MEDICINES CO /DE
Form 8-K
October 04, 2011

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): **September 30, 2011**

The Medicines Company

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-31191**	**04-3324394**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8 Sylvan Way

Parsippany, New Jersey	**07054**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s telephone number, including area code: **(973) 290-6000**

Not applicable.

(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry Into a Material Definitive Agreement.

On September 30, 2011, The Medicines Company (the Company) and Teva Pharmaceuticals USA, Inc. and its affiliates (collectively, Teva) entered into a Settlement Agreement (the Settlement Agreement) and a License Agreement (the License Agreement , and together with the Settlement Agreement, the Settlement Documents) relating to *The Medicines Company v. Teva Parenteral Medicines, Inc., et al.*, and *The Medicines Company v. PLIVA HRVATSKA d.o.o., et al.*, actions for patent infringement in the U.S. District Court for the District of Delaware (the Pending Litigation).

In the Pending Litigation, the Company alleges that the generic bivalirudin for injection Abbreviated New Drug Applications (ANDAs) filed by Teva Parenteral Medicines, Inc. and its affiliate, Pliva Hrvatska d.o.o. with the U.S. Food and Drug Administration infringe the Company s U.S. Patent Nos. 7,582,727 and 7,598,343 that cover bivalirudin for injection (the Litigated Patents). The Company markets and sells a branded bivalirudin for injection product in the United States under the name Angiomax® (bivalirudin).

Contemporaneously with entering into the Settlement Documents, the Company and Plantex USA Inc. (Plantex), a Teva affiliate, entered into a Supply Agreement (the Supply Agreement , and together with the Settlement Documents, the Agreements) under which Plantex will supply to the Company the active pharmaceutical ingredient bivalirudin (the API).

The following is a summary of the material terms of the Agreements.

Settlement Agreement

Under the Settlement Agreement, Teva admits that the Litigated Patents are valid and enforceable and that the Litigated Patents would be infringed by Teva s generic bivalirudin for injection products. The Settlement Agreement provides that the Company and Teva will not pursue litigation activities related to the Pending Litigation and will file a Judgment and Order of permanent Injunction concluding the Pending Litigation within three business days following the execution of the Settlement Documents. Under the Settlement Agreement, the Company will make a one-time payment to Teva within five business days following the date of execution in recognition of the savings inuring to the Company in terms of the avoidance of costs and burden associated with prosecuting the Pending Litigation. The Settlement Agreement terminates upon the earlier of the expiration of the Litigated Patents and the termination of the License Agreement. The Litigated Patents are currently due to expire on July 27, 2028. The Settlement Agreement provides that the Company and Teva will submit the Settlement Documents to the U.S. Federal Trade Commission and the U.S. Department of Justice within ten business days following the date of execution.

License Agreement

Under the License Agreement, the Company grants Teva a non-exclusive license under the Litigated Patents to sell a generic bivalirudin for injection product under a Teva ANDA (the Teva Product) in the United States beginning June 30, 2019 or earlier under certain conditions. Under the License Agreement, Teva will be required to pay the Company royalties on gross profits of its sales of the Teva Product under certain circumstances.

The License Agreement also contains a grant by Teva to the Company of an exclusive (except as to Teva), license under Teva s bivalirudin patents and right to enforce Teva s bivalirudin patents, in consideration of which the Company will make a one-time payment to Teva within five days after entering into the License Agreement.

The license to Teva will remain in effect until the expiration of all of the Company patents covering Angiomax. Each of the Company and Teva may terminate the License Agreement in the event of a material breach by the other party, unless the material breach is cured within 60 days of a written notice. The Company may terminate the License Agreement, effectively immediately, for certain breaches of the License Agreement.

Supply Agreement

Under the Supply Agreement, the Company agrees to purchase from Plantex certain minimum quantities of bivalirudin API for the Company s commercial supply. The initial term of the Supply Agreement ends December

31, 2015 and will automatically be renewed for successive three-year periods unless terminated by the Company with at least six-month written notice or by Teva with at least 24-months written notice prior to the expiration of the initial term or either renewal term. The Company has the right to terminate the Supply Agreement, effectively immediately, if a generic form of bivalirudin is launched after January 1, 2013. Each of the Company and Teva may terminate the Supply Agreement in the event of a material breach by the other party, unless the material breach is cured within 30 days of a written notice, and the Company may terminate the Supply Agreement upon breach of the Settlement Agreement and certain breaches of the License Agreement.

The Agreements also contain provisions including indemnification, confidentiality, dispute resolution and other customary provisions for agreements of these kinds.

The foregoing descriptions of the Agreements do not purport to be complete and are qualified in their entirety by reference to the complete texts of the Agreements, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission as exhibits to the Company s Quarterly Report on Form 10-Q for the period ending on September 30, 2011.

Item 8.01. Other Events

On October 3, 2011, the Company issued a press release to announce that it has settled the Pending Litigation with Teva. The Company remains in infringement litigation involving the Litigated Patents with APP Pharmaceuticals, Hospira, Mylan Pharmaceuticals and Dr. Reddy s Laboratories. The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1.

Safe Harbor

Statements contained in this Form 8-K about The Medicines Company that are not purely historical, and all other statements that are not purely historical, may be deemed to be forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, the words believes, anticipates and expects and similar expressions, including the Company s preliminary revenue results, are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that may cause the Company s actual results, levels of activity, performance or achievements to be materially different from those expressed or implied by these forward-looking statements. Important factors that may cause or contribute to such differences are set forth in the risk factors detailed from time to time in the Company s periodic reports and registration statements filed with the Securities and Exchange Commission including, without limitation, the risk factors detailed in the Company s Quarterly Report on Form 10-Q filed on August 2, 2011, which are incorporated herein by reference. The Company specifically disclaims any obligation to update these forward-looking statements.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	Press release dated October 3, 2011 entitled The Medicines Company Settles Angiomax® (bivalirudin) Patent Litigation with Teva

SIGNATURE

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.

THE MEDICINES COMPANY

Date: October 3, 2011

By: /s/ Paul M. Antinori
Name: Paul M. Antinori
Title: Senior Vice President and General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated October 3, 2011 entitled The Medicines Company Settles Angiomax® (bivalirudin) Patent Litigation with Teva