MEDICINES CO /DE
Form 8-K
February 04, 2013
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): February 3, 2013

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 (Address of Principal Executive Offices)	07054 (Zip Code)

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

(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 February 3, 2013, The Medicines Company (the "Company") entered into a license and collaboration agreement (the "Agreement") with Alnylam Pharmaceuticals, Inc. ("Alnylam") to develop, manufacture and commercialize therapeutic products targeting the human PCSK-9 gene ("PCSK-9") based on certain of Alnylam's RNA interference technology. Under the terms of the Agreement, the Company obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK-9 products for the treatment, palliation and/or prevention of all human diseases. The Company has agreed to pay Alnylam $25 million in an initial license payment and up to $180 million in success-based development and commercialization milestones. In addition, Alnylam will be eligible to receive scaled double-digit royalties based on annual worldwide net sales of PCSK-9 products by the Company, its affiliates and sublicensees. Royalties to Alnylam are payable on a product-by-product and country-by-country basis until the last to occur of the expiration of patent rights in the applicable country that cover the applicable product, the expiration of non-patent regulatory exclusivities for such product in such country, and the twelfth anniversary of the first commercial sale of the product in such country. The royalties are subject to reduction in specified circumstances. The Company is also responsible for paying royalties, and in some cases milestone payments, owed by Alnylam to its licensors with respect to intellectual property covering these products.

Under the Agreement, a joint steering committee, with equal representation from both parties, will be created to guide the development of the products. In the event of a dispute within the joint steering committee which cannot be resolved by the parties, the Company will have the final decision making authority, subject to specified exceptions. Alnylam had been developing two PCSK-9 product candidates prior to entering into this Agreement. Under the Agreement, Alnylam will direct all non-clinical development activities for these product candidates until the joint steering committee selects one of these two candidate products as the lead product. In accordance with a mutually agreed development plan, Alnylam will use commercially reasonable efforts to develop the two product candidates through the selection of the lead product, to develop the lead product through the end of the first phase 1 clinical trial under the Agreement and to supply the lead product for the first phase 1 clinical trial and the first phase 2 clinical trial of the lead product under the Agreement. Alnylam will bear the costs for these activities, subject to certain caps on its costs. If Alnylam's development and supply costs exceed the applicable cap, Alnylam need not bear any additional development and supply costs except for costs directly caused by Alnylam's gross negligence and the Company shall have the option to assume such excess costs. The Company will direct and pay for all other development, manufacturing and commercialization activities and for all other products under the Agreement.

The parties have agreed that, within a specified period of time, the parties will negotiate a development supply agreement pursuant to which Alnylam will supply the material for the first phase 2 clinical trial of the lead product and will transfer the manufacturing technology for the product to the Company or its third party manufacturers. The parties will also negotiate a pharmacovigilance agreement within a specified period of time.

The Company has granted Alnylam a non-exclusive, royalty-free license under certain of the technology developed by the Company in the course of performing its activities under the Agreement which identifies new uses for the products or which would be dominated by the technology licensed from Alnylam, to use such technology to research, develop, manufacture and commercialize products containing siRNA molecules, subject to the exclusive rights granted to the Company during the term of the Agreement. Other than pursuant to the Agreement, neither the Company nor Alnylam may, directly or indirectly, research, develop, manufacture, or commercialize any product directed to PCSK9 or license others to do so, during the term of the Agreement.

The Agreement expires when the last royalty term expires under the Agreement, unless earlier terminated. The Company may terminate the Agreement at any time with four months prior written notice to Alnylam. Either party may terminate the Agreement on 60 days (10 days in the event of a payment breach) prior written notice if the other party materially breaches the Agreement and fails to cure such breach within the applicable notice period. Such cure period may be extended in certain circumstances. Alnylam may terminate the Agreement upon 30 days prior written notice to the Company if a lead product has not been designated by the joint steering committee prior to the

earlier of (a) the date 30 days after the date Alnylam reaches the development costs cap unless the Company has agreed to pay the relevant extra costs and (b) June 30, 2015. If the Agreement is terminated by the Company for convenience, by Alnylam for the Company's uncured material breach or challenge of the patents licensed from Alnylam, or by Alnylam if the lead product is not designated prior to the deadlines set forth above, the Company has agreed to grant a license to Alnylam under certain of its technology developed in the course of the Company's activities under the Agreement, subject to a royalty to be negotiated between the parties, and the Company will provide certain other assistance to Alnylam to continue the development and commercialization of the products. The exclusivity restrictions imposed on the Company shall survive termination of the Agreement for specified periods of time if the Company terminates the Agreement for convenience or if Alnylam terminates the Agreement for cause or for a patent challenge by the Company.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Agreement, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending March 31, 2013.

The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on February 4, 2013

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: February 4, 2013

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 issued by the Company on February 4, 2013