 Forecast. For the avoidance of doubt, any proposed assignment subsequent to December 31, 2003 will not require the consent of EPI; and

(ii) If BMS Pharma determines to sell or otherwise transfer either or both Facilities prior to December 31, 2003, it may do so and in connection therewith it may assign this Agreement (insofar as applicable to the subject Facility or Facilities) to the acquiring entity; provided that the acquiring entity shall be bound by the terms and conditions of this Agreement and that this Agreement shall be enforceable by EPI against such acquiring party; provided, however, that in the event that EPI determines, in its sole discretion, that the acquiror of the Facility or Facilities would not be an acceptable manufacturer of the Products, then BMS Pharma shall not assign this Agreement (or applicable rights and/or obligations hereunder) to the acquiror but shall instead be responsible at BMS Pharma's cost to implement appropriate arrangements for the manufacture and supply of Products that otherwise would have been manufactured at the subject Facility or Facilities in accordance with the terms hereof at and from the other Facility (if still owned) and/or at and from one or more alternate manufacturers located within the continental

United States or Puerto Rico, satisfactory to EPI in its sole discretion. BMS Pharma will reimburse EPI for incremental distribution costs if transfer of production from the Facility being transferred results in increased distribution costs. Once the foregoing arrangements are implemented in all material respects to the reasonable satisfaction of EPI, BMS Pharma may complete the transfer of the subject Facility or Facilities. Notwithstanding the foregoing, in the event BMS Pharma desires such sale or transfer to occur after August 27, 2003 and on or prior to December 31, 2003, EPI agrees that it will grant its consent to such sale or transfer so long as BMS Pharma guarantees the delivery of 100% of the Products set forth in the 2003 Forecast, provided, however, in the event that such sale or transfer is to a Competitor of EPI with respect to the Products, BMS Pharma will deliver (x) 100% of any such Competitive Product in accordance with this Agreement and (y) 100% of the EPI property referred to in Section 3.4(a) of this Agreement that relate to the Competitive Product, in each case, prior to consummating such sale or transfer. For the purposes of this section, "Competitor" shall mean any third-party that manufactures, markets, sells or distributes any product(s) that contain the same active pharmaceutical ingredient(s) as those used in any Product(s); and "Competitive Product" shall mean any product that contains the same active pharmaceutical ingredient(s) as those used in any Product(s). For the avoidance of doubt, any proposed sale or transfer subsequent to December 31, 2003 will not require the consent of EPI."

28. Survival. Section 3.3 is deleted and replaced in its entirety as follows:

"3.3 Survival. The rights and obligations contained in Sections 3.4(c) [Retained Samples], 10.4 [Retention Samples], 10.7 [Records Retention], 12.2 [EPI Inspections], 12.3 [Audit Rights] and 17.7 [Governing Law] and Articles 11 [Confidential Information], 13 [Complaints, ADERs, Recalls], 14 [Indemnity] and 16 [Mediation/Arbitration] will survive termination or expiration of this Agreement, as will any rights to payment or other rights or obligations that have accrued under this Agreement prior to termination or expiration. Termination or expiration will not affect a party's liability by reason of any act, omission, default or occurrence prior to termination or expiration."

29. *** Agreement. Notwithstanding the conclusion of the Final Term, the parties agree to negotiate in good faith to enter into a separate *** agreement limited to the manufacture and sale of *** on commercially reasonable terms mutually acceptable to both parties. If such agreement has not been executed by the parties on or prior to the sixth (6th) month anniversary of BMS's first delivery to EPI of the first draft agreement containing standard terms and conditions ordinarily found in such an agreement, neither party shall have any obligation to the other to enter into any further discussion in connection with such separate agreement beyond such six-month anniversary; provided that each party hereby agrees to use its commercially reasonable efforts to negotiate and execute such agreement in a timely manner.

30. Effectiveness of Amendment. This Amendment shall take effect as of the Effective Date set forth above so long as the Nine Million Dollar ($9,000,000) payment referred to in Paragraph 17 above has been wire transferred to an account designated by BMS Pharma.

31. All Other Provisions of the Original Agreement in Full Force

and Effect. Except as specifically amended in this Amendment, in all other respects the Original Agreement shall remain in full force effect, is hereby confirmed and is and unaffected by this Amendment.

32. Entire Agreement. This Amendment, together with the Original Agreement, any schedules or exhibits hereto and thereto, constitute the entire agreement between the parties with respect to the subject matter hereof and supersedes any and all prior or contemporaneous understandings, agreements, negotiations, or discussions, whether written or oral, concerning the subject matter hereof. To the extent there is any conflict between this Amendment and the Original Agreement, the applicable provisions of this Amendment shall control.

33. Amendment; Waiver. No terms or provisions of this Amendment shall be varied, amended, extended or modified by any prior or subsequent statement, conduct or act of either of the parties, except by a written instrument executed by the parties in the same manner as this Amendment.

34. References in the Original Agreement. On and after the effectiveness of this Amendment, each reference in the Original Agreement to "this Agreement", "hereunder", "hereof", "herein" or words of like import referring to the Original Agreement shall mean and be a reference to the Original Agreement as amended by this Amendment.

35. Paragraph Headings and Subheadings.Article and subsection headings in this Amendment are included herein for convenience only and shall not constitute a part of this Amendment for any other purpose or be given any substantive effect.

36. Authorization. Both parties acknowledge agreement to the terms of this Amendment by having an authorized representative sign one copy in the space provided below. Each party represents and warrants that the authorized representative has actual power and authority to execute this Amendment on behalf of the respective company, and that this Amendment shall be binding upon the respective company, its successors and assigns.

37. Counterparts. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts together shall constitute but one and the same instrument; signature pages may be attached from multiple separate counterparts and attached to a single counterpart so that all signature pages are physically attached to the same document.

38. Successors and Assigns. This Amendment will be binding upon, inure to the benefit of and be enforceable by the parties and their respective successors and assigns.

IN WITNESS HEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized representatives.

BRISTOL-MYERS SQUIBB PHARMA COMPANY

By: /s/ Thomas M. Primm

Title: Vice President

Date: August 22, 2002

ENDO PHARMACUETICALS INC.

By: /s/ Jeffrey Black

Title: Chief Financial Officer

Date: August 22, 2002

EXHIBIT A

***

EXHIBIT B

***

ATTACHMENT A

***

ATTACHMENT B

***

Exhibit 99.1

[ENDO LOGO]

For Immediate Release

CONTACT:
Bill Newbould
Endo Pharmaceuticals
(610) 558-9800

ENDO PHARMACEUTICALS AMENDS MANUFACTURING AGREEMENT
WITH BRISTOL-MYERS SQUIBB

CHADDS FORD, Pa., August 26, 2002 -- Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW) today announced that it has amended its manufacturing and supply agreement with the Bristol-Myers Squibb Pharma Company ("BMS") as successor-in-interest to DuPont Pharmaceuticals Company, formerly known as The DuPont Merck Pharmaceutical Company. The amended agreement has a term of one year, ending on August 26, 2003.

Carol A. Ammon, chairman and chief executive officer of Endo Pharmaceuticals, said, "This amendment to our existing agreement with BMS allows us to transfer the majority of our manufacturing from BMS to Novartis in an effective manner, with no interruption in supply. Since September 2001, Novartis has been an excellent partner as a key manufacturer of Endo's leading product, Percocet(R), and we look forward to expanding our relationship with them. Novartis will provide Endo with the high-quality, reliable products that our customers expect of us." The transfer of manufacturing and supply from BMS to Novartis is not expected to impact the Company's previously announced guidance for 2002 of $350 million in net sales and $125 million in consolidated EBITDA, which excludes the non-recurring costs of transfer and the transfer fee discussed below.

In May 2001, Endo entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., whereby Novartis agreed to manufacture substantially all of Endo's commercial products and products in development. Endo has incurred, and expects to continue to incur, significant costs associated with the preparation of Novartis' manufacturing operations under this agreement. These costs, which totaled approximately $1.3 million in the second quarter of 2002, primarily relate to the preparation of test batches of drug product for FDA approval and Endo's own quality assessment and administrative costs relating to the transfer of existing production to Novartis.

In consideration for BMS allowing Endo to transfer up to 100% of any Endo product out of any BMS facility at any time, and for its assistance in the transfer, Endo will make a one-time payment to BMS of $9.0 million on August 27, 2002. This transfer fee will be expensed in the third quarter of 2002.

Endo's cash and cash equivalents totaled $151.8 million at June 30, 2002. On August 26, 2002, Endo utilized a portion of its cash and cash equivalents to repay all of the promissory notes that it has issued to BMS, including promissory notes issued under the manufacturing and supply agreement, which totaled $118.9 million. Endo believes that its (a) cash and cash equivalents, (b) cash flow from operations and (c) its credit

facility (which has an available unused line of credit of $75 million) will be sufficient to meet Endo's normal operating, investing and financing requirements in the foreseeable future. This includes the funding of its pipeline projects in the event that its collaboration partners are unable to fund their portion of any particular project. In the future, Endo may use a portion of its cash and cash equivalents for possible acquisitions or licenses. For the six months ended June 30, 2002, Endo generated cash flow from operating activities of $64.0 million.

About Endo
A wholly owned subsidiary of Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW), Endo Pharmaceuticals Inc. is a fully integrated specialty pharmaceutical company with market leadership in pain management products. The company researches, develops, produces and markets a broad product offering of both branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. More information, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at www.endo.com.

Forward-Looking Statements This press release contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on management's beliefs and assumptions, current expectations, estimates and projections. These statements are subject to risks and uncertainties and, therefore, actual results may differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are not historical facts and include information regarding the Company's possible or assumed results of operations. Also, statements or expressions that are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects," "intends," "estimates" or similar expressions are forward-looking statements. Endo's estimated or anticipated future results, product performance or other non- historical facts are forward-looking and reflect Endo's current perspective on existing trends and information. Many of the factors that will determine the Company's future results are beyond the ability of the Company to control or predict. The reader should not rely on any forward-looking statement. The Company undertakes no obligations to update any forward-looking statements whether as a result of new information, future events or otherwise. Several important factors, in addition to the specific factors discussed in connection with these forward-looking statements individually, could affect the future results of the Endo and could cause those results to differ materially from those expressed in the forward-looking statements contained herein. Important factors that may affect future results include, but are not limited to: market acceptance of the Company's products and the impact of competitive products and pricing; dependence on sole source suppliers; the success of the Company's product development activities and the timeliness with which regulatory authorizations and product launches may be achieved; successful compliance with extensive, costly, complex and evolving governmental regulations and restrictions; the availability on commercially reasonable terms of raw materials and other third party manufactured products; exposure to product liability and other lawsuits and contingencies; dependence on third party suppliers, distributors and collaboration partners; the ability to timely and cost effectively integrate acquisitions; uncertainty associated with pre-clinical studies and clinical trials and regulatory approval; uncertainty of market acceptance of new products; the difficulty of predicting FDA approvals; risks with respect to technology and product development; the effect of competing products and prices; uncertainties regarding intellectual property protection; uncertainties as to the outcome of litigation; changes in operating results; impact of competitive products and pricing; product development; changes in laws and regulations; customer demand; possible future

litigation; availability of future financing and reimbursement policies of government and private health insurers and others; and other risks and uncertainties detailed in Endo's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended, and in Endo's Registration Statement on Form S-3 dated October 17, 2001. Readers should evaluate any statement in light of these important factors.

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