

NUPATHE INC.  
Form 10-Q  
August 14, 2012  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended June 30, 2012

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

**NuPathe Inc.**

Edgar Filing: NUPATHE INC. - Form 10-Q

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-2218246**  
(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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data 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  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. :

Large accelerated filer  Accelerated filer   
Non-accelerated filer  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

As of August 13, 2012, there were 14,763,801 outstanding shares of the registrant's common stock, \$0.001 par value.

Table of Contents

NUPATHE INC.

Form 10-Q for the Quarter Ended June 30, 2012

Table of Contents

	Page No.
<b><u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u></b>	i
<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>1</b>
<u>Item 1. Financial Statements (Unaudited)</u>	1
<u>Balance Sheets as of June 30, 2012 and December 31, 2011</u>	1
<u>Statements of Operations for the Three and Six Months Ended June 30, 2012 and 2011</u>	2
<u>Statements of Cash Flows for the Six Months Ended June 30, 2012 and 2011</u>	3
<u>Notes to Financial Statements</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
<u>Item 4. Controls and Procedures</u>	17
<b><u>PART II. OTHER INFORMATION</u></b>	<b>18</b>
<u>Item 5. Other Information</u>	18
<u>Item 6. Exhibits</u>	18
<b><u>SIGNATURES</u></b>	<b>19</b>
<b><u>EXHIBIT INDEX</u></b>	<b>20</b>

In this Form 10-Q, unless otherwise stated or the context otherwise indicates, references to NuPathe, the Company, we, us, our, and similar references refer to NuPathe Inc.

NuPathe®, Zelrix®, SmartRelief® and LAD® are trademarks of NuPathe Inc. All other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners.



Table of Contents

**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:

- the sufficiency of our cash and cash equivalents to fund our debt service and interest obligations and continue operations until the end of the third quarter of 2012;
- the consequences of failing to obtain additional capital including, without limitation, the ability of the lenders under our Term Loan Facility to proceed against the collateral granted thereunder upon an event of default, the breach or termination of agreements pursuant to which we license valuable intellectual property rights, and the need to pursue a plan to license or sell our assets and/or seek bankruptcy protection;
- future expenses and capital requirements;
- 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 referred to as Zelrix and our migraine patch) and the outcome of our end-of-review meeting with the FDA relating to the CRL;
- the adequacy of the activities undertaken to address the questions raised in the CRL and obtain FDA approval to market NP101;
- the timing of the FDA's review of our NDA resubmission for NP101 and the potential commercial launch of NP101;
- our development and commercialization plans regarding NP101 and our other product candidates;
- the timing of our planned submission of an Investigation New Drug application for NP202; and
- duration and scope of patent protection afforded by referenced patents

## Edgar Filing: NUPATHE INC. - Form 10-Q

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 appear in this Form 10-Q in Part I., Item 1

Notes to Unaudited Financial Statements and Part I., Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements generally can be identified by words such as may, will, could, would, should, expect, intend, 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, plans and beliefs and are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements including, among others:

- our ability to obtain additional capital on a timely basis and on agreeable terms to continue as a going concern;
- the consequences of failing to obtain additional capital on a timely basis including, without limitation, the ability of the lenders under our Term Loan Facility to proceed against the collateral granted thereunder upon an event of default, the breach or termination of agreements pursuant to which we license valuable intellectual property rights, and the need to pursue a plan to license or sell our assets and/or seek bankruptcy protection;
- our ability to obtain FDA approval to market NP101;
- the extent to which the FDA may request or require us to provide additional information, undertake additional trials or studies or redesign NP101;
- serious adverse events or other safety risks that that could require us to abandon or delay development of, or preclude or limit approval of, our product candidates;
- varying interpretation of clinical and non-clinical data;

Table of Contents

- our ability to establish and effectively manage our supply chain;
- risks and uncertainties relating to intellectual property; and
- the other risks, uncertainties and factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 (2011 Annual Report) under the caption "Item 1.A Risk Factors".

As a result, you should not place undue reliance on forward-looking statements. Additionally, the forward-looking statements contained in this Form 10-Q represent our 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 with the SEC. Our SEC filings are available free of charge through the "Investor Relations - SEC filings" page of our website ([www.nupathe.com](http://www.nupathe.com)). This reference to our website address is intended to be an inactive textual reference only; the content of our website is not part of this Form 10-Q.

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NUPATHE INC.****(A Development-Stage Company)****Balance Sheets****(in thousands, except share and per share data)****(Unaudited)**

	<b>June 30,</b>		<b>December 31,</b>
	<b>2012</b>		<b>2011</b>
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 7,450	\$	23,059
Prepaid expenses and other	170		333
Total current assets	7,620		23,392
Property and equipment, net	468		213
Other assets	352		481
Other assets-equipment funding (Note 3(d))	6,763		6,763
Total assets	\$ 15,203	\$	30,849
<b>Liabilities and Stockholders Equity</b>			
Current liabilities:			
Current portion of long-term debt	\$ 8,222	\$	8,412
Accounts payable	1,912		1,967
Accrued expenses	2,418		2,018
Total current liabilities	12,552		12,397
Long-term debt	1,370		5,481
Total liabilities	13,922		17,878
Stockholders equity:			
Preferred stock, \$0.001 par value. Authorized 10,000,000 shares. None issued and outstanding			
Common stock, \$0.001 par value. Authorized 90,000,000 shares; issued and outstanding 14,754,819 and 14,748,582 shares at June 30, 2012 and December 31, 2011, respectively	15		15
Additional paid-in capital	116,702		115,940
Deficit accumulated during the development stage	(115,436)		(102,984)
Total stockholders equity	1,281		12,971



Edgar Filing: NUPATHE INC. - Form 10-Q

Total liabilities and stockholders equity	\$	15,203	\$	30,849
---	----	--------	----	--------

See accompanying notes to unaudited financial statements.

Table of Contents**NUPATHE INC.****(A Development-Stage Company)****Statements of Operations****(in thousands, except share and per share data)****(Unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>		<b>Period from</b>
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>	<b>January 7, 2005</b>
					<b>(inception) through</b>
					<b>June 30, 2012</b>
Grant Revenue	\$	\$	\$	\$	\$ 650
Operating expenses:					
Research and development		3,359	3,703	6,813	5,277
Acquired in-process research and development					68,071
Selling, general and administrative		2,420	2,530	4,807	4,500
Total operating expenses		5,779	6,233	11,620	9,777
Loss from operations		(5,779)	(6,233)	(11,620)	(9,777)
Interest income		6	17	16	42
Interest expense		(395)	(249)	(848)	(452)
Loss before tax benefit		(6,168)	(6,465)	(12,452)	(10,187)
Income tax benefit					698
Net loss		(6,168)	(6,465)	(12,452)	(10,187)
Basic and diluted net loss per common share	\$	(0.42)	\$	(0.44)	\$
Weighted average basic and diluted common shares outstanding		14,736,809	14,561,519	14,734,696	14,557,655

See accompanying notes to unaudited financial statements.

Table of Contents

## NUPATHE INC.

(A Development-Stage Company)

## Statements of Cash Flows

(in thousands, except share and per share data)

(Unaudited)

	Six Months Ended June 30,		Period from
	2012	2011	January 7, 2005
			(inception) through
			June 30, 2012
Cash flows from operating activities:			
Net loss	\$ (12,452)	\$ (10,187)	\$ (109,054)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	52	30	307
Loss on asset disposal			24
Acquired in-process research and development			5,500
Stock-based compensation	750	527	3,098
Noncash interest expense	129	87	5,644
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	163	786	810
Accounts payable	(55)	360	1,912
Accrued expenses	400	(754)	2,397
Net cash used in operating activities	(11,013)	(9,151)	(89,362)
Cash flows from investing activities:			
Purchase of in-process research and development			(5,500)
Payments under equipment funding agreement		(2,993)	(6,763)
Purchases of property and equipment	(307)	(134)	(798)
Net cash used in investing activities	(307)	(3,127)	(13,061)
Cash flows from financing activities:			
Proceeds from issuance of debt		10,000	17,500
Payment of debt issuance costs		(59)	(325)
Repayment of debt	(4,301)	(402)	(8,950)
Proceeds from sale of preferred stock, net			43,576
Proceeds from sale of common stock, net	12	29	43,605
Proceeds from sale of convertible notes, net			14,467
Net cash (used in) provided by financing activities	(4,289)	9,568	109,873
Net increase (decrease) in cash and cash equivalents	(15,609)	(2,710)	7,450
Cash and cash equivalents, beginning of period	23,059	38,918	
Cash and cash equivalents, end of period	\$ 7,450	\$ 36,208	\$ 7,450
Supplemental cash flow disclosures:			
Noncash investing and financing activities:			
Conversion of note principal and accrued interest to redeemable convertible preferred stock	\$	\$	\$ 4,547

Edgar Filing: NUPATHE INC. - Form 10-Q

Conversion of note principal and accrued interest to common stock			10,337
Conversion of redeemable convertible preferred stock into common stock			58,072
Reclassification of warrant liability			1,113
Fair value of warrants issued in connection with loan facility	272		272
Financing arrangement with third party vendors			991
Accretion of redeemable convertible preferred stock			9,948
Cash paid for interest	701	203	2,793

See accompanying notes to unaudited financial statements.

Table of Contents

**NuPathe Inc.**

**(A Development-Stage Company)**

**Notes to Unaudited Financial Statements**

**(in thousands, except share and per share data)**

**(1) Background**

NuPathe Inc. (the Company) is a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system. The Company was incorporated in Delaware on January 7, 2005 (inception) and has its principal office in Conshohocken, Pennsylvania. The Company operates as a single business segment and is a development stage company.

**(2) Development-Stage Risks and Liquidity**

The Company has incurred losses and negative cash flows from operations since inception and has accumulated a deficit during the development stage of \$115,436 as of June 30, 2012. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development.

As of June 30, 2012, the Company had \$7,450 of cash and cash equivalents and a working capital deficit of \$4,932. On August 13, 2012, the Company entered into an amendment to its Term Loan Facility to temporarily reduce the minimum unrestricted cash balance that the Company is required to maintain from \$3,000 to \$1,000 (see footnotes 4(a) and 6(c) for additional information regarding the Term Loan Facility and the referenced amendment). Management estimates that the Company's cash and cash equivalents as of June 30, 2012, of which \$1,000 is required to be maintained under the terms of the amended Term Loan Facility, will be sufficient to fund debt service and interest obligations and continue operations until the end of the third quarter of 2012. Additional capital will be needed by the Company to fund its capital requirements and continue operations beyond that point. There is no assurance that such capital will be available when needed or on acceptable terms. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings, corporate collaboration and licensing agreements and other funding transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. If the Company is unable to obtain the necessary capital, it will need to pursue a plan to license or sell its assets and/or seek bankruptcy protection.

The Company is subject to those risks associated with any development-stage specialty pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially successful. In addition, the Company operates in an environment of rapid technological change, and is largely dependent on the services of its employees and consultants.

**(3) Summary of Significant Accounting Policies**

*(a) Basis of Presentation*

The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States ( U.S. GAAP ) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, include all adjustments, consisting of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented.

Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission ( SEC ).

Table of Contents

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying unaudited interim financial statements should be read in conjunction with the financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC, which includes annual audited financial statements as of and for the year ended December 31, 2011.

*(b) Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from such estimates.

*(c) Fair Value of Financial Instruments*

Management believes that the carrying amounts of its financial instruments, including cash equivalents, prepaid expenses and other, accounts payable and accrued expenses, approximate fair value due to the short-term nature of those instruments. The carrying amount of the Company's debt obligations approximate fair value based on interest rates available on similar borrowings.

The Company follows Financial Accounting Standards Board ( FASB ) accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- *Level 1:* Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- *Level 2:* Quoted prices in markets that are not active, or input which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities; or
- *Level 3:* Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The Company had Level 1 fair value measurements of its cash equivalents of \$6,633 and \$22,144 at June 30, 2012 and December 31, 2011, respectively. The Company had no Level 2 or Level 3 fair value instruments at June 30, 2012 or December 31, 2011.

*(d) Other Assets-Equipment Funding*

In June 2010, the Company entered into an equipment funding agreement with LTS Lohmann Therapie-Systeme AG ( LTS ), under which the Company agreed to fund the purchase by LTS of manufacturing equipment for the Company's primary product candidate, NP101. The Company has made 14 monthly installments to LTS that commenced in June 2010, according to an agreed upon payment schedule. As of June 30, 2012, 4,970, or \$6,763 based on exchange rates in effect at the time the payments were made, has been recorded as a noncurrent asset in the accompanying balance sheet. All amounts owed under this funding agreement were paid in full as of June 30, 2012. Amounts capitalized under the LTS funding agreement will be amortized to cost of goods sold upon the commencement of commercial sales of NP101. If the Company were to ever cease development of NP101, amounts capitalized under this agreement would be immediately expensed.

LTS owns the purchased equipment and is responsible for its routine and scheduled maintenance and repair and is required to use the purchased equipment solely to manufacture NP101 for the Company. The equipment funding agreement will remain in effect until the later of the completion by LTS of all installation activities or the execution of a commercial manufacturing agreement.

*(e) Net Loss per Common Share*

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding less the weighted-average shares subject to repurchase during the period. For all periods presented, common stock options, unvested restricted shares of common stock and stock warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.



Table of Contents

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of June 30, 2012 and 2011, as they would be anti-dilutive:

	2012	June 30,	2011
Shares underlying outstanding options to purchase common stock	2,308,290		1,497,878
Shares of unvested restricted stock	12,000		16,000
Shares underlying outstanding warrants to purchase common stock	200,268		200,268

**(4) Capital Facilities*****(a) Credit Facility and Vendor Debt***

In May 2010, the Company executed a loan and security agreement with lenders to fund working capital requirements (the Term Loan Facility). The Company's obligations under the Term Loan Facility are secured by a lien on all of the Company's assets, excluding intellectual property, which is subject to a negative pledge prohibiting the granting of liens thereon to any third party. The Term Loan Facility also includes customary events of default including upon the occurrence of a payment default, a covenant default, a material adverse change (as defined therein) and insolvency. Upon the occurrence of an event of default, the interest on outstanding loans will be increased by 3% over the rate that would otherwise be applicable. In addition, the occurrence of an event of default could result in the acceleration of our obligations under the Term Loan Facility as well as grant the Lenders the right to exercise remedies with respect to the collateral.

Upon execution of the Term Loan Facility, the Company received \$5,000 of loan proceeds (Term A Loans). The Company was required to make interest-only payments for the first twelve months of the Term A Loans' 39-month term; principal payments commenced in June 2011. At June 30, 2012, the balance of the Term A Loans was \$2,592, with \$2,222 of that amount being classified as current. The Term A Loans originally bore interest at an annual rate of LIBOR plus 8.75%, subject to a LIBOR floor of 3.00%. In June 2011, the interest rate was reduced to an annual rate of LIBOR plus 8.50%, subject to a LIBOR floor of 3.00%, in accordance with the amendment discussed below. The Term A Loans bear interest at 11.5% at June 30, 2012. In connection with the Term A Loans, the lenders received warrants to purchase 255,376 shares of Series B preferred stock at \$0.93 per share, which, upon the Company's IPO, converted into warrants to purchase 31,861 shares of common stock at \$7.45 per share. The fair value of the warrants at the date of issuance of \$204 was recorded as deferred financing costs and is being amortized to interest expense through the maturity date of the Term A Loans. As a result of the completion of the Company's IPO in August 2010, an additional \$6,000 of funding became available to the Company under the Term Loan Facility (Term B Loans).

In June 2011, the Company and the lenders amended the Term Loan Facility to:

- increase the amount of Term B Loans available to the Company from \$6,000 to \$10,000;
- require the Company to maintain at least \$3,000 of unrestricted cash, which cash requirement was scheduled to expire after the occurrence of an equity event resulting in unrestricted cash proceeds to the Company of at least \$15,000. As discussed in more detail in footnote 6(c), on

## Edgar Filing: NUPATHE INC. - Form 10-Q

August 13, 2012 this requirement was temporarily reduced to \$1,000; and

- reduce the LIBOR rate margin for term loans under the facility from 8.75% to 8.50%.

Concurrently with the amendment, the Company received \$10,000 of Term B Loans (representing the total amount of Term B Loans available to the Company under the amended facility). The Company was required to make interest-only payments for the first six months of the Term B Loan's 26-month term; principal payments commenced in January 2012. At June 30, 2012, the balance of the Term B Loans was \$7,000 with \$6,000 of that amount being classified as current. The Term B Loans bear interest at an annual rate of LIBOR plus 8.50%, subject to a LIBOR floor of 3.00%. The Term B Loans bear interest at 11.5% at June 30, 2012. In connection with the Term B Loans, the lenders received warrants to purchase 59,748 shares of common stock at \$7.95 per share. The fair value of the warrants at the date of issuance of \$272 has been recorded as deferred financing costs and is being amortized to interest expense through the maturity date of the Term B Loans.

### ***(b) Equity Facility***

In August 2011, the Company entered into a common stock purchase agreement ( Purchase Agreement ) with Aspire Capital Fund, LLC ( Aspire Capital ), which provides that Aspire Capital is committed to purchase up to an aggregate of \$30,000 of the Company's common stock over the term of the Purchase Agreement, subject to the terms and limitations set forth therein. As of June 30, 2012, the Company has not made any sales to Aspire Capital other than the 70,721 shares of common stock sold to Aspire Capital upon execution of the Purchase Agreement and the 84,866 shares of common stock issued to Aspire Capital as a commitment fee in consideration for entering into the Purchase Agreement

Table of Contents**(5) Stockholders Equity****(a) Warrants**

As of June 30, 2012, the following warrants to purchase common stock were outstanding:

	Number of Shares	Exercise Price	Expiration
Common Stock	140,520	\$ 7.45	2016 through 2020
Common Stock	59,748	\$ 7.95	2016
	200,268		

**(b) Stock Options**

On January 3, 2012, an additional 737,429 shares of common stock were made available under the Company's 2010 Omnibus Incentive Compensation Plan, as amended and restated effective April 11, 2011 (the 2010 Plan), pursuant to its evergreen provision bringing the total shares authorized under the 2010 Plan to 2,975,385. As of June 30, 2012, there were 2,308,290 incentive and non-qualified stock options and 12,000 shares of restricted stock outstanding under this plan. At June 30, 2012 there were 559,892 shares of common stock available for future grants under the 2010 Plan.

The following is a summary of stock option activity for the six months ended June 30, 2012:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2012	1,784,285	\$ 4.31		
Granted	714,630	3.09		
Exercised	(6,237)	1.92		
Cancelled/forfeited	(184,388)	8.80		
Outstanding at June 30, 2012	2,308,290	3.58	7.95	\$ 3,031
Vested and expected to vest at June 30, 2012	2,197,952	3.61	7.86	\$ 2,924
Exercisable at June 30, 2012	1,199,334	3.03	6.74	\$ 2,100

Of the 714,630 stock options that were granted during the six months ended June 30, 2012, 83,042 were granted to certain directors pursuant to an election by such directors to receive all or a portion of their cash director fees in stock options.

## Edgar Filing: NUPATHE INC. - Form 10-Q

The aggregate intrinsic value represents the total amount by which the value of the shares of common stock subject to such options exceeds the exercise price of such options, based on the Company's closing stock price of \$4.03 as of June 30, 2012.

Stock-based compensation expense related to stock options for the six months ended June 30, 2012 and 2011 was \$734 and \$522, respectively. As of June 30, 2012, there was \$2,640 of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.0 years.

Management calculates the fair value of stock options based upon the Black Scholes option pricing model. The following table summarizes the fair value and assumptions used in determining the fair value of stock options issued during the six months ended June 30, 2012.

Table of Contents

Weighted- average fair value of stock options granted	\$	2.14
---	----	------

**Assumptions Used:**

Risk-free interest rate		0.73 - 1.18%
Expected life in Years		5.0 - 6.1 years
Expected volatility		80.5- 88.1%
Dividend Yield		0%

The Company determined the options' life based on the use of the simplified method. As a newly public company, sufficient history to estimate the volatility of our common stock price is not available. The Company uses a basket of comparable public companies as a basis for the expected volatility assumption and dividend yield. The Company intends to continue to consistently apply this process using comparable companies until a sufficient amount of historical information regarding the volatility and dividend yield of the Company's share price becomes available. The risk free interest rate is based on the yield of an applicable term Treasury instrument.

**(c) Restricted Stock**

The following is a summary of restricted stock activity for the six months ended June 30, 2012:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested shares at December 31, 2011	16,000	\$ 7.73
Granted		
Vested	(4,000)	
Forfeited/repurchased		
Nonvested shares at June 30, 2012	12,000	\$ 7.73

Stock-based compensation expense related to restricted stock for the six months ended June 30, 2012 and 2011 was \$16 and \$5, respectively. As of June 30, 2012, there was \$88 of unrecognized compensation expense related to unvested restricted stock, which is expected to be recognized over a weighted average period of 2.9 years.

**(6) Subsequent Events****(a) Resignation of Jane H. Hollingsworth as Chief Executive Officer and Director**

## Edgar Filing: NUPATHE INC. - Form 10-Q

On July 25, 2012, Jane H. Hollingsworth resigned as chief executive officer and as a member of the Company's board of directors. On the same date, the Company entered into a Severance Agreement and Release of Claims (the "Severance Agreement") and a Consulting Agreement (the "Consulting Agreement") with Ms. Hollingsworth. In connection with the Severance Agreement, the Company expects to record approximately \$1,130 in severance expense during the three months ending September 30, 2012, which includes approximately \$350 of non-cash expense related to the modification of previously awarded equity-based awards. Payments made to Ms. Hollingsworth under the Severance Agreement will be paid over 18 months through February 2014.

The Consulting Agreement provides that from August 1, 2012 through July 31, 2013, Ms. Hollingsworth shall be available to provide up to 20 hours per month of consulting services to the Company. For her services, the Company will pay Ms. Hollingsworth a non-refundable monthly retainer of \$10. The Consulting Agreement may be terminated by Ms. Hollingsworth, for any reason, upon 30 days notice to the Company and by the Company only upon Ms. Hollingsworth's material breach of her obligations under the Consulting Agreement or the Severance Agreement.

Table of Contents

***(b) Appointment of Armando Anido as Chief Executive Officer and Director***

Effective as of July 25, 2012, the Company entered into an Employment Agreement with Armando Anido to serve as chief executive officer of the Company. On the same date, Mr. Anido was also appointed to the Company's board of directors. Mr. Anido received an initial grant of time-based options to purchase an aggregate of 738,190 shares of the Company's common stock at an exercise price per share equal to \$3.81, which was the closing price of the Company's common stock on July 25, 2012 (the "Initial Options"). These Initial Options have a ten-year term and will vest and become exercisable as to 25% of such Initial Options on July 25, 2013 (one year after the date of grant), with the balance vesting in 12 equal quarterly installments thereafter until July 25, 2016; provided, however, that 442,914 of the Initial Options have the potential for accelerated vesting upon the achievement of certain specified milestones relating to financing, FDA approval of Company's migraine patch and the first commercial sale of the Company's migraine patch. The accounting for the Initial Options under ASC 718 will be reflected commencing in the Company's financial results for the three months ending September 30, 2012 with an estimated aggregate fair value of approximately \$2,040.

In addition, upon the completion of any equity financing (as such term is defined in Mr. Anido's employment agreement) in 2012, the Company will provide Mr. Anido with additional time-based options to purchase such additional number of shares of the Company's common stock as is equal to 5% of the number of shares of common stock issued by the Company in the applicable equity financing (the "Additional Options"). Any Additional Options issued to Mr. Anido will have an exercise price per share equal to the closing price of the Company's common stock on the date the Additional Options are granted. The Additional Options will have the same ten-year term and will vest according to the same schedule as the Initial Options and with the same relative proportion having the potential for accelerated vesting upon the achievement of the milestones applicable to the Initial Options.

The Initial Options and any Additional Options are being made as inducement grants pursuant to NASDAQ Listing Rule 5635(c)(4) and are outside of the 2010 Plan.

***(c) Amendment to Term Loan Facility***

On August 13, 2012, the Company entered into an amendment to the Term Loan Facility to temporarily reduce the minimum unrestricted cash balance that the Company is required to maintain from \$3,000 to \$1,000. Upon the completion of an additional capital raise, as defined in the amendment, the minimum unrestricted cash balance requirement will revert to \$3,000 and will remain in effect until the Term Loan Facility is fully repaid. As consideration for this modification, the Company is obligated to pay an amendment fee of approximately \$80 to the lenders upon the closing of an additional capital raise, as defined in the amendment, and an additional \$300 in final interest payment due in August 2013.

Table of Contents

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following commentary should be read in conjunction with:*

- *our unaudited financial statements and accompanying notes included in Part I, Item 1 of this Quarterly Report; and*
- *our audited financial statements and accompanying notes included in our 2011 Annual Report, as well as the information relating to such audited financial statements contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the 2011 Annual Report.*

**Overview**

We are a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system, including neurological and psychiatric disorders. Our most advanced product candidate, NP101 (also referred to as Zelrix and our migraine patch), is an active, single-use transdermal sumatriptan patch that we are developing for the treatment of migraine. NP101 uses our proprietary SmartRelief technology. If approved, NP101 will be the first transdermal patch indicated for the treatment of migraine. Following approval, we plan to build our own specialty sales force to launch NP101 in the U.S. along with a complementary partner to expand our physician reach and intend to seek a partner to market NP101 outside the U.S. We have two other proprietary product candidates in preclinical development that address large market opportunities, NP201 for the continuous symptomatic treatment of Parkinson's disease, and NP202 for the long-term treatment of schizophrenia and bipolar disorder. We are seeking a partner for further development of NP201 and we plan to submit an Investigational New Drug application (IND) for NP202 in 2013.

We were incorporated in the State of Delaware in January 2005 and are a development stage company. Since our inception, we have invested a significant portion of our efforts and financial resources in the development of NP101. NP101 is the only product candidate for which we have conducted clinical trials, and to date we have not marketed, distributed or sold any products. As a result, we have generated no product revenue and have never been profitable. Our net loss for the six months ended June 30, 2012 and June 30, 2011 was \$12.5 million and \$10.2 million, respectively. As of June 30, 2012, we had an accumulated deficit of \$115.4 million.

We have funded our operations to date primarily with the proceeds of the sale of common stock, convertible preferred stock, warrants, convertible notes and borrowings under credit facilities. From inception through June 30, 2012, we have received net proceeds of \$101.6 million from the sale of common stock, convertible preferred stock, warrants and convertible notes. Since inception, we have also received \$17.5 million of gross proceeds from term loans, of which \$9.6 million was outstanding as of June 30, 2012.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop, seek marketing approval for, and commercialize NP101 and our other product candidates. If we obtain marketing approval for NP101, we will incur significant sales, marketing, manufacturing and distribution expenses.



Our future capital needs will depend on many factors, including:

- the timing and outcome of the U.S. Food and Drug Administration's (FDA) review of our NDA resubmission for NP101, including the extent to which the FDA may request or require us to provide additional information or undertake additional trials or studies or redesign NP101;
- the cost, scope and timing of activities undertaken to prepare for commercialization of NP101;
- the scope, progress, results and costs of development for our product candidates;
- the extent to which we acquire or invest in new products, businesses and technologies; and
- the extent to which we establish collaboration, co-promotion, distribution or other similar arrangements for NP101 and our other product candidates.

We believe that our existing cash and cash equivalents will be sufficient to fund our debt service and interest obligations and continue operations until the end of the third quarter of 2012. We will require additional capital to fund our capital requirements and continue operations beyond that point. There is no assurance that such capital will be available when needed or on acceptable terms. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2011 related to our ability to continue as a going concern. If we are unable to obtain the

Table of Contents

necessary capital, we will need to pursue a plan to sell or license our assets or seek bankruptcy protection.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

**NP101 Regulatory Status**

We submitted a NDA for NP101 to the FDA in October 2010. In August 2011 we received a complete response letter (CRL) from the FDA. A CRL is issued by the FDA when the questions remain that preclude the FDA from approving the NDA in its present form. In the CRL, the FDA acknowledged that the efficacy of NP101 in the overall migraine population was established. The CRL primarily contained chemistry, manufacturing and safety questions. In November 2011, we had an end-of-review meeting with the FDA to discuss certain questions contained in the CRL and our approach for addressing such questions. We resubmitted a NDA for NP101 on July 16, 2012. On July 30, 2012, the FDA acknowledged receipt of the NDA, informed us that the submission is considered a complete, Class 2 response, and assigned a target date of January 13, 2013 for completing its review of the NDA. We believe that we have addressed all the questions contained in the CRL including the following primary issues:

- *product containment and uniformity of dosage.* We have made minor modifications to the product packaging to address the FDA's questions relating to product containment and provided additional data in our resubmission to characterize the uniformity of dosage.
- *demonstrating that NP101 can be used correctly by patients.* We conducted a new patient usability study with NP101's revised packaging, demonstrating that NP101 could be easily used by patients during a migraine.
- *development and validation of a new in vitro testing method.* We have developed and validated a new *in vitro* testing method that we believe meets FDA acceptance criteria. The new method will be used to qualify newly manufactured product.
- *the potential for NP101 to cause application site adverse events that result in permanent skin effects.* In our Phase III clinical program, consisting of 796 patients applying approximately 10,000 NP101 patches, four patients (0.5%) experienced application site adverse events that resulted in a small mark on the skin. These marks occurred because NP101 was not applied correctly. To address this issue we implemented a device enhancement that prevents NP101 from activating in the event that it is applied incorrectly. We verified the performance of this enhancement in the Phase I trial discussed below and believe that it addresses the FDA's questions relating to the potential for NP101 to cause permanent skin effects.
- *completion of two Phase I trials.* One trial was to verify the performance of our device enhancement and the other was a repeat of a Phase I trial that assessed the pharmacokinetics of NP101 compared to oral Imitrex. This pharmacokinetics study was repeated because the clinical site

that performed the original trial did not retain sufficient samples.

- *justification for waiver of a dermal carcinogenicity study.* In order to qualify for a waiver, we believe that we must demonstrate that sumatriptan is not passively absorbed through the skin. We have included clinical, preclinical, and laboratory data which confirms no passive absorption of sumatriptan through the skin in our resubmission.

By addressing the primary issues discussed above and the other questions contained in the CRL, we believe our NDA resubmission is sufficient for approval of NP101.

## **Recent Developments**

### *Appointment of Armando Anido as Chief Executive Officer*

Armando Anido was appointed chief executive officer and a member of the Company's board of directors, effective as of July 25, 2012. Mr. Anido has more than 30 years of executive, operational and commercial leadership experience in the biopharmaceutical industry. Most recently, he served as president and CEO of Auxilium Pharmaceuticals (NASDAQ: AUXL), where under his leadership, sales grew from \$42 million in 2005 to more than \$260 million in 2011 and market capitalization increased from \$200 million to more than \$900 million.

Table of Contents

*Patent Issuances and Allowance*

In April 2012, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 8,155,737 entitled Pharmacokinetics of Iontophoretic Sumatriptan Administration. This patent is generally directed towards methods of treating a migraine by administering sumatriptan using an iontophoretic patch to achieve consistent therapeutic plasma levels with low patient-to-patient variability. This patent, which expires in April 2027, is expected to provide additional patent protection for NP101.

In July 2012, the USPTO issued U.S. Patent No. 8,221,778 entitled Drug Containing Implants and Methods of Use Thereof and issued a Notice of Allowance for U.S. Patent Application 11/195,845, a related application that has the same title. These patents are generally directed towards a rod-shaped implant or structure that delivers therapeutic levels of risperidone for 20 to 190 days as well as to methods for treating medication noncompliance-associated diseases including schizophrenia and bipolar disorder. These patents, which expire in November 2027 and (once issued) December 2027, respectively, are expected to provide additional patent protection for NP202.

*Amendment to Term Loan Facility*

On August 13, 2012, we entered into an amendment to the Term Loan Facility to temporarily reduce the minimum unrestricted cash balance that we are required to maintain from \$3.0 million to \$1.0 million. Upon the completion of an equity financing, as defined in the amendment, the minimum unrestricted cash balance requirement will revert to \$3.0 million, and will remain in effect until the Term Loan Facility is fully repaid. As consideration for this modification, we are obligated to pay an amendment fee of approximately \$0.1 million to the lenders upon the closing of an equity financing, as defined in the amendment, and an additional \$0.3 million in final interest payment due in August 2013.

**Liquidity and Capital Resources**

Our principal sources of liquidity are cash and cash equivalents. As of June 30, 2012, we had \$7.5 million of cash and cash equivalents and a working capital deficit of \$4.9 million. On August 13, 2012, we entered into an amendment to our Term Loan Facility to temporarily reduce the minimum unrestricted cash balance that we are required to maintain from \$3.0 million to \$1.0 million. Management estimates that our cash and cash equivalents as of June 30, 2012, of which \$1.0 million is required to be maintained under the terms of our amended Term Loan Facility, will be sufficient to fund our debt service and interest obligations and continue operations until the end of the third quarter of 2012. We will require additional capital to fund our capital requirements and continue operations beyond that point.

To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings, corporate collaboration and licensing agreements, and other funding transactions. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. Furthermore, the covenants and the pledge of our assets as collateral under the Term Loan Facility limit our ability to obtain additional debt financing.

If we obtain additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, will result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific

## Edgar Filing: NUPATHE INC. - Form 10-Q

actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt or equity financing may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we obtain additional capital through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

If we are unable to obtain the necessary capital, we will need to pursue a plan to license or sell our assets and/or seek bankruptcy protection. Bankruptcy or similar proceedings may result in the termination of agreements pursuant to which we license important intellectual property rights. Additionally, failure to timely obtain the necessary capital may result in an event of default under our Term Loan Facility and in the breach or termination of agreements pursuant to which we license important intellectual property rights. Our Term Loan Facility contains customary events of default including upon the occurrence of a payment default, a covenant default (including the modified covenant that requires us to maintain at least \$1.0 million of unrestricted cash), a material adverse change (as defined in the Term Loan Facility) and insolvency. Upon the occurrence of an event of default, the interest on outstanding loans will be increased by 3% over the rate that would otherwise be applicable. In addition, the occurrence of an event of default could result in the acceleration of our obligations under the facility as well as grant the lenders the right to exercise remedies with respect to the collateral which secures the facility.

Table of Contents**Results of Operations*****Three months Ended June 30, 2012 compared to the Three months Ended June 30, 2011****Research and Development Expense*

Research and development expense for the three months ended June 30, 2012 and 2011 were comprised of the following:

	Three months Ended		June 30,		Increase/(Decrease)	
	2012	2011				
	(in thousands)					
Clinical development	\$ 636	\$ 574	\$		62	11%
Chemistry, manufacturing and controls (CMC)	1,515	1,767			(252)	(14)
Regulatory and quality assurance	63	98			(35)	(36)
Medical affairs	31	208			(177)	(85)
Compensation and related	1,013	937			76	8
Facilities and related	101	119			(18)	(15)
	\$ 3,359	\$ 3,703	\$		(344)	(9)

Research and development expenses decreased by \$0.3 million to \$3.4 million in the three months ended June 30, 2012 from \$3.7 million in the three months ended June 30, 2011. The significant variances from period to period, by area of research and development, are as follows:

*Clinical development*

- During the second quarter of 2012, we incurred \$0.1 million more related to clinical development compared to the second quarter of 2011 comprised of:
  - \$0.4 million incurred for the conduct of several NP101 clinical studies conducted to address questions raised in the FDA's complete response letter (CRL).
  - Studies completed to support our response to the CRL were partially offset by a reduction in expenses for the clinical development of NP201 or NP202, resulting in savings of \$0.3 million compared to the 2011 period, as we focused our efforts on NP101 during the second quarter of 2012.

*Chemistry, manufacturing and controls (CMC)*

- During the second quarter of 2012, we incurred \$0.3 million less related to CMC compared to the second quarter of 2011 comprised of:
  - The second quarter of 2011 included \$1.0 million for the purchase of materials for the manufacture of NP101 supplies, including \$0.3 million for the active product ingredient used in NP101 and \$0.5 million incurred with our third party manufacturer for these supplies. Also included in the second quarter of 2011 was \$0.2 million of non-cash amortization related to previously capitalized supplies that were used in the continued development and testing of NP101.
  - Partially offsetting the second quarter 2011 CMC expenses were higher consulting and third party expenses of \$0.8 million during the second quarter of 2012 related to the preparation of our response to the FDA's CRL.
  - Also contributing to the 2012 decrease in CMC expenses is the fact that during the second quarter of 2012, as we focused our efforts on NP101, we did not incur any expenses for CMC related to NP201 or NP202, whereas in the second quarter of 2011 we incurred a total of \$0.1 million for CMC on these two projects.

*Medical affairs*

- Expenses for NP101 medical affairs decreased by \$0.2 million in 2012 as we focused our efforts on the submission of our response to the NP101 CRL.

*Compensation and related*

- Higher compensation and related expenses were attributable to incremental headcount as well as annual salary increases for research and development personnel.

Table of Contents

Research and development expenses by program for the three months ended June 30, 2012 and 2011 were as follows:

	Three months Ended		June 30,		Increase/(Decrease)		
	2012	2011	2012	2011			
	(in thousands)						
NP101	\$	2,217	\$	2,272	\$	(55)	(2)%
NP201				247		(247)	(100)
NP202		27		128		(101)	(79)
General development		1,115		1,056		59	6
	\$	3,359	\$	3,703	\$	(344)	(9)

NP101 expenses for the three months ended June 30, 2012 were \$2.2 million, compared to \$2.3 million for the same period in 2011. As discussed above, higher spending for clinical trials needed to address questions raised in the CRL were offset by lower spending for CMC expenses and medical affairs. While the second quarter of 2012 included \$1.5 million for NP101 CMC, primarily for work related to address questions in the CRL, this is \$0.2 million lower than the second quarter of 2011. The 2011 period included \$1.0 million for the manufacture of CMC supplies. Lower expenses in 2012 for NP201 and NP202 result from focusing our efforts on NP101 and the resubmission of our NDA. Personnel related expenses, including salaries and benefits, are included in the table above as general development expenses as we do not allocate these expenses to specific programs. The 2012 increase shown for general development expenses is primarily related to incremental headcount as well as annual salary increases for research and development personnel.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased to \$2.4 million in the three months ended June 30, 2012 from \$2.5 million for the three months ended June 30, 2011. Higher spending during the second quarter of 2012, compared to 2011, for personnel related expenses, legal fees and insurance was offset by reduced spending in the area of commercial operations.

*Interest Expense*

Interest expense increased to \$0.4 million in the three months ended June 30, 2012, from \$0.2 million in the three months ended June 30, 2011. The increase results from the Term B Loans obtained under the Term Loan Facility in June 2011.



Table of Contents*Six months Ended June 30, 2012 compared to the Six months Ended June 30, 2011**Research and Development Expense*

Research and development expense for the six months ended June 30, 2012 and 2011 were comprised of the following:

	Six months Ended		June 30,		Increase/(Decrease)
	2012	(in thousands)	2011		
Clinical development	\$	993	\$	1,291	\$ (298) (23)%
Chemistry, manufacturing and controls (CMC)		3,269		2,958	311 11
Regulatory and quality assurance		126		(1,371)	1,497 (109)
Medical affairs		69		402	(333) (83)
Compensation and related		2,143		1,736	407 23
Facilities and related		213		261	(48) (18)
	\$	6,813	\$	5,277	\$ 1,536 29

Research and development expenses increased by \$1.5 million to \$6.8 million in the six months ended June 30, 2012 from \$5.3 million in the six months ended June 30, 2011. The primary reason for the increase is a \$1.5 million credit received in the first quarter of 2011 related to a waiver of the NDA filing fee that we had paid to the FDA in the fourth quarter of 2010. Exclusive of this one-time expense reduction in 2011, our research and development expenses for the six months ended June 30, 2012 were consistent with the six months ended June 30, 2011, although there were fluctuations within each operating area, as explained:

*Clinical development*

- During the six months ended June 30, 2012, we incurred \$0.3 million less related to clinical development compared to the same 2011 period, due primarily to:
  - As we focused our efforts on the NP101 NDA resubmission during the second quarter of 2012, we incurred minimal amounts for the clinical development of NP201 or NP202, a savings of \$0.3 compared to the 2011 period.
  - Expenses incurred for clinical studies were consistent from the 2011 to the 2012 period. While 2011 included expenses for the completion of our final open label study, the 2012 period included significant expenses related to several NP101 clinical studies conducted to address questions raised in the FDA's CRL.

*Chemistry, manufacturing and controls (CMC)*

## Edgar Filing: NUPATHE INC. - Form 10-Q

- During the six months ended June 30, 2012, we incurred \$0.3 million more related to CMC compared to the same period in 2011 comprised of:
  - The increase primarily relates to expenses incurred in order to address questions raised in the CRL, as well as continued manufacturing scale-up for NP101, partially offset by significant expenses incurred in the 2011 period for CMC supplies that did not recur in the 2012 period.
  - Additionally, the CMC increase in 2012 was partially offset by a \$0.1 million decrease related to formulation development activities for NP201 and NP202 which occurred in the first half of 2011 but did not recur in 2012.

### *Regulatory and quality assurance*

- Excluding the effect of the \$1.5 million NDA filing fee credit on the 2011 period, our regulatory and quality assurance expenses were consistent period to period.

### *Medical affairs*

- Expenses for NP101 medical affairs decreased by \$0.3 million in 2012 as we focused our efforts on the resubmission of our NDA.

### *Compensation and related*

- Higher compensation and related expenses were attributable to incremental headcount as well as annual salary increases for research and development personnel.

Table of Contents

Research and development expenses by program for the six months ended June 30, 2012 and 2011 were as follows:

	Six months Ended		2011	Increase/(Decrease)		
	2012	June 30,				
	(in thousands)					
NP101	\$	4,374	\$	2,516	\$ 1,858	74%
NP201		2		514	(512)	(100)
NP202		81		251	(170)	(68)
General development		2,356		1,996	360	18
	\$	6,813	\$	5,277	\$ 1,536	29

NP101 expenses for the six months ended June 30, 2012 were \$4.4 million, compared to \$2.5 million for the same period in 2011. As discussed above, part of the increase is due to the 2011 credit of \$1.5 million related to the refund of the NDA filing fee. Exclusive of this \$1.5 million reduction, NP101 expenses were \$4.0 million for the six months ended June 30, 2011, compared to \$4.4 million for the 2012 period. The increase from 2011 to 2012, as explained above, results primarily from higher CMC expenses incurred to address questions raised in the CRL and to scale up the manufacturing of NP101, with partial offsets for savings in the areas of clinical and medical affairs. Higher expenses in 2011 for NP201 and NP202 result from focusing our 2012 efforts on NP101 and the resubmission of our NDA. Personnel related expenses, including salaries and benefits, are included in the table above as general development expenses as we do not allocate these expenses to specific programs. The 2012 increase shown for general development expenses is primarily related to incremental headcount as well as annual salary increases for research and development personnel.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased to \$4.8 million in the six months ended June 30, 2012 from \$4.5 million for the six months ended June 30, 2011. This increase results primarily from higher headcount in the sales and marketing area during the first six months of 2012 compared to 2011, as well as higher legal and insurance expense for the 2012 period, partially offset by reduced third party spending in the area of commercial operations.

*Interest Expense*

Interest expense increased to \$0.8 million in the six months ended June 30, 2012, from \$0.5 million in the six months ended June 30, 2011. The increase results from the Term B Loans obtained under the Term Loan Facility in June 2011.

**Cash Flow Analysis**

Net cash used in operating activities for the six months ended June 30, 2012 was \$11.0 million, primarily the result of spending for normal operating activities, activities to address questions raised in the CRL and the continued development of NP101. During the six months ended

## Edgar Filing: NUPATHE INC. - Form 10-Q

June 30, 2012, we used \$0.3 million of cash in investing activities and \$4.3 million for financing activities related to contractual debt repayments.

Net cash used in operating activities for the six months ended June 30, 2011 was \$9.2 million, primarily the result of spending for normal operating activities, the continued development of NP101 and commercial operations as we prepared for the launch of NP101. During the six months ended June 30, 2011, we used \$3.1 million of cash in investing activities, almost solely for the purchase of equipment related to the commercial manufacture of NP101. For the six months ended June 30, 2011, we had net cash provided by financing activities of \$9.6 million resulting from \$10.0 million proceeds from venture debt entered in to in June 2011, offset by contractual debt repayments of \$0.4 million.

### **Critical Accounting Policies and Use of Estimates**

A summary of our critical accounting policies and use of estimates can be found in Item 7 of our Annual report on Form 10-K for the year ended December 31, 2011. There have been no changes to our critical accounting policies during the six months ended June 30, 2012.

Table of Contents

**Future Payments Under Contractual Obligations**

During the six month period ended June 30, 2012, other than discussed below, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our Annual Report on Form 10-K for the year ended December 31, 2011.

On April 23, 2012, we entered into an Equipment Purchase Agreement (Purchase Agreement) with Automated Engineering, LLC (AE). Pursuant to the terms of the Purchase Agreement, AE will design, assemble, test, deliver and install equipment which will be used to manufacture commercial supply of components of our migraine patch. Based on the current work specifications, we expect to pay AE an aggregate of \$1.0 million during 2012, of which \$0.3 million has been paid as of June 30, 2012.

On July 25, 2012, we entered into a severance agreement with our former CEO, Jane Hollingsworth. Under the terms of this agreement, beginning in September 2012 and continuing for eighteen months, we expect to make aggregate payments of approximately \$0.8 million. Such payments encompass severance, earned bonus and continued medical coverage.

Additionally, in August 2012 we entered into an agreement to modify the covenant of our existing Term Loan Facility. The terms of the agreement have temporarily reduced the minimum cash balance requirement to be maintained by the Company from \$3.0 million to \$1.0 million. Upon a successful capital raise by the Company, as defined in the agreement, the minimum cash balance requirement will revert to \$3.0 million. As consideration for this modification, the Company has agreed to pay an amendment fee upon the closing of an equity financing, as defined in the agreement, of approximately \$0.08 million and an additional \$0.3 million in final interest payments due in August 2013.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the applicable rules of the SEC.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities

## Edgar Filing: NUPATHE INC. - Form 10-Q

Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### **Changes to Internal Controls Over Financial Reporting**

There has been no change in internal controls over financial reporting that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**Item 5. Other Information.**

On August 13, 2012, NuPathe Inc. ( NuPathe ) entered into a Second Loan Modification Agreement (the Amendment ) with MidCap Funding III, LLC ( MidCap ) and Silicon Valley Bank ( SVB and together with MidCap, the Lenders ). The Amendment modifies the Loan and Security Agreement, dated as of May 13, 2010, by and among NuPathe and the Lenders, as amended by that certain First Loan Modification Agreement, dated June 13, 2011 (the Term Loan Facility ) to, among other things:

- temporarily reduce the minimum unrestricted cash balance that NuPathe is required to maintain from \$3.0 million to \$1.0 million, which will revert back to \$3.0 million upon completion of an additional capital raise, as defined in the Amendment, and remain in effect until the Term Loan Facility is fully repaid;
- provide for payment of an amendment fee equal to one percent (1%) of the aggregate outstanding principal amount of the term loans under the facility on August 13, 2012, which amendment fee (\$0.08 million) shall be due and payable upon the occurrence of an additional capital raise, as defined in the Amendment; and
- increases the final payment, as defined in the Term Loan Facility, from two percent (2%) to four percent (4%) of the original principal amount of the term loans under the facility, which final payment (\$0.6 million) is due upon the earlier of acceleration of the term loans, prepayment of the term loans or the maturity date.

All other provisions of the Term Loan Facility are unchanged by the Amendment and remain in full force and effect.

The foregoing is a summary description of certain terms of the Amendment and the Term Loan Facility and, by its nature, is incomplete. A copy of the Amendment is filed as Exhibit 10.2 to this Form 10-Q and is incorporated herein by reference. A copy of the Term Loan Facility was previously filed by NuPathe on August 2, 2011 as Exhibit No. 10.7 to its Form S-1 Registration Statement (File No. 333-175987) and is incorporated herein by reference. All readers are encouraged to read the entire text of the Amendment and the Term Loan Facility.

**Item 6. Exhibits.**

The information required by this Item 6 is set forth in the Exhibit Index hereto which is incorporated herein by reference.





Table of Contents

**SIGNATURES**

Pursuant to the requirements of Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NUPATHE INC.

Date: August 14, 2012

By:

/s/ Keith A. Goldan  
Keith A. Goldan  
Vice President and Chief Financial Officer  
*(Duly authorized officer and principal financial and  
accounting officer of the registrant)*

Table of Contents**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>Incorporated by Reference File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed Herewith</b>
10.1	Equipment Purchase Agreement, dated April 23, 2012, by and between Automated Engineering, LLC and NuPathe Inc.	8-K	001-34836	10.1	April 26, 2012	
10.2	Second Loan Modification Agreement, dated August 13, 2012, by and among MidCap Funding III, LLC, Silicon Valley Bank and NuPathe Inc.					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 (a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification by Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					*
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*

---

\* Furnished herewith.