

NOVADEL PHARMA INC

Form 8-K

November 16, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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) November 16, 2009

NOVADEL PHARMA INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-32177
(Commission File No.)

22-2407152
(I.R.S. Employer
Identification No.)

25 Minneakoning Road
Flemington, New Jersey 08822
(Address of principal executive offices) (Zip Code)

(908) 782-3431
(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 (see General Instruction A.2. below):

- ☐ 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))
- ☐

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Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On November 16, 2009, NovaDel Pharma Inc. (“NovaDel”), a Delaware corporation, issued a press release to announce that it had entered into an exclusive license and distribution agreement (the “Agreement”) with ECR Pharmaceuticals Company, Inc. (“ECR”) to commercialize and manufacture NovaDel’s ZolpiMist™ in the United States and Canada. ZolpiMist™ is NovaDel’s oral spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the Agreement, ECR will pay NovaDel \$3,000,000 upon the execution of the Agreement and ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the Agreement. A performance milestone will be due to NovaDel if net sales reach a certain level.

NovaDel has an opportunity to co-promote zolpidem tartrate oral spray in the United States and Canada with ECR’s consent, and retains commercialization rights for all other territories. ECR will assume responsibility for manufacturing the product for commercialization in the United States and Canada, including any activities required from the date of the Agreement.

The Agreement contains customary termination provisions. In addition, the Agreement may be terminated by ECR for any reason upon written notice to NovaDel, which will be effective 180 days from the date of receipt of such notice, provided that ECR may not terminate until the second anniversary after the first commercial sale of ZolpiMist™ by ECR or its affiliates.

The foregoing is a summary of the material terms of the Agreement and does not purport to be complete. You should read the complete Agreement which shall be attached as an exhibit either to an amended Current Report on Form 8-K or NovaDel’s Annual Report on Form 10-K for the period ended December 31, 2009.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release of NovaDel Pharma Inc. dated November 16, 2009, titled “NovaDel Signs Exclusive License and Distribution Agreement with Hi-Tech Pharmacal Co., Inc’s Subsidiary to Commercialize and Manufacture ZolpiMist™ in the US and Canada.”

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.

NovaDel Pharma Inc.

Date: November 16, 2009

By: /s/ Steven B. Ratoff
Steven B. Ratoff
Chairman, Interim Chief Financial
Officer, Interim President and Chief
Executive Officer
