MEDICINES CO /DE
Form 8-K
January 06, 2015

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): **January 6, 2015**

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 2.02. Results of Operations and Financial Condition.

The Medicines Company (the Company) expects on a preliminary basis that its net revenue for 2014 will remain within the range of its previously announced guidance of $720 million to $735 million, but expects it to be at the lower end of that range. The Company also expects on a preliminary basis that its operating expense for 2014 will be within the range of its previously announced expense guidance for 2014, other than total research and development expense which the Company now estimates will be approximately $160 million to $170 million on a GAAP basis for 2014 rather than the previous $150 million to $160 million estimate. This change in research and development expense is primarily due to an accrued $10 million obligation resulting from the earlier than expected initiation of the Phase 1 clinical trial for ALN-PCSsc currently being conducted by Alnylam Pharmaceuticals, Inc. (Alnylam) described below. The Company has not completed its normal year-end closing and review procedures and its auditors have not conducted their audit procedures. As a result, there can be no assurance that the Company s actual net revenue, cost of revenue, research and development expense and sales, general and administrative expense for 2014 will not differ from these preliminary estimates.

Item 7.01. Regulation FD Disclosure.

Cangrelor Regulatory Review. In December 2014, the Company submitted to the U.S. Food and Drug Administration (the FDA) the Company s response to the Complete Response Letter that the Company received from the FDA regarding the Company s New Drug Application (NDA) for cangrelor. In December 2014, the Company also submitted to the Committee for Medicinal Products for Human Use (the CHMP) the Company s response to the Day 180 List of Outstanding Issues (LOI) that the Company received from the CHMP regarding the Company s marketing authorization application (MAA) for cangrelor.

In the third quarter of 2013, the Company s NDA for cangrelor for use in patients undergoing percutaneous coronary intervention (PCI) or those that require bridging for oral antiplatelet therapy to surgery was accepted for filing by the FDA. In February 2014, the FDA Cardiovascular and Renal Drugs Advisory Committee advised against approval of the Company s NDA. On April 30, 2014, the FDA issued the Complete Response Letter regarding the Company s NDA for cangrelor. For the PCI indication, the FDA stated that the NDA cannot be approved at the present time and the FDA suggested that the Company perform a series of clinical data analyses of the CHAMPION PHOENIX study, review certain processes regarding data management, and provide bioequivalence information on the clopidogrel clinical supplies for the CHAMPION trials. For the BRIDGE indication, the FDA concluded that a prospective, adequate and well-controlled study in which outcomes such as bleeding are studied would be required to provide the clinical data necessary to assess the benefit-risk relationship in this indication. The FDA also provided additional comments for the Company to address, stating that the comments are not currently approvability issues, but could affect labeling. The Company submitted its response to the Complete Response Letter with respect to the PCI indication only, and, in the response, withdrew its request for approval for the BRIDGE indication.

In the fourth quarter of 2013, the Company s MAA for cangrelor was accepted for review in the European Union. In September 2014, the Company received the LOI from the CHMP regarding the MAA for cangrelor. The LOI contained one major objection regarding the benefit-risk relationship of cangrelor. Following a request from CHMP, a Cardiovascular Scientific Advisory Group (SAG) meeting was convened on December 1, 2014. The Company believes that each of the issues raised at the meeting, including the major objection included in the LOI, was resolved to the satisfaction of the SAG. The Company believes that its response to the LOI is consistent with the discussions at the meeting and that it will resolve all outstanding issues in the LOI.

There can be no assurance, however, that the Company s response to the Complete Response Letter or the LOI will be adequate or that the NDA or MAA for cangrelor will be approved.

IONSYS. In September 2014, the FDA accepted for filing a Supplemental New Drug Application (sNDA) that the Company had submitted for IONSYS in the United States. The FDA action date, known as the PDUFA date, which is the date by which the FDA is expected to make a decision on the sNDA, is April 30, 2015. In September 2014, the European Medicines Agency (EMA) accepted for review the MAA for IONSYS that the Company had submitted in the European Union. Subsequent to the FDA s acceptance for filing of the sNDA, the Company received in November 2014 a Discipline Review Letter from the FDA, which is a letter the FDA uses to convey early thoughts on possible deficiencies in a marketing approval application. In the letter, the FDA identified deficiencies in the results of human factors validation studies of IONSYS that the Company had included in the sNDA. Human factors validation studies focus on the interactions between people and devices to evaluate use-related risks and confirm that users can use the device safely and effectively. Based on discussions with the FDA, the Company plans to implement additional risk mitigations to reduce use errors associated with IONSYS and to conduct additional human factors validation studies to support these mitigations. Based on these discussions with the FDA, the Company believes it is possible to conduct these studies without the need to redesign the IONSYS device and, assuming the results of these studies are satisfactory, to submit the results to the FDA in sufficient time to enable the FDA to review the results as part of the Company s sNDA submission without causing a delay in the PDUFA date. However, there can be no assurance

that the results of the studies will be satisfactory or that the Company will be able to conduct the studies and submit the results of the studies in sufficient time to avoid a delay in the PDUFA date.

Recothrom. On August 6, 2014, pursuant to a master transaction agreement with Bristol-Myers Squibb Company (BMS), the Company exercised its option (Recothrom Option Exercise) to acquire certain assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom, and assume certain liabilities of BMS and its affiliates related to those assets. Under the terms of the master transaction agreement, upon the closing of the transactions contemplated by the option, the Company will be obligated to pay to BMS a purchase price equal to the multiple of average net sales over each of the two 12-month periods preceding the closing (unless such closing occurs prior to February 8, 2015, in which case, the measurement period would be the 12-month period preceding the closing), plus an additional amount equal to the net book value of the inventory included in the acquired assets. As previously reported, the Company expects the closing for the transactions contemplated by the option exercise to occur in the first quarter of 2015. The Company anticipates that the purchase price to be paid to BMS based on the multiple of average net sales will equal approximately $85.0 million and that it will pay BMS an additional amount equal to approximately $40.0 to $45.0 million for the inventory to be acquired based on the Company s estimate of the net book value of such inventory. This inventory includes both raw materials and work in process components, some of which require long ordering lead times, that are used in the production of saleable finished goods.

ABP-700. The Company intends to exercise in the first half of January 2015 the Company s option under its purchase option agreement with Annovation Biopharma, Inc. (Annovation) and its equityholders to purchase all of the outstanding equity of Annovation. The Company expects the closing to occur in the first quarter of 2015. At closing, the Company expects to pay approximately $28.4 million in cash to Annovation s equityholders. In addition, the Company has agreed to pay to Annovation s equityholders following closing an aggregate of approximately $26.3 million in cash upon the achievement of certain clinical and regulatory milestones and additional amounts based on a low single digit percentage of worldwide net sales, if any, of Annovation s products during a specified period.

ALN-PCSsc. In December 2014, under the terms of the Company s license and collaboration agreement with Alnylam, Alnylam initiated a Phase 1 clinical trial of ALN-PCSsc, an investigational agent for the treatment of hypercholesterolemia that the Company has licensed from Alnylam. The Phase 1 trial is being conducted as a randomized, single-blind, placebo-controlled, single ascending- and multi-dose, subcutaneous dose-escalation study. Alnylam plans to enroll up to 76 volunteer subjects with elevated baseline LDL-C ($\geq$ 100 mg/dL), with subjects randomized 3:1, drug:placebo. The trial is designed to be conducted in two phases: a single ascending dose phase and a multiple dose (MD) phase. In the MD phase, subjects will receive two subcutaneous doses of either ALN-PCSsc or placebo administered four weeks apart. The MD phase will also include subjects both on and off statin co-medication.

Anticipated 2015 Milestone and Acquisition Payments. Based on the Company s earliest anticipated timeline for the achievement of development, regulatory and commercial milestones and for the acquisition of assets and assumption of liabilities related to Recothrom, except as provided in the following paragraph, as of January 6, 2015, the Company expects that it would make total option and milestone payments under its license agreements and acquisition agreements of up to $389.3 million during 2015. The adjustment from the previously reported figure of up to $380.0

million reflects adjustments to the Company s milestone payment obligations to the former equityholders of Incline Therapeutics, Inc. which were adjusted in connection with an amendment of the acquisition agreement to settle a dispute with respect to a matter unrelated to the IONSYS Discipline Review Letter. The majority of these anticipated payments for 2015 relate to the achievement of regulatory approval milestones for cangrelor, IONSYS, Raplixa, RPX-602 and PreveLeak, and the remainder of these payments relate to the achievement of development and commercial milestones for the Company s other products in development and the acquisition, and potential acquisition, of assets and businesses.

The $389.3 million in anticipated 2015 option and milestone payments described above excludes payments with respect to the Recothrom inventory to be acquired from BMS and the Company s anticipated acquisition of Annovation. The Company anticipates that, upon closing the transactions contemplated by the Recothrom Option Exercise, the Company will pay BMS an additional amount equal to approximately $40.0 to $45.0 million for the inventory to be acquired based on the Company s estimate of the net book value of such inventory. As described above, this inventory includes both raw materials and work in process components, some of which require long ordering lead times, that are used in the production of saleable finished goods. The Company expects to pay approximately $28.4 million in cash to Annovation s equityholders upon the closing of the anticipated acquisition of Annovation.

Strategic Collaboration with SciClone Pharmaceuticals. On December 16, 2014, the Company entered into strategic collaboration with SciClone Pharmaceuticals (SciClone) under which the Company granted SciClone a license and the exclusive rights to promote, market and sell Angiomax and Cleviprex in China. Under the terms of the collaboration, SciClone will be responsible for all aspects of commercialization, including pre- and post-launch activities, for both products in the China market (excluding Hong Kong and Macau) and will assist the Company in the registration process for both products in China. The Company has filed in China for marketing approval of Angiomax and to conduct clinical trials of Cleviprex. SciClone has agreed to pay the Company an upfront payment, a product support services fee and regulatory/commercial success milestone payments of up to an aggregate of $50.5 million, and royalties based on net sales of Angiomax and Cleviprex in China.

Co-promotion Agreements. Effective December 31, 2014, the Company s co-promotion agreement with Boston Scientific Corporation and its Global Collaboration Agreement with AstraZeneca LP were each terminated. As a result, as of December 31, 2014, the Company ceased to co-promote the Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System and BRILINTA® (ticagrelor).

Forward-Looking Statements. Statements contained in this Form 8-K 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 expects and potential and similar expressions, 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 include whether the Company s products will advance in the clinical trials process on a timely basis or at all; whether in the case of IONSYS, the mitigations that the Company proposes or the results of the human factor validation studies will be satisfactory and whether any product redesigns will be necessary; whether the Company will make regulatory submissions for product candidates on a timely basis and, in the case of IONSYS, avoid a delay in the PDUFA date; whether its regulatory submissions such as the cangrelor NDA and MAA and the IONSYS sNDA will receive approvals from regulatory agencies on a timely basis or at all; whether the Company s net revenue estimate will be subject to adjustment; and such other factors as 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 with the SEC on November 7, 2014, which are incorporated herein by reference. The Company specifically disclaims any obligation to update these forward-looking statements.

The information furnished pursuant to Items 2.02 and 7.01 of this current report shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. As such, this information shall not be incorporated by reference into any of the Company s reports or other filings made with the Securities and Exchange Commission. The furnishing of the information in this current report is not intended to, and does not, constitute a determination or admission by the Company that the information in this current report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

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.

Date: January 6, 2015

THE MEDICINES COMPANY

By:	/s/ Stephen M. Rodin
Name:	Stephen M. Rodin
Title:	Senior Vice President and General Counsel