

NUPATHE INC.
Form 10-Q
May 10, 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 March 31, 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.

(Exact name of registrant as specified in its charter)

Edgar Filing: NUPATHE INC. - Form 10-Q

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. 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
(Do not check if a smaller reporting company)

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 May 9, 2012, the number of shares outstanding of the registrant's common stock, \$0.001 par value, was 14,748,582.

Table of Contents

NUPATHE INC.

Form 10-Q for the Quarter Ended March 31, 2012

Table of Contents

	Page No.
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	i
<u>PART I. FINANCIAL INFORMATION</u>	1
<u>Item 1.</u> <u>Financial Statements (Unaudited)</u>	1
<u>Balance Sheets as of March 31, 2012 and December 31, 2011</u>	1
<u>Statements of Operations for the Three Months Ended March 31, 2012 and 2011</u>	2
<u>Statements of Cash Flows for the Three Months Ended March 31, 2012 and 2011</u>	3
<u>Notes to Financial Statements</u>	4
<u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
<u>Item 4.</u> <u>Controls and Procedures</u>	15
<u>PART II. OTHER INFORMATION</u>	16
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	16
<u>Item 6.</u> <u>Exhibits</u>	16
<u>SIGNATURES</u>	17
<u>EXHIBIT INDEX</u>	18

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.

Edgar Filing: NUPATHE INC. - Form 10-Q

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 operations, debt service and interest obligations into the third quarter of 2012;
- 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;
- 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, packaging modification and other activities to support the resubmission of our NDA for NP101 and our ability to obtain a waiver of a dermal carcinogenicity study;
- the timing of our resubmission of the NDA for NP101 and the FDA's review of such resubmission;
- our ability to obtain marketing approval of NP101 and the timing of any such approval;
- our ability to obtain commercial and development partners for NP101 and our other product candidates and the timing of any such partnerships;
- our development and commercialization plans regarding NP101 and our other product candidates; and
- the timing of our planned submission of an Investigation New Drug application for NP201;

Edgar Filing: NUPATHE INC. - Form 10-Q

as well as other statements relating to our future operations, future performance, future financial condition, prospects, expectations, beliefs, plans or objectives (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, plan, anticipate, believe, estimate, predict, project, potential, continue, ongoing and similar expressions, although not all forward statements 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 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 to continue as a going concern;
- our ability to address the issues raised by the FDA in the CRL and 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;
- the ability of the lenders under our loan and security agreement to proceed against the collateral granted thereunder upon an event of default; 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

Table of Contents

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). 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)**

	March 31,		December 31,
	2012		2011
Assets			
Current assets:			
Cash and cash equivalents	\$ 14,574	\$	23,059
Prepaid expenses and other	275		333
Total current assets	14,849		23,392
Property and equipment, net	299		213
Other assets	417		481
Other assets-equipment funding (Note 3(d))	6,763		6,763
Total assets	\$ 22,328	\$	30,849
Liabilities and Stockholders Equity			
Current liabilities:			
Current portion of long-term debt	\$ 8,297	\$	8,412
Accounts payable	1,552		1,967
Accrued expenses	2,035		2,018
Total current liabilities	11,884		12,397
Long-term debt	3,426		5,481
Total liabilities	15,310		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 14,748,582 shares at March 31, 2012 and December 31, 2011	15		15
Additional paid-in capital	116,271		115,940
Deficit accumulated during the development stage	(109,268)		(102,984)
Total stockholders equity	7,018		12,971

Edgar Filing: NUPATHE INC. - Form 10-Q

Total liabilities and stockholders equity	\$	22,328	\$	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)**

	Three Months Ended March 31,		Period from
	2012	2011	January 7, 2005
			(inception) through
			March 31, 2012
Grant Revenue	\$	\$	\$ 650
Operating expenses:			
Research and development		3,454	1,574
Acquired in-process research and development			64,712
Selling, general and administrative		2,387	1,970
Total operating expenses		5,841	3,544
Loss from operations		(5,841)	(3,544)
Interest income		10	24
Interest expense		(453)	(203)
Loss before tax benefit		(6,284)	(3,723)
Income tax benefit			698
Net loss	\$	(6,284)	\$ (3,723)
Basic and diluted net loss per common share	\$	(0.43)	\$ (0.26)
Weighted average basic and diluted common shares outstanding		14,732,582	14,553,748

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)

	Three Months Ended March 31,		Period from
	2012	2011	January 7, 2005 (inception) through March 31, 2012
Cash flows from operating activities:			
Net loss	\$ (6,284)	\$ (3,723)	\$ (102,886)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	25	15	280
Loss on asset disposal			24
Acquired in-process research and development			5,500
Stock-based compensation	331	254	2,679
Noncash interest expense	65	54	5,580
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	58	(1,112)	705
Accounts payable	(415)	482	1,552
Accrued expenses	17	(1,448)	2,014
Net cash used in operating activities	(6,203)	(5,478)	(84,552)
Cash flows from investing activities:			
Purchase of in-process research and development			(5,500)
Payments under equipment funding agreement		(536)	(6,763)
Purchases of property and equipment	(112)	(28)	(603)
Net cash used in investing activities	(112)	(564)	(12,866)
Cash flows from financing activities:			
Proceeds from issuance of debt			17,500
Payment of debt issuance costs			(325)
Repayment of debt	(2,170)	(129)	(6,819)
Proceeds from sale of preferred stock, net			43,576
Proceeds from sale of common stock, net		21	43,593
Proceeds from sale of convertible notes, net			14,467
Net cash (used in) provided by financing activities	(2,170)	(108)	111,992
Net increase (decrease) in cash and cash equivalents	(8,485)	(6,150)	14,574
Cash and cash equivalents, beginning of period	23,059	38,918	
Cash and cash equivalents, end of period	\$ 14,574	\$ 32,768	\$ 14,574
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
Financing arrangement with third party vendors			991
Accretion of redeemable convertible preferred stock			9,948
Cash paid for interest	378	149	2,470

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 biopharmaceutical 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 \$109,268 as of March 31, 2012. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development.

Management estimates that cash and cash equivalents of \$14,574 as of March 31, 2012, of which \$3,000 is required to be maintained under the terms of our Term Loan Facility, will be sufficient to fund operations, debt service and interest obligations into the third quarter of 2012. Additional capital will be needed by the Company to fund its operations and capital requirements 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. Until such time as the Company is able to secure the necessary funding, it plans to continue conserving its capital resources, predominantly by focusing on activities related to NP101.

Edgar Filing: NUPATHE INC. - Form 10-Q

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 \$13,661 and \$22,144 at March 31, 2012 and December 31, 2011, respectively. The Company had no Level 2 or Level 3 fair value instruments at March 31, 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 agreed to make 14 monthly installments to LTS that commenced in June 2010, according to an agreed upon payment schedule. As of March 31, 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 have been paid in full as of March 31, 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

Table of Contents

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.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of March 31, 2012 and 2011, as they would be anti-dilutive:

	2012	March 31, 2011
Shares underlying outstanding options to purchase common stock	2,410,386	1,455,834
Shares of unvested restricted stock	16,000	
Shares underlying outstanding warrants to purchase common stock	200,268	140,520

(f) Recently Issued Accounting Standards

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). The issuance of ASU 2011-05 is intended to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 supersedes the presentation options in ASC Topic 220 and facilitates convergence of U.S. GAAP and IFRS by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity and requiring that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 is effective for interim periods and years beginning after December 15, 2011. The adoption of ASU 2011-05 did not have an impact on the Company's financial statements.

In December 2011, the FASB issued ASU No. 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 (ASU 2011-12). The amendments are being made to allow the FASB time to redeliberate whether to present on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. All other requirements in ASU 2011-05 are not affected by this Update, including the requirement to report comprehensive income either in a single continuous financial statement or in two separate but consecutive financial statements. The adoption of ASU 2011-12 did not have an impact on the Company's financial statements.

(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

Edgar Filing: NUPATHE INC. - Form 10-Q

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 Loan s 39-month term; therefore at March 31, 2012, the balance of the Term A Loans was \$3,148, 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 March 31, 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

Table of Contents

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 shall expire after the occurrence of an equity event resulting in unrestricted cash proceeds to the Company of at least \$15,000; 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 Loans' 26-month term; therefore at March 31, 2012, the balance of the Term B Loans was \$8,500 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 March 31, 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.

In August 2011, the Company entered into two short-term agreements with third party vendors to finance insurance premiums. The amount originally financed under the agreements was \$532 and was later reduced to \$401 due to a reduction of the Company's insurance premiums. These notes originally had a nine month term and an annual interest rate of 4.5%. In November 2011, one of the loans was paid in full, and as of March 31, 2012 the balance of the remaining short-term loan was \$75, which is required to be repaid by May 2012.

(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. Upon execution of the Purchase Agreement, the Company issued 84,866 shares of common stock to Aspire Capital as a commitment fee in consideration for entering into the Purchase Agreement (the Commitment Shares) and the Company sold 70,721 shares of common stock to Aspire Capital at a per share purchase price of \$7.07 resulting in gross proceeds to the Company of \$500 (the Initial Purchase Shares). As of March 31, 2012, other than the Commitment Shares and Initial Purchase Shares referenced above, the Company has not made any sales to Aspire Capital. In order to make future sales of common stock to Aspire Capital pursuant to the Purchase Agreement, the Company must first file, and have declared effective by the SEC, a post-effective amendment to the Company's S-1 registration statement (File No. 333-175987) covering Aspire Capital's sale of shares that are issued pursuant to the Purchase Agreement.

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

As of March 31, 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 March 31, 2012, there were 2,410,386 incentive and non-qualified stock options and 16,000 shares of restricted stock outstanding under this plan. At March 31, 2012 there were 464,033 shares of common stock available for future grants under the 2010 Plan.

The following is a summary of stock option activity for the three months ended March 31, 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	654,346	3.04		
Exercised				
Cancelled/forfeited	(28,245)	6.11		
Outstanding at March 31, 2012	2,410,386	3.95	8.16	\$ 2,433
Vested and expected to vest at March 31, 2012	2,155,559	3.61	8.06	\$ 2,362
Exercisable at March 31, 2012	1,077,472	2.75	6.83	\$ 1,718

Of the 654,346 stock options that were granted during the three months ended March 31, 2012, 22,758 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 \$3.70 as of March 31, 2012.

Stock-based compensation expense related to stock options for the three months ended March 31, 2012 and 2011 was \$331 and \$254, respectively. As of March 31, 2012, there was \$3,157 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 three months ended March 31, 2012.

Table of Contents

Weighted- average fair value of stock options granted \$ 2.11

Assumptions Used:

Risk-free interest rate	1.01	1.18%
Expected life in Years	5.0	6.1 years
Expected volatility	81.2-	81.8%
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 three months ended March 31, 2012:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested shares at December 31, 2011	16,000	\$ 7.73
Granted		
Vested		
Forfeited/repurchased		
Nonvested shares at March 31, 2012	16,000	\$ 7.73

As of March 31, 2012, there was \$96 of unrecognized compensation expense related to unvested restricted stock, which is expected to be recognized over a weighted average period of 3.1 years.

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 biopharmaceutical 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 partner 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 co-development partner for 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 three months ended March 31, 2012 and March 31, 2011 was \$6.3 million and \$3.7 million, respectively. As of March 31, 2012, we had an accumulated deficit of \$109.3 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 March 31, 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.

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.

Edgar Filing: NUPATHE INC. - Form 10-Q

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

- our ability to successfully complete the additional trials, tests, device enhancement, packaging modification and other activities to support the resubmission of our New Drug Application (NDA) for NP101 and our ability to obtain a waiver of a dermal carcinogenicity study;
- 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;
- 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 choose to establish collaboration, co-promotion, distribution or other similar agreements for NP101 and our other product candidates.

Table of Contents

We believe that our existing cash and cash equivalents will be sufficient to fund our operations, debt service and interest obligations into the third quarter of 2012. We will require additional capital to fund our operations and capital requirements 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.

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.

If we are unable to raise the necessary capital, we will need to curtail operations significantly and modify our business strategy which may require us to delay, modify or abandon our operations and plans related to NP101 and our other product candidates, pursue a plan to sell our assets or seek bankruptcy protection.

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. Based on the CRL and our discussions with FDA, we believe the primary outstanding issues are:

- *product containment and uniformity of dosage.* We have made minor modifications to the product packaging and will be providing additional data in our resubmission to characterize the uniformity of dosage.
- *demonstrating that NP101 can be used correctly by patients.* We are conducting a new patient usability study with NP101's revised packaging.
- *development and validation of a new in vitro testing method.* We have developed a new *in vitro* testing method and validation is ongoing. The new method will be included in our resubmission and 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 have

Edgar Filing: NUPATHE INC. - Form 10-Q

implemented a device enhancement that prevents NP101 from activating in the event that it is applied incorrectly.

- *completion of two Phase I trials.* One trial is to verify the performance of our device enhancement and the other, which has been completed, was a repeat of a Phase I trial that assessed the pharmacokinetics of NP101 compared to oral Imitrex 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 we must demonstrate that sumatriptan is not passively absorbed through the skin. We have clinical and preclinical data confirming that there is no passive absorption and will include these data and our justification for the waiver in our resubmission.

In addition to these primary issues, we are addressing the other questions raised by the FDA in the CRL. By providing additional data, completing the activities discussed above and following FDA recommendations, we believe our NDA resubmission will be sufficient for approval of NP101. We expect to resubmit our NDA in the first half of 2012 after completing the activities discussed above. We believe our resubmission will result in a six month review period under the Prescription Drug User Fee Act, which will be the target date for the FDA to complete its review of the NDA.

Table of Contents

Liquidity and Capital Resources

Our principal sources of liquidity are cash and cash equivalents of \$14.6 million as of March 31, 2012, of which \$3.0 million is required to be maintained under the terms of our loan and security agreement (Term Loan Facility). As of March 31, 2012, we had working capital of \$3.0 million. During the three months ended March 31, 2012, we used \$6.2 million of cash for operating activities, \$0.1 million for investing activities, and \$2.2 million for financing activities related to contractual debt repayments. We expect to use a similar aggregate amount of cash for operating activities, financing activities and investing activities for the three months ending June 30, 2012. We believe that our existing cash and cash equivalents will be sufficient to fund our operations, debt service and interest obligations into the third quarter of 2012. We will require additional capital to fund our operations and capital requirements 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. If we are unable to successfully complete the additional trials, tests, device enhancement, packaging modification and other activities to support the resubmission of our NDA in a timely manner, our ability to obtain additional capital may be adversely affected. Furthermore, the covenants and the pledge of our assets as collateral under the Term Loan Facility limit our ability to obtain additional debt financing. Until such time as we are able to secure the necessary capital, we plan to continue conserving our capital resources, predominantly by focusing on activities related to NP101.

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 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 curtail operations significantly and modify our business strategy which may require us to delay, modify or abandon our operations and plans related to NP101 and our other product candidates, pursue a plan to sell our assets or seek bankruptcy protection. Bankruptcy proceedings may result in the termination of agreements pursuant to which we license certain intellectual property rights. Additionally, failure to obtain the necessary capital may result in an event of default under our Term Loan Facility. Our Term Loan Facility contains customary events of default including upon the occurrence of a payment default, a covenant default, 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.

Results of Operations

Three Months Ended March 31, 2012 compared to the Three Months Ended March 31, 2011

Edgar Filing: NUPATHE INC. - Form 10-Q

Research and Development Expense

Research and development expense for the three months ended March 31, 2012 and 2011 were comprised of the following:

	Three Months Ended		2011	Increase/(Decrease)	
	2012	March 31, (in thousands)			
Clinical development	\$	342	\$	644	\$ (302) (47)%
Chemistry, manufacturing and controls (CMC)		1,754		1,191	563
Regulatory and quality assurance		63		(1,469)	1,532
Medical affairs		39		194	(155) (80)
Compensation and related		1,130		800	330
Facilities and related		126		214	(88) (41)
	\$	3,454	\$	1,574	\$ 1,880

Table of Contents

Research and development expenses increased by \$1.9 million to \$3.5 million in the three months ended March 31, 2012 from \$1.6 million in the three months ended March 31, 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 three months ended March 31, 2012 were \$0.4 million higher than the three months ended March 31, 2011. Clinical development expenses decreased by \$0.3 million during the 2012 period due, in large part, to the fact that the first quarter of 2011 included \$0.3 million for one of our long-term, open label NP101 clinical studies. This study was substantially complete by the first quarter of 2012. These savings were partially offset by expenses incurred in the first quarter of 2012 for two small studies being conducted to support our NDA resubmission for NP101. CMC expense increased by \$0.6 million to \$1.8 million during the three months ended March 31, 2012 compared to \$1.2 million during the same period in 2011. 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. The CMC increase in 2012 was partially offset by a \$0.2 million decrease related to formulation development activities for NP201 and NP202 which occurred in the first quarter of 2011 but did not recur in 2012. 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. Expenses for NP101 medical affairs decreased by \$0.2 million in 2012 as we focused our efforts on the resubmission of our NDA. Higher compensation and related expenses were attributable to incremental headcount as well as annual salary increases for research and development personnel.

Research and development expenses by program for the three months ended March 31, 2012 and 2011 were as follows:

	Three Months Ended		March 31,		Increase/(Decrease)	
	2012	2011	2012	2011		
	(in thousands)					
NP101	\$ 2,156	\$ 244	\$ 1,912	\$ 244	784%	
NP201	2	268	(266)	268	(99)	
NP202	54	123	(69)	123	(56)	
General development	1,242	939	303	939	32	
	\$ 3,454	\$ 1,574	\$ 1,880	\$ 1,574	119	

NP101 expenses for the three months ended March 31, 2012 were \$2.2 million, compared to \$0.2 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 \$1.7 million for the three months ended March 31, 2011, compared to \$2.2 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 \$2.4 million in the three months ended March 31, 2012 from \$2.0 million for the three months ended March 31, 2011. This increase resulted primarily from higher headcount in the sales and marketing area during the first quarter of 2012 compared to 2011.

Interest Expense

Interest expense increased by \$0.3 million to \$0.5 million in the three months ended March 31, 2012, from \$0.2 million in the three months ended March 31, 2011. The increase results from the Term B Loans obtained under the Term Loan Facility in June 2011.

Table of Contents

Cash Flow Analysis

Net cash used in operating activities for the three months ended March 31, 2012 was \$6.2 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 three months ended March 31, 2012, we used \$0.1 million of cash in investing activities and \$2.2 million for financing activities related to contractual debt repayments.

Net cash used in operating activities for the three months ended March 31, 2011 was \$5.5 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 three months ended March 31, 2011, we used \$0.6 million of cash in investing activities, almost solely for the purchase of equipment related to the commercial manufacture of NP101. For the three months ended March 31, 2011, we made contractual debt repayments of \$0.1 million, which was partially offset by proceeds from the exercise of stock options during the first quarter of 2011.

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 three months ended March 31, 2012.

Future Payments Under Contractual Obligations

During the three month period ended March 31, 2012, 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 \$976,250 during 2012.

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.

Table of Contents

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 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from Registered Securities

On August 11, 2010, we completed the sale of 5,000,000 shares of our common stock in our IPO at a price of \$10.00 per share pursuant to a Registration Statement on Form S-1 (File No. 333-166825), which was declared effective by the SEC on August 5, 2010 (the Effective Date). After deducting underwriting discounts and commissions and other expenses of the offering, we received net offering proceeds of \$43.0 million, which we have used as follows:

- approximately \$20.6 million for further clinical development, manufacturing development, preparation and submission of an NDA and responding to the CRL for NP101;
- approximately \$2.0 million for the further preclinical development of NP201 and NP202; and
- approximately \$13.1 million for salaries and related personnel expenses for research and development and administrative personnel and approximately \$7.3 million for working capital and other general corporate purposes.

The foregoing amounts represent the Company's reasonable estimate of the amount of net offering proceeds applied to such activities instead of the actual amount of net offering proceeds used. None of the net proceeds, were directly or indirectly paid to any of our directors, officers or their associates, any person(s) owning 10% or more of any class of our equity securities, or any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in our planned use of proceeds from the IPO from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on August 6, 2010.

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: May 10, 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

Exhibit Number	Exhibit Description	Form	Incorporated by Reference File No.	Exhibit	Filing Date	Filed Herewith
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.