MEDICIS PHARMACEUTICAL CORP
Form 8-K
August 15, 2012

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

August 8, 2012

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:

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

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

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

¨ 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 Receives a Paragraph IV Patent Certification from Actavis Mid Atlantic LLC

On August 8, 2012, Medicis Pharmaceutical Corporation (the Company) received a Paragraph IV Patent Certification (Paragraph IV Certification) from Actavis Mid Atlantic LLC (Actavis) advising that Actavis has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for a generic version of the Company s product ZYCLARA® (imiquimod) Cream, 3.75%. Actavis has not advised the Company as to the timing or status of the FDA s review of its filing, or whether Actavis has complied with FDA requirements for proving bioequivalence. Actavis Paragraph IV Certification alleges that the Company s U.S. Patent No. 8,236,816 (the 816 Patent) is invalid, unenforceable and/or will not be infringed by Actavis manufacture, use or sale of the product for which the ANDA was submitted. The expiration date for the 816 Patent is in 2029. The Company is evaluating the details of Actavis certification letter.

As previously reported, the Company received an Issue Notification for a second patent covering ZYCLARA® Cream, 3.75%, which patent was expected to issue on August 14, 2012 pursuant to U.S. Patent Application No. 13/182,433 (the 433 Application). As a result of receiving the Paragraph IV Certification prior to the issuance of the 433 Application as a patent, and in light of having already secured patent protection on ZYCLARA® Cream, 3.75% with the 816 Patent, the Company voluntarily elected to file a Request for Continued Examination with the USPTO for the 433 Application, which will allow the USPTO to consider the Paragraph IV Certification. The Company continues to anticipate that a patent will issue pursuant to the 433 Application prior to the expiration of the Company s regulatory exclusivity for ZYCLARA® Cream, 3.75% for the treatment of actinic keratosis in March 2013. The Company further believes that the issuance of the 433 Application as a patent following the Request for Continued Examination will provide additional protection around ZYCLARA®. The Company intends to vigorously defend its intellectual property rights relating to ZYCLARA®, including its rights under the 816 Patent.

Forward Looking Statements:

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act. All statements included 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, including those relating to the results of the Request for Continued Examination of the 433 Application and the timing of any patent issuance thereafter, are based on 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. Several of these risks are outlined in the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 and the Annual Report on Form 10-K for the year ended December 31, 2011, and other documents we file with the Securities and Exchange Commission. Forward-looking statements represent the judgment of Company management as of the date of this Current Report on Form 8-K, and the Company disclaims any intent or obligation to update any forward-looking statements contained herein, which speak as of the date hereof. Among other things, there can be no assurance as to the issuance of a patent pursuant to the 433 Application, including the timing of such issuance, and the additional patent protection around ZYCLARA® resulting from such issuance.

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: August 15, 2012

By: /s/ Seth L. Rodner
Seth L. Rodner
Executive Vice President, Chief Legal Officer and Corporate Secretary