Edgar Filing: MEDICIS PHARMACEUTICAL CORP - Form 8-K

MEDICIS PHARMACEUTICAL CORP Form 8-K June 01, 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 May 25, 2011

> 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))

Edgar Filing: MEDICIS PHARMACEUTICAL CORP - Form 8-K

Item 8.01 Other Events.

The Company Receives Correspondence from the FDA

On May 25, 2011, the U.S. Food and Drug Administration (FDA) notified Medicis Pharmaceutical Corporation (the Company) of its decision to reopen the Company s 510(k) application to market its LIPOSOM System in the U.S for further review based on a determination that the primary endpoint of the Company s clinical trial had been achieved. The Company had appealed the previously reported FDA determination that the data presented in the Company s 510(k) application were not sufficient to support a finding of substantial equivalence without additional information in a new submission. The FDA has requested that the Company submit certain labeling revisions to support 510(k) clearance. The Company is actively pursuing a meeting with the FDA at its request to agree on such revisions and clarify the next steps. As previously announced, the Company has classified the LipoSonix business as a discontinued operation for financial statement reporting purposes. The Company intends to continue exploring strategic alternatives for the business, including, but not limited to, the sale of the stand-alone business.

Edgar Filing: MEDICIS PHARMACEUTICAL CORP - Form 8-K

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: June 1, 2011 By: /s/ Seth L. Rodner

Seth L. Rodner

Senior Vice President, General Counsel

and Corporate Secretary