

NOVEN PHARMACEUTICALS INC
Form 8-K
March 16, 2009

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):

March 16, 2009

Noven Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

0-17254

59-2767632

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

11960 S.W. 144th Street, Miami, Florida

33186

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

305-253-5099

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:

- ☐ 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.

Noven Pharmaceuticals, Inc. ("Noven") today confirmed that Shire plc ("Shire"), the global licensee of Daytrana® (methylphenidate transdermal system), has announced its withdrawal of the European Marketing Authorization Application ("MAA") for Daytrana for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD"). Shire stated that its decision to withdraw the MAA was based on the fact that European regulatory authorities had requested an additional clinical study for Daytrana in a European patient population, and that Shire planned to enter the European ADHD market through the previously-announced pending acquisition of an oral methylphenidate product that is already approved in Europe. Noven further confirmed that its 2009 financial guidance in its Annual Report on Form 10-K, dated March 13, 2009 did not include any revenues or other financial contribution from European sales of Daytrana.

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SIGNATURES

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.

Noven Pharmaceuticals, Inc.

March 16, 2009

By: */s/ Jeff Mihm*

Name: Jeff Mihm

Title: Vice President, General Counsel and Corporate Secretary