

MEDICIS PHARMACEUTICAL CORP

Form 8-K

March 18, 2009

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**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

March 17, 2009

Date of Report (Date of earliest event reported)

Medicis Pharmaceutical Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

001-14471
(Commission File Number)

52-1574808
(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))
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Item 8.01 Other Events.

As previously reported, on February 13, 2009, Medicis Pharmaceutical Corporation (the Company) submitted a Citizen Petition to the U.S. Food and Drug Administration (the FDA) arguing that the FDA could not approve the Abbreviated New Drug Applications (ANDAs) of Mylan Inc., Sandoz, Inc., a division of Novartis AG, and Barr Laboratories, Inc. for generic versions of SOLODYN® for thirty (30) months pursuant to Section 505(j)(5)(B)(iii) of the Federal Food, Drug and Cosmetic Act (FDCA) because the Company sued the submitters of all three ANDAs for patent infringement within 45 days of receiving notice from them of the submission of a paragraph IV certification. In light of the recently enacted QI Program Supplemental Funding Act of 2008, Pub. L. No. 110-379, 122 Stat. 4075 (2008) (the Antibiotic Act), the Company argued that neither the Food and Drug Administration Modernization Act (FDAMA) nor the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) stood as a barrier to SOLODYN® receiving a 30-month stay. On March 17, 2009, the Company received a response from the FDA in which the FDA concluded that the Antibiotic Act does not impose a 30-month stay of approval on ANDA applicants that have been sued by the new drug application (NDA) holder or patent owner as a result of notice of a paragraph IV certification to a patent, when the patent was submitted to an old antibiotic NDA and the ANDA was pending with the FDA at the time the patent was submitted. The FDA therefore denied the petition. The Company is currently evaluating the FDA's response and its options.

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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.

Date: March 17, 2009

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