NUPATHE INC. Form 10-Q November 14, 2011 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)	
R	Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
	For the quarterly period ended September 30, 2011
	OR
£	Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
	For the transition period from to
	Commission file number 001-34836

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## NuPathe Inc.

(Exact name of registrant as specified in its charter)

**Delaware** 

20-2218246

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification number)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes R No £

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes R No £

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer £

Accelerated filer £

Non-accelerated filer R

Smaller reporting company £

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes £ No R

As of November 11, 2011, the number of shares outstanding of the registrant s common stock, \$0.001 par value, was 14,748,582.

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## NUPATHE INC.

## FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2011

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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 10-Q that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to:

- our interpretation of the complete response letter (CRL) that we received from the U.S. Food and Drug Administration (FDA) regarding our new drug application (NDA) for NP101 (also known as Zelrix and our migraine patch) and the outcome of the End-of-Review meeting with the FDA relating to the CRL;
- our plans to address the questions raised in the CRL and the sufficiency of such plans, including our ability to successfully complete the additional trials, tests, device enhancement and other activities to support the resubmission of our NDA for NP101;
- our resubmission of the NDA for NP101, the timing of such resubmission and the timing of the FDA s review of such resubmission;
- our ability to obtain marketing approval of NP101 and our other product candidates and the timing of any such approval;
- our development and commercialization plans regarding NP101 and our other product candidates;
- our development, manufacturing and commercialization capabilities;
- our ability to establish and effectively manage our supply chain;
- our ongoing and planned preclinical studies, clinical trials and regulatory submissions;
- the implication of results from clinical trials and other research activities;
- future expenses and capital requirements;
- the sufficiency of our cash and cash equivalents to fund our operations beyond the planned resubmission of our NDA for NP101 and into the second half of 2012; and
- the timing of and our ability to raise additional capital in sufficient amounts or on terms acceptable to us;

as well as other statements relating to our projections, expectations, beliefs, future performance or plans or objectives for future operations (including assumptions underlying or relating to any of the foregoing). Forward-looking statements may appear throughout this Form 10-Q, including without limitation, in the following sections: Notes to Unaudited Financial Statements contained in Part I., Item 1, Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Part I., Item 2, and Risk Factors contained in Part II, Item 1A. Forward-looking statements generally can be identified by words such as may, will, could, would, should, expect, integrating anticipate, believe, estimate, predict, project, potential, continue, ongoing and similar expressions, although not all forward-looking contain these identifying words.

Forward-looking statements are based upon our current expectations and beliefs and are subject to risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-Q and our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 ( 2010 Annual Report ), and in particular the risks and uncertainties discussed under Item 1.A - Risk Factors of such reports and those discussed in other documents we file with the Securities and Exchange Commission ( SEC ). As a result, you should not place undue reliance on forward-looking statements.

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Additionally, the forward-looking statements contained in this Form 10-Q represent management s views as of the date of this Form 10-Q (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, whether as a result of new information, future developments or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in the periodic and current reports that we file

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with the SEC. The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-Q.

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## PART I. FINANCIAL INFORMATION

## **Item 1. Financial Statements**

## NUPATHE INC.

(A Development-Stage Company)

## **Balance Sheets**

(Unaudited)

(in thousands, except share and per share data)

		September 30, 2011	December 31, 2010
Assets			
Current assets:			
Cash and cash equivalents		\$ 29,991	\$ 38,918
Prepaid expenses and other current assets		<u>610</u>	1,008
Total current assets		30,601	39,926
Property and equipment, net		230	98
Other assets		547	319
Other assets-equipment funding (Note 3(d))		6,763	3,410
Total assets		\$ 38,141	\$ 43,753
Liabilities and Stockholders Equity			
Current liabilities:			
Current portion of long-term debt		\$ 7,174	\$ 1,513
Accounts payable		2,679	1,198
Accrued expenses		2,608	3,073
Total current liabilities		12,461	5,784
Long-term debt		7,537	3,704
Total liabilities		19,998	9,488