MEDICIS PHARMACEUTICAL CORP
Form 8-K
July 06, 2010

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
July 1, 2010
Date of Report (Date of earliest event reported)
Medicis Pharmaceutical Corporation
(Exact name of registrant as specified in its charter)

Delaware	**001-14471**	**52-1574808**
(State of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

7720 North Dobson Road
Scottsdale, Arizona 85256
(Address of principal executive offices) (Zip Code)
(602) 808-8800
(Registrant s telephone number, including area code)
N/A
(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:

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 8.01 Other Events.

The Company Amends its Complaint against Lupin Ltd.

On July 1, 2010, Medicis Pharmaceutical Corporation (the Company) amended its patent infringement complaint against Lupin Ltd. (Lupin) in the United States District Court for the District of Maryland. The Company amended the complaint to assert new claims 19, 21, 23, 25 and 27-34 included in the Reexamination Certificate received by the Company from the U.S. Patent and Trademark Office (USPTO) on June 1, 2010 in connection with the USPTO s reexamination of U.S. Patent No. 5,908,838 (the 838 Patent) related to the Company s acne medication SOLODYN®. The complaint seeks an adjudication that Lupin has infringed one or more claims of the 838 Patent, including the new claims, by submitting to the U.S. Food and Drug Administration (FDA) an Abbreviated New Drug Application, and amendments or supplements thereto, for generic SOLODYN® in its forms of 45mg, 65mg, 90mg, 115mg and 135mg strengths.

The Company Receives Correspondence from the FDA

On July 1, 2010, the Company received a letter from the FDA with respect to the Company s 510(k) application to market its LIPOSONIX™ system in the U.S. In the letter, the FDA indicated that the data presented in the 510(k) submission were not sufficient to support a finding of substantial equivalence without additional information in a new submission. The FDA provided general guidance in the letter on the additional information that would be needed to support 510(k) clearance. The Company believes it has additional data and analyses that are responsive to the FDA s guidance, and will actively pursue a meeting with the FDA to clarify the next steps. The FDA did not request in its letter any specific safety data or additional analysis of the existing safety data. The Company notes that the primary endpoint of the clinical trial, as agreed to with the FDA prior to the start of the trial, was achieved.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements included in this Form 8-K that address activities, events or developments that the Company expects, believes or anticipates will or may occur in the future are forward-looking statements. These statements are based on certain assumptions made by the Company based on its experience and perception of historical trends, current conditions, expected future developments and other factors it believes are appropriate in the circumstances. No assurances can be given, however, that these activities, events or developments will occur or that such results will be achieved. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond the control of the Company. These risks and uncertainties include the outcome of any pending patent infringement litigation and that 510(k) or other FDA clearance for the LIPOSONIX™ system could be lengthy and costly and may not be received at all. Additional risks are outlined in the Company s most recent annual report on Form 10-K for the year ended December 31, 2009, and other documents the Company files with the Securities and Exchange Commission. Forward-looking statements represent the judgment of the Company s management as of the date of this release, and the Company disclaims any intent or obligation to update any forward-looking statements contained herein, which speak as of the date hereof.

SIGNATURES

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

Medicis Pharmaceutical Corporation

Date: July 6, 2010

By: /s/ Jason D. Hanson
Jason D. Hanson
Executive Vice President, Chief Operating Officer, Acting General Counsel and Corporate Secretary