NUPATHE INC.
Form 8-K
January 18, 2013

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): **January 17, 2013**

NuPathe Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34836**	**20-2218246**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

227 Washington Street **Suite 200** **Conshohocken, Pennsylvania**	**19428**
(Address of Principal Executive Offices)	(Zip Code)

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

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:

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))

Item 7.01 Regulation FD Disclosure.

On January 17, 2013, NuPathe Inc. (the Company) issued a press release announcing that the U.S. Food and Drug Administration (FDA) approved Zecuity (sumatriptan iontophoretic transdermal system) for the acute treatment of migraine, with or without aura, in adults. 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.

NuPathe will host a conference call on Friday, January 18, 2013 at 8:30 a.m. EST to discuss the FDA approval of Zecuity. A question-and-answer session will follow NuPathe s remarks. The press release attached as Exhibit 99.1 to this Form 8-K contains information for dialing-in to the live conference call and for accessing a live audio webcast of the call via the Investor Relations page of NuPathe s website, www.nupathe.com. The press release also contains information for accessing replays of the conference call.

Item 8.01 Other Events.

FDA Approval of Zecuity

On January 17, 2013, the FDA approved Zecuity (sumatriptan iontophoretic transdermal system) for the acute treatment of migraine, with or without aura, in adults. NuPathe expects to launch Zecuity in the U.S. in the fourth quarter of 2013.

Post-Marketing Requirements

In connection with the receipt of FDA approval of Zecuity, NuPathe is required to conduct the following post-marketing studies:

- three pediatric studies in 12-to-17 year olds in order to access the safety and efficacy of Zecuity in adolescents (a study to characterize the pharmacokinetics of Zecuity in adolescents; a placebo-controlled, single-dose efficacy study; and a 12-month, open-label safety study); and

- a seven-day, repeat dose rodent dermal study and a rodent dermal carcinogenicity study in order to access the dermal carcinogenicity of sumatriptan.

Cautionary Note About Forward-Looking Statements

Statements in this Form 8-K about the commercial launch of Zecuity in the U.S. and the timing of such launch are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These statements are not guarantees of future performance and involve risks and uncertainties including

- NuPathe s ability to complete manufacturing scale-up, product validation and manufacture of Zecuity launch supplies;
- NuPathe s ability to establish and manage its supply chain;
- NuPathe s ability to obtain additional capital to fund the launch of Zecuity;
- NuPathe s ability to obtain a U.S. commercial partner for Zecuity;
- NuPathe s ability to establish marketing and sales capabilities;
- adverse events or safety risks that could limit Zecuity s usefulness or require its withdrawal;
- the performance of NuPathe s partners and other third parties; and

- compliance with legal and regulatory requirements.

These and additional factors that could cause actual results to differ materially from those reflected in forward-looking statements are discussed under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2011 and in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2012. Readers are cautioned not to place undue reliance on forward-looking statements.

Forward-looking statements contained in this Form 8-K reflect NuPathe s beliefs and expectations only as of the date of this report. NuPathe undertakes no obligation to update or revise forward-looking statements whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description of Exhibit**
99.1	Press release issued by NuPathe Inc. on January 17, 2013

* * *

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 and shall not be incorporated by reference into any filings of NuPathe Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934 (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/ Armando Anido
Armando Anido
Chief Executive Officer

Dated: January 18, 2013

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
99.1	Press release issued by NuPathe Inc. on January 17, 2013