

NUPATHE INC.
Form 10-Q
November 09, 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 September 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 November 7, 2012, there were 14,754,694 outstanding shares of the registrant's common stock, \$0.001 par value.

Table of Contents

NUPATHE INC.

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

Table of Contents

	Page No.
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	3
<u>PART I. FINANCIAL INFORMATION</u>	5
<u>Item 1. Financial Statements (Unaudited)</u>	5
<u>Balance Sheets as of September 30, 2012 and December 31, 2011</u>	5
<u>Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011</u>	6
<u>Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011</u>	7
<u>Notes to Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 4. Controls and Procedures</u>	23
<u>PART II. OTHER INFORMATION</u>	24
<u>Item 1A. Risk Factors</u>	24
<u>Item 6. Exhibits</u>	24
<u>SIGNATURES</u>	25
<u>EXHIBIT INDEX</u>	26

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®, Zecuity, 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 into the fourth quarter of 2013;
- the effect of cost-containment measures;
- future expenses and capital requirements;
- the timing of the FDA's review of our NDA resubmission for Zecuity and the potential approval and commercial launch of Zecuity;
- our development and commercialization plans regarding Zecuity and our other product candidates; and
- the effect of the rights and other privileges relating to our Series A Preferred Stock;

as well as other statements relating to our future performance or projections, expectations, beliefs, plans and objectives for future operations and events (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, scheduled, and similar expressions, although forward-looking 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, 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 meet our debt service and interest obligations and fund operations;
- our ability to address the issues raised by the FDA in the CRL letter regarding our NDA for Zecuity;
- additional information, trials, studies or redesign of Zecuity that may be required by the FDA, which could delay, limit or preclude marketing approval of Zecuity;
- our ability to obtain marketing approval for Zecuity and our other product candidates;
- our ability to obtain commercial and development partners for Zecuity and our other product candidates;
- our reliance on third parties to manufacture Zecuity and our other product candidates;
- our ability to establish and effectively manage our supply chain;

Edgar Filing: NUPATHE INC. - Form 10-Q

- our ability to establish effective marketing and sales capabilities or enter into agreements with third parties to perform these functions;
- market acceptance among physicians and patients and the availability of adequate reimbursement from third party payors for Zecuity and any other product candidates for which we obtain marketing approval;
- adverse event profiles discovered after marketing approval and use of a product in a larger number of subjects for longer periods of time than in clinical trials, that could limit such product's usefulness or require its withdrawal;
- serious adverse events or other safety risks that could require us to abandon or delay development of, or preclude or limit approval of, our product candidates;

Table of Contents

- varying interpretation of trial, study and market data;
- our ability to obtain and maintain intellectual property protection and the scope of such protection;
- the performance of our partners and other third parties;
- compliance with legal and regulatory requirements;
- the rights and other privileges relating to our Series A Preferred Stock that may make it more difficult for other stockholders to influence significant corporate decisions and may adversely affect the value of our shares of common stocks; and
- the other risks, uncertainties and factors discussed in this Form 10-Q and 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) and through the SEC's website at www.sec.gov. The information contained on our website, or accessible thereby, is not a 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)**

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,277	\$ 23,059
Prepaid expenses and other	880	333
Total current assets	2,157	23,392
Property and equipment, net	445	213
Other assets	337	481
Other assets-equipment funding (Note 3(d))	6,763	6,763
Total assets	\$ 9,702	\$ 30,849
Liabilities and Stockholders Equity (Deficit)		
Current liabilities:		
Current portion of long-term debt	\$ 3,803	\$ 8,412
Accounts payable	2,111	1,967
Accrued expenses	3,857	2,018
Total current liabilities	9,771	12,397
Long-term debt	4,100	5,481
Total liabilities	13,871	17,878
Stockholders' equity (deficit):		
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 14,752,801 and 14,748,582 shares at September 30, 2012 and December 31, 2011, respectively	15	15
Additional paid-in capital	117,441	115,940
Deficit accumulated during the development stage	(121,625)	(102,984)
Total stockholders' equity (deficit)	(4,169)	12,971

Edgar Filing: NUPATHE INC. - Form 10-Q

Total liabilities and stockholders equity (deficit)	\$	9,702	\$	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 September 30,		Nine Months Ended September 30,		Period from	
	2012	2011	2012	2011	January 7, 2005	
					(inception) through	
					September 30, 2012	
Grant Revenue	\$	\$	\$	\$	\$ 650	
Operating expenses:						
Research and development		2,220	3,927	9,033	9,204	70,291
Acquired in-process research and development						5,500
Selling, general and administrative		3,525	3,010	8,332	7,510	32,347
Total operating expenses		5,745	6,937	17,365	16,714	108,138
Loss from operations		(5,745)	(6,937)	(17,365)	(16,714)	(107,488)
Interest income		2	17	17	58	663
Interest expense		(446)	(522)	(1,293)	(974)	(9,116)
Loss before tax benefit		(6,189)	(7,442)	(18,641)	(17,630)	(115,941)
Income tax benefit						698
Net loss		(6,189)	(7,442)	(18,641)	(17,630)	(115,243)
Basic and diluted net loss per common share	\$	(0.42)	\$	(0.51)	\$	(1.21)
Weighted average basic and diluted common shares outstanding		14,752,214	14,670,247	14,740,578	14,595,598	

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)

	Nine Months Ended September 30,		Period from
	2012	2011	January 7, 2005
			(inception) through
			September 30, 2012
Cash flows from operating activities:			
Net loss	\$ (18,641)	\$ (17,630)	\$ (115,243)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	79	53	334
Loss on asset disposal			24
Acquired in-process research and development			5,500
Stock-based compensation	1,475	831	3,823
Noncash interest expense	195	194	5,710
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(164)	922	483
Accounts payable	144	1,481	2,111
Accrued expenses	1,839	(534)	3,836
Net cash used in operating activities	(15,073)	(14,683)	(93,422)
Cash flows from investing activities:			
Purchase of in-process research and development			(5,500)
Payments under equipment funding agreement		(3,352)	(6,763)
Purchases of property and equipment	(311)	(185)	(802)
Net cash used in investing activities	(311)	(3,537)	(13,065)
Cash flows from financing activities:			
Proceeds from issuance of debt		10,000	17,500
Payment of debt issuance costs		(76)	(325)
Repayment of debt	(6,424)	(1,036)	(11,073)
Proceeds from sale of preferred stock, net			43,576
Proceeds from sale of common stock, net	26	405	43,619
Proceeds from sale of convertible notes, net			14,467
Net cash (used in) provided by financing activities	(6,398)	9,293	107,764
Net increase (decrease) in cash and cash equivalents	(21,782)	(8,927)	1,277
Cash and cash equivalents, beginning of period	23,059	38,918	
Cash and cash equivalents, end of period	\$ 1,277	\$ 29,991	\$ 1,277
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	434	532	1,425
Accretion of redeemable convertible preferred stock			9,948
Cash paid for interest	964	643	3,056

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, including neurological and psychiatric disorders. 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 \$121,625 as of September 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 September 30, 2012, the Company had \$1,277 of cash and cash equivalents and a working capital deficit of \$7,614. On October 23, 2012, the Company completed a sale of securities resulting in net proceeds to the Company of approximately \$26,254 (the October 2012 Financing) (see footnote 5d for additional information regarding the October 2012 Financing).

Management estimates that the Company's cash and cash equivalents as of September 30, 2012 plus the \$26,254 of net proceeds from the October 2012 Financing will be sufficient to fund debt service and interest obligations and continue operations into the fourth quarter of 2013. Additional capital will be needed by the Company to fund its debt service and interest obligations 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 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).

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.

Table of Contents

(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 \$1,114 and \$22,144 at September 30, 2012 and December 31, 2011, respectively. The Company had no Level 2 or Level 3 fair value instruments at September 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, Zecuity. The Company made 14 monthly installments to LTS that commenced in June 2010, according to an agreed upon payment schedule. As of September 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 have been paid in full. Amounts capitalized under the LTS funding agreement will be amortized to cost of goods sold upon the commencement of commercial sales of Zecuity. If the Company were to ever cease development of Zecuity, 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 Zecuity for the Company. The equipment funding agreement will remain in effect until the later of the

Edgar Filing: NUPATHE INC. - Form 10-Q

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.

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

	2012	September 30, 2011
Shares underlying outstanding options to purchase common stock	2,911,632	1,604,426
Shares of unvested restricted stock		16,000
Shares underlying outstanding warrants to purchase common stock	200,268	200,268

Table of Contents

(4) Capital Facilities

(a) Term Loan Facility and Vendor Debt

Term Loan Facility

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 Loan's 39-month term; principal payments commenced in June 2011. As discussed below, in September 2012, the Term Loan Facility was amended to provide for reduced principal payments through June 2013, followed by straight line amortization through June 2014. At September 30, 2012, the balance of the Term A Loans was \$2,037 with \$1,286 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%. The interest rate of the Term A Loans at September 30, 2012 was 11.50%. In connection with the Term A Loans, the lenders received 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. These warrants were cancelled and replaced in October 2012, as discussed below.

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 below, in amendments to the Term Loan Facility on August 13 and September 25, 2012 this requirement was 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 June 2011 amendment, the Company received \$10,000 of Term B Loans. The Company was required to make interest-only payments for the first six months of the Term B Loans 26-month term; principal payments commenced in January 2012. As discussed below, in September 2012, the Term Loan Facility was amended to provide for reduced principal payments through June 2013, followed by straight line amortization through June 2014. At September 30, 2012, the balance of the Term B Loans was \$5,500 with \$2,151 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 interest rate of the Term B Loans at September 30, 2012 was 11.50%. 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. These warrants were cancelled and replaced in October 2012, as discussed below.

On August 13, 2012 and September 25, 2012, the Company entered into amendments to the Term Loan Facility, which, among other things:

- reduced the minimum unrestricted cash balance that the Company is required to maintain from \$3,000 to \$1,000;
- reduced the monthly principal payments under the Term Loan Facility from \$685 to \$230 upon completion of the October 2012 Financing through June 30, 2013, after which the principal balance will amortize straight-line through June 2014; and
- temporarily eliminated the prepayment fee under the Term Loan Facility if certain conditions are met through January 16, 2013.

As consideration for these amendments, the Company paid an amendment fee of \$82 to the lenders upon the closing of the

Table of Contents

October 2012 Financing and is required to pay an additional \$300 (for a total of \$600) in final interest payment at the maturity of the facility in June 2014. The Company also issued warrants to purchase 188,426 shares of common stock (at an exercise price of \$2.00 per share) to the lenders in connection with the October 2012 Financing, and canceled warrants to purchase 91,609 shares of common stock that were previously issued to the lenders.

Vendor Debt

In August and September 2012, the Company entered into two short-term agreements with third party vendors to finance insurance premiums. The amount originally financed under the agreements was \$434. These notes mature in March and April 2013 and bear interest at rates ranging from 3.65% to 4.75%. As of September 30, 2012 the balance of these short-term loans was \$366, which is included in the current portion of long term debt on the Company's balance sheet.

(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 September 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. As of September 30, 2012 this facility is not available to the Company as a source of liquidity as there is not a current Form S-1 on file with the SEC, as required under the terms of the Purchase Agreement.

(5) Stockholders' Equity

(a) Warrants

As of September 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		

Edgar Filing: NUPATHE INC. - Form 10-Q

In addition, as discussed in footnote 5d, in connection with the October 2012 Financing, the Company issued warrants to purchase 14,000,000 shares of common stock at an exercise price of \$2.00 per share. These warrants have a five year term and become exercisable six months after issuance. The exercise price of the warrants is subject to antidilution price protection, such that, in the event the Company issues shares of common stock or securities convertible into shares of common stock, at an effective price per share less than the exercise price of the warrants then in effect, the exercise price shall be reduced to the effective price per share for such additional shares of common stock. This antidilution feature of the warrants will terminate concurrently with the automatic conversion of the Series A Preferred Stock. As discussed in footnote 4a, in connection with an amendment to the Company's Term Loan Facility, in October 2012 the Company issued warrants to purchase 188,426 shares of common stock at an exercise price of \$2.00 per share with a five year term, and canceled warrants to purchase 91,609 shares of common stock that had been previously issued to the lenders. Beginning in the fourth quarter of 2012, all of the warrants issued in connection with the October 2012 Financing as well as the warrants issued under the recent modifications to the Term Loan Facility will be classified as liabilities for accounting purposes at their estimated fair value while subject to antidilution protection. Changes in that estimated fair value will be reflected in the Company's statement of operations. A portion of the proceeds, equal to the estimated fair value of the warrants, will be recognized as a liability with the remainder allocated to equity. This allocation, as well as the difference between the fair value of the Company's common stock and the conversion price of the Series A Preferred Stock constitute a beneficial conversion feature which will have the effect of increasing net loss applicable to common shareholders.

(b) Stock Options

The Company is authorized to grant shares of common stock under the NuPathe Inc. 2010 Omnibus Incentive Compensation Plan (the 2010 Plan), which was approved in July 2010 and amended and restated effective April 11, 2011. As of January 2012, there were 2,975,385 total shares authorized under the 2010 Plan. As of September 30, 2012, there were 2,173,442 incentive and non-qualified stock options and no shares of restricted stock outstanding under the 2010 Plan, as well as 738,190 non-qualified stock options that were granted outside of the 2010 Plan, as discussed below. At September 30, 2012 there were 696,758 shares of common

Table of Contents

stock available for future grants under the 2010 Plan.

The following is a summary of all stock option activity for the nine months ended September 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	1,515,487	3.46		
Exercised	(15,219)	1.73		
Cancelled/forfeited	(372,921)	6.46		
Outstanding at September 30, 2012	2,911,632	3.60	8.20	\$ 2,071
Vested and expected to vest at September 30, 2012	2,801,294	3.63	8.15	\$ 2,016
Exercisable at September 30, 2012	1,266,827	3.19	6.60	\$ 1,661

Of the 1,515,487 stock options that were granted during the nine months ended September 30, 2012, 105,709 were granted to certain directors pursuant to an election by such directors to receive all or a portion of their director fees in stock options.

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 \$3.56 as of September 30, 2012.

Stock-based compensation expense related to stock options for the nine months ended September 30, 2012 and 2011 was \$1,456 and \$819, respectively. As of September 30, 2012, there was \$3,530 of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.3 years.

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 recorded \$380 of non-cash expense related to the modification of previously awarded equity-based awards.

On July 25, 2012, the Company entered into an Employment Agreement with Armando Anido to serve as chief executive officer of the Company. 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 options are included in the above table as granted during 2012. These Initial Options have a ten-year term and will vest and become exercisable as follows: 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 the Company's Zecuity product and the first commercial sale of Zecuity. The Initial Options have an aggregate fair value of \$2,040 that will be recognized as expense over the

vesting term of the options.

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.

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 nine months ended September 30, 2012.

Table of Contents

Weighted- average fair value of stock options granted	\$	2.45
Assumptions Used:		
Risk-free interest rate		0.64 - 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 nine months ended September 30, 2012:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested shares at December 31, 2011	16,000	\$ 7.73
Granted		
Vested	(5,000)	
Forfeited/repurchased	(11,000)	7.73
Nonvested shares at September 30, 2012		\$

Stock-based compensation expense related to restricted stock for the nine months ended September 30, 2012 and 2011 was \$19 and \$12, respectively. There is no unrecognized compensation expense related to unvested restricted stock.

(d) October 2012 Financing

On September 25, 2012, the Company entered into a Securities Purchase Agreement (the Purchase Agreement) with certain qualified institutional purchasers and individual investors (each, an Investor and, collectively, the Investors), pursuant to which the Company sold units of the Company's securities (the Units) to the Investors for an aggregate purchase price of \$28,000 (the October 2012 Financing). The October 2012 Financing closed on October 23, 2012 and resulted in net proceeds to the Company of approximately \$26,254. The per Unit purchase price for the Units was \$2.00 and each Unit consisted of one one-thousandth (1/1,000) of a share of the Company's newly designated Series A Preferred Stock, par value \$0.001 per share (the Series A Preferred Stock), and a warrant to purchase one share of the Company's common stock, par value

Edgar Filing: NUPATHE INC. - Form 10-Q

\$0.001 per share, at an exercise price of \$2.00 per share (the Warrants). Under the Purchase Agreement, the Company issued 14,000,000 Units representing 14,000 shares of Series A Preferred Stock and warrants to purchase 14,000,000 shares of common stock.

The holders of the Series A Preferred Stock are entitled to receive cumulative dividends at a rate per annum of 8% of \$2.00 per 1/1,000 of a share of Series A Preferred Stock (which rate shall increase to 12% if the Company has not obtained approval by the United States Food and Drug Administration (the FDA) of the Company's Zecuity product on or before June 30, 2013). Upon the liquidation, sale or merger of the Company, each holder of Series A Preferred Stock is entitled to receive for each 1/1,000 of a share owned by such holder an amount equal to the greater of (i) \$2.00, plus all accrued but unpaid dividends and interest, and (ii) the amount such holder would have received if such 1/1,000 of a share had been converted to common stock immediately prior to such event.

Each 1/1,000 of a share of Series A Preferred Stock is convertible, at the holder's option, into such number of shares of common stock equal to (i) \$2.00 divided by the conversion price then in effect (which conversion price is initially equal to \$2.00), plus (ii) an amount equal to all accrued but unpaid dividends on such fractional share divided by the closing price of Common Stock on the trading day immediately preceding the date of conversion, unless the Company has elected to pay the dividend amount in cash upon conversion. The conversion price of the Series A Preferred Stock is subject to antidilution price protection such that, in the event the Company issues shares of Common Stock or securities convertible into shares of Common Stock at an effective per share price less than the conversion price then in effect, the conversion price shall be reduced to the effective price per share for such additional

Table of Contents

shares of Common Stock. This antidilution feature of the Series A Preferred Stock will terminate concurrently with the automatic conversion of the Series A Preferred Stock.

The shares of Series A Preferred Stock will automatically convert into shares of common stock upon (i) the consent of the holders of a majority of the shares of the Series A Preferred Stock, (ii) the conversion of the majority of shares of the Series A Preferred Stock, or (iii) the second to occur of (A) FDA approval of the Company's Zecuity product and (B) consummation of a financing, licensing, partnership or other corporate collaboration resulting in gross proceeds to the Company of at least \$22 million.

The Warrants have 5 year terms and are exercisable commencing six months from the date of issuance, and may be exercised by paying the exercise price of \$2.00 per share, or pursuant to a cashless exercise. See note 5a for discussion related to the accounting for the Warrants.

(6) Other Events

Reduction in Work Force

On September 25, 2012, the Company reduced its workforce by eliminating 15 full-time equivalent positions. In connection with the separation of these employees, the Company agreed to pay severance in the form of continued salary and medical benefits. As of September 30, 2012, the Company has recorded \$708 for accrued separation payments as well as accrued but unused vacation owed to the separated employees. None of these amounts have been paid as of September 30, 2012. These amounts are reflected in operating expenses (both R&D and SG&A).

Resignation of Ms. Hollingsworth

As previously discussed, 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 a Consulting Agreement with Ms. Hollingsworth. In connection with the Severance Agreement, the Company recorded approximately \$1,172 in severance expense during the three months ending September 30, 2012, which includes \$380 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. As of September 30, 2012 the remaining balance of the severance accrual was \$758.

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. As of September 30, 2012 there was \$100 included in accrued liabilities related to this Consulting Agreement.

(7) Subsequent Events

On October 23, 2012, the Company closed the October 2012 Financing. This financing, which is described more fully in footnote 5(d), resulted in approximately \$26,254 of net proceeds to the Company.

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 Form 10-Q; 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, Zecuity (also referred to as Zelrix, NP101 and our migraine patch), is an active, single-use transdermal sumatriptan patch that we are developing for the treatment of migraine. Zecuity uses our proprietary SmartRelief technology. If approved, Zecuity will be the first and only transdermal patch indicated for the treatment of migraine. Following approval in the U.S., we plan to secure a commercial partner and build our own specialty sales force to maximize the commercial opportunity for Zecuity. We also intend to seek partners to market Zecuity outside of 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 partners for further development of NP201 and NP202.

We submitted a NDA for Zecuity 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 questions remain that preclude the FDA from approving the NDA in its present form. In the CRL, the FDA acknowledged that the efficacy of Zecuity in the overall migraine population was established. The CRL primarily contained chemistry, manufacturing and safety questions. We resubmitted a NDA for Zecuity on July 16, 2012, which we believe addresses the questions raised by the FDA in its CRL. 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 17, 2013 for completing its review of the NDA. If approved in January 2013, we expect that the commercial launch of Zecuity would occur in the fourth quarter of 2013.

Since our inception, we have invested a significant portion of our efforts and financial resources in the development of Zecuity. Zecuity 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 nine months ended September 30, 2012 and September 30, 2011 was \$18.6 million and \$17.6 million, respectively. As of September 30, 2012, we had an accumulated deficit of \$121.6 million. 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 Zecuity and our other product candidates. If we obtain marketing approval for Zecuity, we will incur significant sales, marketing, manufacturing and distribution expenses.

Capital Resources and Liquidity

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 September 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 \$7.5 million was outstanding as of September 30, 2012. Additionally, on October 23, 2012, we completed a sale of Series A Preferred Stock and common stock warrants resulting in net proceeds of \$26.3 million (the October 2012 Financing).

Our principal sources of liquidity are cash and cash equivalents. As of September 30, 2012, we had \$1.3 million of cash and cash equivalents and a working capital deficit of \$7.6 million. On October 23, 2012, we completed the October 2012 Financing resulting in net proceeds of \$26.3 million. We are required to maintain a minimum unrestricted cash balance of \$1.0 million under our Term Loan Facility.

We believe that our cash and cash equivalents as of September 30, 2012 plus the \$26.3 million of net proceeds from the October 2012 Financing will be sufficient to meet our debt service and interest obligations and continue operations into the fourth quarter of 2013. We will require additional capital to meet our debt service and interest obligations and fund operations beyond that point. Factors that may require us to expend more or less capital prior to such time include, among others:

- the timing and outcome of the FDA's review of our NDA resubmission for Zecuity, including the extent to which the FDA may request or require us to provide additional information or undertake additional trials or studies or redesign Zecuity;

Table of Contents

- the cost, scope and timing of activities undertaken to prepare for commercialization of Zecuity;
- 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 Zecuity and our other product candidates.

To meet our capital needs, we regularly explore and evaluate equity financings, debt financings, corporate collaboration and licensing arrangements, and other capital-raising transactions. However, 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 and the holders of our Series A Preferred Stock may prevent our issuance of securities with equal or superior rights, preferences or privileges to those of the Series A Preferred Stock, prevent the sale, license or other divestiture of material assets and prevent us from obtaining additional debt financing.

If we are able to obtain additional capital 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 corporate collaboration or 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 capital when needed, 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.

These factors raise substantial doubt about the Company's ability to continue as a going concern. 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 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.

Recent Developments

October 2012 Financing

On September 25, 2012, we entered into a Securities Purchase Agreement (the Purchase Agreement) with certain qualified institutional purchasers and individual investors (each, an Investor and, collectively, the Investors), pursuant to which we sold units of our securities (the Units) to the Investors for an aggregate purchase price of \$28.0 million (the October 2012 Financing). The per Unit purchase price for the Units was \$2.00, and each Unit consisted of one one-thousandth (1/1,000) of a share of our newly-designated Series A Preferred Stock, par value \$0.001 per share (the Series A Preferred Stock), and a warrant (the Warrants) to purchase one share of the our common stock, par value \$0.001 per share (Common Stock), at an exercise price of \$2.00 per share. We completed the October 2012 Financing on October 23, 2012 and received net proceeds of \$26.3 million.

As required by the Purchase Agreement, on November 2, 2012, we filed with the SEC a registration statement covering the resale of 125% of the number of shares of Common Stock issuable upon conversion of the Series A Preferred Stock or exercise of the

Table of Contents

Warrants purchased by the Investors and certain other shares of Common Stock held by the Investors as of the date of the Purchase Agreement. We are required to use commercially reasonable efforts to cause such registration statement to be declared effective within 105 days of the closing of the October 2012 Financing and to remain effective during the periods specified in the Purchase Agreement. If we breach our obligations to have the registration statement declared effective or remain effective then we will be obligated to pay to the Investors liquidated damages in certain circumstances. Such liquidated damages are capped at 10% of the Registrable Securities Value (as defined in the Purchase Agreement).

Series A Preferred Stock

The terms, rights and privileges of the Series A Preferred Stock are set forth in the Certificate of Powers, Designations, Preferences Rights and Qualifications, Limitations or Restrictions of Series A Preferred Stock (the Certificate of Designation) that we filed with the Delaware Secretary of State.

The holders of the Series A Preferred Stock are entitled to receive cumulative dividends at a rate per annum of 8% of \$2.00 per 1/1,000 of a share of Series A Preferred Stock (which rate shall increase to 12% if Zecuity has not been approved by the FDA on or before June 30, 2013). Upon our liquidation, sale or merger, each holder of Series A Preferred Stock is entitled to receive for each 1/1,000 of a share owned by such holder an amount equal to the greater of (i) \$2.00, plus all accrued but unpaid dividends and interest, and (ii) the amount such holder would have received if such 1/1,000 of a share had been converted to Common Stock immediately prior to such event.

The holders of the Series A Preferred Stock are entitled to vote as a single class with the holders of the Common Stock, with each 1/1,000 of a share of Series A Preferred Stock having the right to 0.461 votes. The holders of the Series A Preferred Stock, voting together as a single class, are entitled to elect a number of directors (the Series A Directors) equal to (A) the total number of directors on the board multiplied by (B) a fraction, the numerator of which is the total number of votes that the holders of the shares of Series A Preferred Stock are entitled to cast with respect to such shares of Series A Preferred Stock, and the denominator of which is the total number of votes that may be cast by all of the holders of the Common Stock and the Series A Preferred Stock, voting together as a single class, and (C) rounded up to the next whole number. The holders of the Series A Preferred Stock were initially entitled to elect three Series A Directors. Pursuant to the terms of the Purchase Agreement, the Investors delivered irrevocable proxies to Quaker BioVentures II, L.P. and Safeguard Delaware, Inc. (the Lead Investors) to empower the Lead Investors to vote for the individuals to be designated by such Lead Investors as the Series A Directors. On October 23, 2012, James Datin, Richard Kollender and Brian Sisko were appointed to serve on our Board of Directors as Series A Directors .

Each 1/1,000 of a share of Series A Preferred Stock is convertible, at the holder's option, into such number of shares of Common Stock equal to (i) \$2.00 divided by the conversion price then in effect (which conversion price is initially equal to \$2.00), plus (ii) an amount equal to all accrued but unpaid dividends on such fractional share divided by the closing price of Common Stock on the trading day immediately preceding the date of conversion, unless we elect to pay the dividend amount in cash upon conversion. The conversion price of the Series A Preferred Stock is subject to antidilution price protection such that, in the event we issue shares of Common Stock or securities convertible into shares of Common Stock at an effective per share price less than the conversion price then in effect, the conversion price shall be reduced to the effective price per share for such additional shares of Common Stock.

The shares of Series A Preferred Stock will automatically convert into Common Stock upon:

Edgar Filing: NUPATHE INC. - Form 10-Q

- the consent of the holders of a majority of the shares of the Series A Preferred Stock;
- the conversion of the majority of shares of the Series A Preferred Stock; or
- the second to occur of (A) FDA approval of Zecuity and (B) consummation of a financing, licensing, partnership or other corporate collaboration resulting in gross proceeds to the Company of at least \$22 million.

For so long as any shares of Series A Preferred Stock are outstanding, the vote or consent of the holders of a majority of the then outstanding shares of Series A Preferred Stock is required to approve:

- any change in the rights or preferences of the Series A Preferred Stock;
- any increase in the authorized number of shares of Series A Preferred Stock;
- the creation or issuance of any securities senior or pari passu to the Series A Preferred Stock;
- any liquidation, sale or merger transaction;
- any exclusive license of Zecuity;

Table of Contents

- any increase in the amount of our indebtedness in excess of \$9,000,000;
- any prepayment of indebtedness;
- any issuance of equity compensation to employees or consultants outside of our equity incentive plan; or
- any dividend on the Common Stock.

Warrants

The Warrants entitle the holder thereof to purchase one share of Common Stock at a price of \$2.00 per share. The exercise price of the Warrants is subject to antidilution price protection such that, in the event the we issue shares of Common Stock or securities convertible into shares of Common Stock at an effective per share price less than the exercise price then in effect, the exercise price shall be reduced to the effective price per share for such additional shares of Common Stock. The antidilution feature of the Warrants will terminate concurrently with the automatic conversion of the Series A Preferred Stock. The Warrants have five year terms and become exercisable commencing six months from the date of issuance, and may be exercised by paying the exercise price of \$2.00 per share, or pursuant to a cashless exercise.

The Warrants will be classified as liabilities for accounting purposes at their estimated fair value while subject to antidilution protection. Changes in that estimated fair value will be reflected in the Company's statement of operations. A portion of the proceeds, equal to the estimated fair value of the warrants, will be recognized as a liability with the remainder allocated to equity. This allocation, as well as the difference between the fair value of the Company's common stock and the conversion price of the Series A Preferred Stock constitute a beneficial conversion feature which will have the effect of increasing net loss applicable to common shareholders.

Cost-Containment Measures

In connection with the October 2012 Financing, we undertook certain cost containment measures in order to focus our expenditures on gaining FDA approval of Zecuity, securing commercial partners and select pre-launch activities. The cost containment measures include, among others:

- a reduction of 15 full-time-equivalent positions in our workforce;
- reducing expenditures relating to commercialization activities for Zecuity and our earlier stage product candidates;

Edgar Filing: NUPATHE INC. - Form 10-Q

- delaying the filing of an Investigational New Drug application for NP202 until a co-development partner is obtained; and
- amendment to our Term Loan Facility to restructure our outstanding indebtedness thereunder, as discussed below.

During the three months ended September 30, 2012, we recorded \$0.7 million for accrued separation payments related to the reduction in our workforce.

Amendment to Term Loan Facility

On September 25, 2012, we entered into a Third 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 us and the Lenders, as amended by that certain First Loan Modification Agreement, dated June 13, 2011, and that certain Second Loan Modification Agreement, dated August 13, 2012 (the Term Loan Facility), to, among other things:

- delay the due date of the principal amount owing on October 1, 2012 until the closing of the October 2012 Financing;
- reduce the amount of the monthly principal payments owing under the Term Loan Facility to \$0.2 million through June 30, 2013, after which such principal payments will reflect a straight line amortization schedule ending on the maturity date, which was amended to be June 1, 2014;

Table of Contents

- eliminate the prepayment fee under the Term Loan Facility if all amounts owing are prepaid on or before January 16, 2013;
- reduce the minimum unrestricted cash balance that the Company is required to maintain from \$3.0 million to \$1.0 million; and
- include as an event of default the failure to receive marketing approval of Zecuity from the FDA on or before June 30, 2013, which date may be extended to the earlier of September 30, 2013 and the date on which we cease to have unrestricted cash in an amount greater than 1.25 times the aggregate outstanding principal amount under the Term Loan Facility.

All other provisions of the Term Loan Facility are unchanged by the Amendment and remain in full force and effect. As consideration for this Amendment, we paid an amendment fee of \$0.08 million to the Lenders upon the closing of the October 2012 Financing and an incremental \$0.3 million (for a total of \$0.6 million) in final interest payment will be due at the maturity of the facility in June 2014. We also were required to issue warrants to purchase 188,426 shares of common stock to the Lenders in connection with the October 2012 Financing and also canceled warrants to purchase 91,609 shares of common stock that were previously issued to the Lenders. The new warrants contain the same terms, including anti-dilution protection, as the warrants issued as part of the October 2012 Financing.

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

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

	Three months Ended		2011	Increase/(Decrease)	
	2012	September 30, (in thousands)			
Clinical development	\$	229	\$	800	\$(571) (71)%
Chemistry, manufacturing and controls (CMC)		697		1,533	(836) (55)
Regulatory and quality assurance		145		70	75 107
Medical affairs		26		191	(165) (86)
Compensation and related		1,031		1,176	(145) (12)
Facilities and related		92		157	(65) (41)
	\$	2,220	\$	3,927	\$(1,707) (43)

Edgar Filing: NUPATHE INC. - Form 10-Q

Research and development expenses decreased by \$1.7 million to \$2.2 million in the three months ended September 30, 2012 from \$3.9 million in the three months ended September 30, 2011. The significant variances from period to period, by area of research and development, are as follows:

Clinical development

- During the third quarter of 2012, we incurred \$0.6 million less related to clinical development compared to the third quarter of 2011. This decrease is primarily comprised of:
 - \$0.6 million incurred during the 2011 period for the conclusion of a Zecuity open-label study, as well as the execution of a bioequivalence study during the third quarter of 2011.
 - \$0.07 million incurred during the 2011 period for clinical development work related to NP201 and NP202 which did not recur during the 2012 period.
 - The 2011 amounts discussed above were partially offset by expenses incurred during the third quarter of 2012 related to the response to the CRL, which we submitted in July 2012.

Chemistry, manufacturing and controls (CMC)

- During the third quarter of 2012, we incurred \$0.8 million less related to CMC expenses compared to the third quarter of 2011. This decrease is primarily comprised of:

Table of Contents

- The third quarter of 2011 included \$0.4 million for the purchase of materials and components for the manufacture of Zecuity supplies, compared to \$0.1 million incurred during the third quarter of 2012. The higher amounts incurred in 2011 were driven by the anticipated approval of our NDA.
- The third quarter of 2011 included an incremental \$0.5 million of expense with our primary Zecuity manufacturer related to manufacturing scale up and production of clinical supplies.
- As a result of focused efforts on Zecuity during the 2012 period, we did not incur any expenses for CMC related to NP201 or NP202, whereas in the third quarter of 2011 we incurred a total of \$0.08 million for CMC on these two projects.

Regulatory and quality assurance

- Expenses for regulatory and quality assurance increased by \$0.1 million in 2012 due to the July 2012 resubmission of the Zecuity NDA.

Medical affairs

- Expenses for medical affairs decreased by \$0.2 million in 2012 as we focused our resources on the resubmission of the Zecuity NDA.

Compensation and related

- Compensation and related expenses are personnel related expenses, including salaries and benefits, which we do not allocate to specific programs. The third quarter of 2012 was \$0.2 million lower than the same period in 2011 due to lower headcount during 2012, partially offset by \$0.2 million accrued for separation payments incurred during the three months ended September 30, 2012. The 2011 period also included \$0.2 million for higher recruiting and bonus expense compared to the 2012 period.

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

	Three months Ended		September 30,		Increase/(Decrease)		
	2012	(in thousands)	2011				
Zecuity	\$	1,043	\$	2,371	\$	(1,328)	(56)%
NP201				37		(37)	(100)
NP202		55		186		(131)	(70)

Edgar Filing: NUPATHE INC. - Form 10-Q

General development	1,122	1,333	(211)	(16)
	\$ 2,220	\$ 3,927	\$ (1,707)	(43)

Zecuity expenses for the three months ended September 30, 2012 were \$1.0 million, compared to \$2.4 million for the same period in 2011. As discussed above, the 2011 period included a bioequivalence study as well as the conclusion of an open label study which, together, were approximately \$0.6 million during the third quarter of 2011. Additionally, 2011 included significantly higher CMC related expense for the production of clinical supplies and manufacturing scale-up. Regulatory and quality assurance expenses for Zecuity were \$0.1 million higher during the 2012 period due to fees incurred in connection with the July 2012 resubmission of the NDA. All other Zecuity expenses were lower during the 2012 period due to cost containment efforts during the third quarter of 2012. The lower expenses in 2012 for NP201 and NP202 result from focusing our resources on the resubmission of the Zecuity NDA, as well as cost containment efforts. 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 decrease shown for general development expenses is primarily related to reduced research and development headcount during the 2012 period, partially offset by \$0.2 million accrued for separation payments incurred during the three months ended September 30, 2012. The 2011 period also included \$0.2 million for higher recruiting and bonus expense compared to the 2012 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$0.5 million to \$3.5 million in the three months ended September 30, 2012 from \$3.0 million for the three months ended September 30, 2011. The higher 2012 expense is due, in large part, to the accrual of \$1.2 million related to the separation of our former CEO in July 2012. This amount includes \$0.8 million for severance and benefits and \$0.4 million of non-cash stock compensation expense related to modifications made to stock options upon the CEO's separation. The third quarter of 2012 also includes \$0.5 million accrued for separation payments incurred in September 2012. These

Table of Contents

amounts in the third quarter of 2012 are partially offset by lower expenses of \$1.1 million in the area of commercial operations as we curtailed these activities while we focused our resources on the resubmission of the Zecuity NDA.

Interest Expense

Interest expense was \$0.5 million in the three months ended September 30, 2012, which is consistent with the three months ended September 30, 2011.

Nine months Ended September 30, 2012 compared to the Nine months Ended September 30, 2011

Research and Development Expense

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

	Nine months Ended September 30,		2011	Increase/(Decrease)	
	2012	(in thousands)			
Clinical development	\$	1,222	\$	2,092	\$ (870) (42)%
Chemistry, manufacturing and controls (CMC)		3,966		4,491	(525) (12)
Regulatory and quality assurance		270		(1,301)	1,571 (121)
Medical affairs		96		593	(497) (84)
Compensation and related		3,173		2,912	261 9
Facilities and related		306		417	(111) (27)
	\$	9,033	\$	9,204	\$ (171) (2)

Research and development expenses decreased by \$0.2 million to \$9.0 million in the nine months ended September 30, 2012 from \$9.2 million in the nine months ended September 30, 2011. The 2011 period includes 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 nine months ended September 30, 2012 were \$1.7 million less than the nine months ended September 30, 2011, as explained below:

Clinical development

- During the nine months ended September 30, 2012, we incurred \$0.9 million less related to clinical development compared to the same 2011 period, due primarily to:

Edgar Filing: NUPATHE INC. - Form 10-Q

- As we focused our efforts on the Zecuity NDA resubmission during the 2012 period, we incurred minimal expense for the development of NP201 or NP202, a reduction of \$0.5 million compared to the 2011 period.
- Expenses incurred for Zecuity clinical studies during the 2012 period were \$0.5 million less than the 2011 period. While 2012 included \$0.7 million expenses for the completion of several Zecuity clinical studies conducted to address questions raised in the FDA's CRL, during the 2011 period we incurred \$1.2 million to finalize an open label study and conduct a bioequivalence study.

Chemistry, manufacturing and controls (CMC)

- During the nine months ended September 30, 2012, we incurred \$0.5 million less related to CMC compared to the same period in 2011 comprised of:
 - CMC expenses decreased in 2012 primarily due to \$0.4 million incurred in the 2011 period related to development activities for NP201 and NP202 that did not recur in 2012 as we focused efforts on Zecuity.
 - The 2012 decrease is also partially related to a \$0.2 million decrease in CMC activities for Zecuity. The 2011 period included expenses for manufacturing scale-up and the production of clinical supplies for Zecuity, whereas the 2012 expenses were incurred to address questions raised in the CRL, as well as for continued development of Zecuity.

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 slightly higher during the 2012 period due to fees incurred in connection with the resubmission of our Zecuity NDA in July 2012.

Table of Contents*Medical affairs*

- Expenses for Zecuity medical affairs decreased by \$0.5 million in 2012 as we focused our resources on the submission of NDA.

Compensation and related

- Compensation and related expenses are personnel related expenses, including salaries and benefits, which we do not allocate to specific programs. The 2012 period was \$0.3 million higher than the same period in 2011. The 2012 period included a few key research and development positions that were not included in the 2011 period, as well as \$0.2 million in separation payments incurred in September 2012. These 2012 increases were partially offset by the fact that the 2011 period included \$0.2 million for higher recruiting and bonus expense compared to the 2012 period.

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

	Nine months Ended		September 30,		Increase/(Decrease)	
	2012	(in thousands)	2011			
Zecuity	\$	5,417	\$	4,887	\$	530
NP201				552		(100)
NP202		137		437		(300)
General development		3,479		3,328		151
	\$	9,033	\$	9,204	\$	(171)
						11%

Zecuity expenses for the nine months ended September 30, 2012 were \$5.4 million, compared to \$4.9 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, Zecuity expenses were \$6.4 million for the nine months ended September 30, 2011, compared to \$5.4 million for the 2012 period. The decrease from 2011 to 2012, as explained above, results primarily from lower CMC and clinical expenses. The lower expenses in 2012 for NP201 and NP202 result from focusing our 2012 resources on Zecuity and the resubmission of the 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 period includes a few key research and development positions that were not included in the 2011 period, as well as \$0.2 million in separation payments incurred in September 2012. These 2012 increases were partially offset by the fact that the 2011 period included higher recruiting and higher bonus expense than the 2012 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$0.8 million to \$8.3 million in the nine months ended September 30, 2012 from \$7.5 million for the nine months ended September 30, 2011. The higher 2012 expense is due primarily to the accrual of \$1.2 million related to the

Edgar Filing: NUPATHE INC. - Form 10-Q

separation of our former CEO in July 2012. This amount includes \$0.8 million for severance and benefits and \$0.4 million of non-cash stock compensation expense related to modifications made to stock options upon the CEO's separation. The 2012 period also includes higher salaries and personnel related expenses in the commercial operations area as well as \$0.5 million accrued for separation payments incurred in September 2012. The 2012 amounts are partially offset by savings of \$1.9 million in the area of commercial operations as we curtailed these activities while we focused our resources on the resubmission of the Zecuity NDA.

Interest Expense

Interest expense increased to \$1.3 million in the nine months ended September 30, 2012, from \$1.0 million in the nine months ended September 30, 2011. The increase results primarily from the Term B Loans obtained under the Term Loan Facility in June 2011, as well as a \$0.1 million amendment fee incurred in August 2012 related to the Term Loan Facility.

Cash Flow Analysis

Net cash used in operating activities for the nine months ended September 30, 2012 was \$15.0 million, primarily related to activities to address questions raised in the CRL, continued development of Zecuity, and spending for normal operating activities. During the nine months ended September 30, 2012, we used \$0.3 million of cash in investing activities and \$6.4 million for financing activities primarily related to contractual debt repayments.

Table of Contents

Net cash used in operating activities for the nine months ended September 30, 2011 was \$14.7 million, primarily the result of spending for the continued development and scale-up of Zecuity, activities related to commercial operations as we prepared for the launch of Zecuity, and normal operating activities. Cash used for investing activities during the nine months ended September 30, 2011 was \$3.5 million, almost solely for the purchase of equipment related to the commercial manufacture of Zecuity. Cash provided by financing activities during the nine months ended September 30, 2011 was \$10.0 million of debt proceeds and \$0.4 million of net proceeds from the sale of common stock, partially offset by contractual debt repayments of \$1.0 million and offering costs of \$0.1 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 nine months ended September 30, 2012.

Future Payments Under Contractual Obligations

During the nine month period ended September 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 and 2013, of which \$0.3 million has been paid as of September 30, 2012.

On July 25, 2012, we entered into a severance agreement and consulting agreement with our former CEO, Jane Hollingsworth. Under the terms of the severance agreement, beginning in September 2012 and continuing for eighteen months, we expect to make aggregate payments of approximately \$0.8 million, of which \$0.03 million was paid by September 30, 2012. Such payments encompass severance, earned bonus and continued medical coverage. Under the terms of the consulting agreement, we expect to make aggregate payments of \$0.1 million, of which \$0.01 million has been paid as of September 30, 2012.

Additionally, in August and September 2012 we entered into two amendments to our Term Loan Facility. The terms of the amendments have, among other things, reduced the minimum cash balance that we are required to maintain from \$3.0 million to \$1.0 million. As consideration for these amendments, the Company has agreed to pay an amendment fee of approximately \$0.08 million and an additional \$0.3 million (for a total of \$0.6 million) in final interest payments due at the maturity of the loan, which is June 2014.

On September 25, 2012, the Company reduced its workforce by eliminating 15 full-time equivalent positions. In connection with the separation of these employees, the Company has agreed to pay severance in the form of continued salary and medical benefits. As of September 30, 2012, the Company has recorded \$0.7 million for accrued separation payments as well as accrued but unused vacation owed to the separated

employees. None of these amounts have been paid as of September 30, 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.

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.

Table of Contents

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.

PART II. OTHER INFORMATION

Item 1A. Risk Factors.

Our business is subject to substantial risks and uncertainties. You should carefully consider each of the risk factors set forth under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2011. The risk factor set forth below supplements those risk factors. The occurrence of any one or more of these risks could materially harm our business, operating results, financial condition and prospects. These risks and uncertainties could also cause actual results to differ materially from those expressed or implied by forward-looking statements that we make from time to time (please read the "Cautionary Note Regarding Forward-Looking Statements" appearing at the beginning of this Form 10-Q).

Certain rights granted to the holders of our Series A Preferred Stock may make it more difficult for other stockholders to influence significant corporate decisions and may hinder a change of control.

Certain terms of our Series A Preferred Stock may make it more difficult for other stockholders to influence significant corporate decisions. For example, the holders of our Series A Preferred Stock:

- are entitled to elect three directors to our Board of Directors;
- can prevent our issuance of securities with equal or superior rights, preferences or privileges to those of the Series A Preferred Stock;
- can prevent the payment of dividends;
- can prevent the sale or other divestiture of material assets; and

- can prevent a change in control of our company.

These rights (and all other rights and privileges relating to the Series A Preferred Stock) may adversely affect the value (or perceived value) of our shares of common stock.

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: November 9, 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		Filing Date	Filed Herewith
			File No.	Exhibit		
4.1	Certificate of Powers, Designations, Preferences, Rights and Qualifications, Limitations or Restrictions of Series A Preferred Stock	8-K	001-34836	99.2	September 26, 2012	
10.1	Securities Purchase Agreement, dated September 25, 2012, among NuPathe Inc. and the investors named therein	8-K	001-34836	99.1	September 26, 2012	
10.2	Form of Common Stock Warrant	8-K	001-34836	99.3	September 26, 2012	
10.3	Third Loan Modification Agreement, dated September 25, 2012, among NuPathe Inc., MidCap Funding III, LLC and Silicon Valley Bank	8-K	001-34836	99.1	September 26, 2012	
10.4	Employment Agreement, dated July 25, 2012, between Armando Anido and NuPathe Inc.	8-K	001-34836	99.1	July 30, 2012	
10.5	Amended and Restated Employment Agreement, dated July 25, 2012, between Terri B. Sebree and NuPathe Inc.	8-K	001-34836	99.2	July 30, 2012	
10.6	Amended and Restated Employment Agreement, dated July 25, 2012, between Bart J. Dunn and NuPathe Inc.	8-K	001-34836	99.3	July 30, 2012	
10.7	Amended and Restated Employment Agreement, dated July 25, 2012, between Keith A. Goldan and NuPathe Inc.	8-K	001-34836	99.4	July 30, 2012	
10.8	Amended and Restated Employment Agreement, dated July 25, 2012, between Michael F. Marino and NuPathe Inc.	8-K	001-34836	99.5	July 30, 2012	
10.9	Amended and Restated Employment Agreement, dated July 25, 2012, between Gerald W. McLaughlin and NuPathe Inc.	8-K	001-34836	99.6	July 30, 2012	
10.10	Severance Agreement and Release of Claims, dated July 25, 2012, between Jane H. Hollingsworth and NuPathe Inc.	8-K	001-34836	99.7	July 30, 2012	
10.11	Consulting Agreement, dated July 25, 2012, between Jane H. Hollingsworth and NuPathe Inc.	8-K	001-34836	99.8	July 30, 2012	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 (a) under the Securities Exchange Act of 1934, as					X

adopted pursuant to Section 302 of the
Sarbanes-Oxley Act of 2002

Table of Contents

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.