

NUPATHE INC.
Form 8-K
August 30, 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

Date of Report (Date of earliest event reported): **August 29, 2011**

NuPathe Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction of
Incorporation)

001-34836
(Commission File Number)

20-2218246
(IRS Employer Identification No.)

227 Washington Street
Suite 200
Conshohocken, Pennsylvania
(Address of Principal Executive Offices)

19428
(Zip Code)

Registrant's telephone number, including area code: **(484) 567-0130**

Not Applicable

(Former name or former address if changed since last report.)

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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 7.01 Regulation FD Disclosure.

On August 30, 2011, NuPathe Inc. issued a press release announcing that it received a Complete Response Letter from the U.S. Food & Drug Administration regarding the New Drug Application for its migraine patch (also referred to as NP101 or Zelrix). A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated by reference into this Item 7.01.

Item 8.01 Other Events.

On August 29, 2011, NuPathe Inc. (the Company) received a Complete Response Letter (CRL) from the U.S. Food & Drug Administration (FDA) regarding the New Drug Application (NDA) for its migraine patch (also referred to as NP101 or Zelrix). A CRL is issued by the FDA Center for Drug Evaluation and Research when the review of an NDA is completed and questions remain that preclude the FDA from approving the NDA at the time. The Company intends to request an End-of-Review meeting with the FDA to discuss the issues cited in the CRL and the Company's approach to resolving them. The issuance of this CRL means that the Company will not launch its migraine patch in the first half of 2012, as previously expected.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.

Description of Exhibit

99.1 Press release issued by NuPathe Inc. on August 30, 2011

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The information contained in Item 7.01, Item 9.01 and Exhibit 99.1 of this Form 8-K are being furnished to the Securities and Exchange Commission. Neither the information contained in Item 7.01, nor Item 9.01 nor Exhibit 99.1 shall be incorporated by reference into any filings of NuPathe Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated into such filing by specific reference to the furnished information contained herein.

SIGNATURE

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.

NUPATHE INC.

By: /s/ Jane H. Hollingsworth
Jane H. Hollingsworth
Chief Executive Officer

Dated: August 30, 2011

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
99.1	Press release issued by NuPathe Inc. on August 30, 2011