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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2011

OR

o 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)

Delaware	**20-2218246**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification number)
227 Washington Street Suite 200 Conshohocken, Pennsylvania	**19428**
(Address of principal executive offices)	(Zip Code)

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

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 x No o

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

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 o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of April 28, 2011, the number of shares outstanding of the registrant s common stock, $0.001 par value, was 14,566,332.

Table of Contents

NUPATHE INC.

Form 10-Q for the Quarter Ended March 31, 2011

Table of Contents

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:

- our plans to develop and commercialize Zelrix and our other product candidates;
- the timing of, and our ability to obtain, marketing approval of Zelrix and our other product candidates;
- the timing of our anticipated commercial launch of Zelrix and our other product candidates;
- our ongoing and planned preclinical studies, clinical trials and regulatory submissions;
- our commercialization and marketing capabilities;
- future expenses and capital requirements;
- the sufficiency of our cash and cash equivalents to fund our operations and capital requirements into the expected commercial launch of Zelrix in the first half of 2012; and
- our ability to raise additional capital in sufficient amounts or on terms acceptable to us;

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

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

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

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NUPATHE INC.

(A Development-Stage Company)

Balance Sheets

(Unaudited)

	March 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 32,767,606	$ 38,918,332
Prepaid expenses and other current assets	2,113,442	1,007,774
Total current assets	34,881,048	39,926,106
Property and equipment, net	111,823	98,266
Other assets	297,744	318,218
Other assets-equipment funding (Note 3(d))	3,946,224	3,410,315
Total assets	$ 39,236,839	$ 43,752,905
Liabilities and Stockholders Equity		
Current liabilities:		
Current portion of long-term debt	$ 1,938,980	$ 1,512,867
Accounts payable	1,680,093	1,198,177
Accrued expenses	1,652,398	3,073,017
Total current liabilities	5,271,471	5,784,061
Long-term debt	3,148,148	3,703,704
Total liabilities	8,419,619	9,487,765
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 14,560,332 and 14,549,461 shares at March 31, 2011 and December 31, 2010, respectively	14,560	14,549
Additional paid-in capital	114,321,819	114,046,923
Deficit accumulated during the development stage	(83,519,159)	(79,796,332)
Total stockholders equity	30,817,220	34,265,140
Total liabilities and stockholders equity	$ 39,236,839	$ 43,752,905

See accompanying notes to unaudited financial statements.

Table of Contents

NUPATHE INC.

(A Development-Stage Company)

Statements of Operations

(Unaudited)

	Three Months Ended March 31,		Period from January 7, 2005 (inception) through March 31, 2011
	2011	2010	
Grant Revenue	$	$	$ 649,959
Operating expenses:			
Research and development	1,574,018	3,389,917	50,425,427
Acquired in-process research and development			5,500,000
Selling, general and administrative	1,970,230	873,018	16,569,257
	(3,544,248)	(4,262,935)	(72,494,684)
Loss from operations	(3,544,248)	(4,262,935)	(71,844,725)
Interest income	24,004	767	597,514
Interest expense	(202,583)	(11,254)	(6,542,806)
Loss before tax benefit	(3,722,827)	(4,273,422)	(77,790,017)
Income tax benefit		320,381	651,400
Net loss	(3,722,827)	(3,953,041)	$ (77,138,617)
Accretion of redeemable convertible preferred stock		(1,033,399)	
Net loss available to common stockholders	$ (3,722,827)	$ (4,986,440)	
Basic and diluted net loss per common share	$ (0.26)	$ (13.06)	
Weighted average basic and diluted common shares outstanding	14,553,748	381,842	

See accompanying notes to unaudited financial statements.

Table of Contents

NUPATHE INC.

(A Development-Stage Company)

Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31,		Period from January 7, 2005 (inception) through March 31, 2011
	2011	2010	
Cash flows from operating activities:			
Net loss	$ (3,722,827)	$ (3,953,041)	$ (77,138,617)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	14,511	11,373	191,985
Loss on asset disposal			23,508
Acquired in-process research and development			5,500,000
Stock-based compensation	254,035	66,580	1,386,731
Noncash interest expense	53,755	(7,211)	5,278,891
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(1,112,026)	90,965	(1,644,603)
Accounts payable	481,916	98,801	1,680,093
Accrued expenses	(1,447,542)	629,039	1,704,400
Net cash used in operating activities	(5,478,178)	(3,063,494)	(63,017,612)
Cash flows from investing activities:			
Purchase of in-process research and development			(5,500,000)
Payments under equipment funding agreement	(535,909)		(3,946,224)
Purchases of property and equipment	(28,068)	(20,000)	(327,315)
Net cash used in investing activities	(563,977)	(20,000)	(9,773,539)
Cash flows from financing activities:			
Proceeds from issuance of debt			7,608,741
Payment of debt issuance costs			(248,358)
Repayment of debt	(129,443)	(253,852)	(3,052,975)
Proceeds from sale of preferred stock, net			43,576,007
Proceeds from sale of common stock	20,872	3,038	43,208,659
Proceeds from sale of convertible notes			14,466,683
Net cash (used in) provided by financing activities	(108,571)	(250,814)	105,558,757
Net increase (decrease) in cash and cash equivalents	(6,150,726)	(3,334,308)	32,767,606
Cash and cash equivalents, beginning of period	38,918,332	3,926,574	
Cash and cash equivalents, end of period	$ 32,767,606	$ 592,266	$ 32,767,606
Supplemental cash flow disclosures:			
Noncash investing and financing activities:			
Conversion of note principal and accrued interest to redeemable convertible preferred stock	$	$	$ 4,547,366
Conversion of note principal and accrued interest to common stock			10,337,009

Conversion of redeemable convertible preferred stock into common stock			58,071,686
Reclassification of warrant liability			1,112,819
Accretion of redeemable convertible preferred stock		1,033,399	9,948,311
Cash paid for interest	148,827	20,628	1,132,574

See accompanying notes to unaudited financial statements.

Table of Contents

NuPathe Inc.

(A Development-stage Company)

Notes to Unaudited Financial Statements

(1) Background

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

(2) Development-Stage Risks and Liquidity

The Company has incurred losses and negative cash flows from operations since inception and has accumulated a deficit during the development stage of $83,519,159 as of March 31, 2011. 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 $32,767,606 as of March 31, 2011 will be sufficient to sustain operations into the first half of 2012. Additional financing will be needed by the Company to fund its operations and the commercialization of its products beyond that point. There is no assurance that such financing will be available when needed or on acceptable terms.

The Company is subject to those risks associated with any 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, 2010filed with the SEC, which includes annual audited financial statements as of and for the year ended December 31, 2010.

(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 current assets, 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 and cash equivalents of $32,271,838 and $38,770,210 at March 31, 2011 and December 31, 2010, respectively. The Company had no Level 2 or Level 3 fair value instruments at March 31, 2011 or December 31, 2010.

(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 Zelrix, the Company s primary product candidate. The Company has agreed to make installment payments to LTS, in the aggregate amount of 5,370,000 in 14 monthly installments that commenced in June 2010, according to an agreed upon payment schedule. As of March 31, 2011, 3,040,250, or $3,946,224 based on exchange rates in effect at the time the payments were made, had been paid and has been recorded as a noncurrent asset in the accompanying balance sheet. Amounts capitalized under the LTS funding agreement will be amortized to cost of goods sold upon the commencement of commercial sales of Zelrix.

LTS will own the purchased equipment and will be responsible for its routine and scheduled maintenance and repair and will be required to use the purchased equipment solely to manufacture Zelrix. 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, the previously outstanding shares of Series A Convertible Preferred Stock (Series A) and Series B Convertible Preferred Stock (Series B), 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 March 31, 2011 and 2010, as they would be anti-dilutive:

	March 31,	
	2011	**2010**
Shares of redeemable convertible preferred stock		6,624,704
Shares issuable pursuant to redeemable convertible preferred stock accretion		1,044,762
Shares underlying outstanding options to purchase common stock	1,455,834	940,084
Shares of unvested restricted stock		8,887
Shares underlying outstanding warrants to purchase stock *	140,520	108,659

Table of Contents

* The 2010 amounts represents warrants to purchase preferred stock, the 2011 amounts represent warrants to purchase common stock

(f) Recently Issued Accounting Standards

In January 2010, the FASB issued Accounting Standards Update (ASU) 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements (ASU 2010-06), which amends the existing fair value measurement and disclosure guidance currently included in Accounting Standards Codification (ASC) Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, ASU 2010-06 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition, ASU 2010-06 also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. The adoption of ASU 2010-06 did not impact the Company s unaudited financial statements.

(4) Credit Facility

In May 2010, the Company executed a term loan facility with lenders to fund working capital requirements (the May 2010 Loan Facility). The Company s obligations under the May 2010 Loan Facility are secured by a lien on all of the Company s assets, excluding intellectual property, which is subject to a negative pledge. Upon execution of the May 2010 Loan Facility, the Company received $5,000,000 of loan proceeds. The May 2010 Loan Facility provides for interest-only payments for the first twelve months of the loans 39-month term; therefore at March 31, 2011, the balance of this loan was $5,000,000, with $1,851,852 of that amount being classified as current. The loan bears interest at an annual rate of LIBOR plus 8.75%, subject to a LIBOR floor of 3.00%. In connection with the loan, the lenders received warrants to purchase 255,376 shares of Series B at $0.93 per share, which, upon the Company s initial public offering (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 $204,224 has been recorded as deferred financing costs and will be amortized to interest expense through the maturity date of the debt. As a result of the completion of the Company s IPO in August 2010, an additional $6,000,000 of funding is available to the Company under the May 2010 Loan Facility, subject to final approval from the lenders. The Company is required to issue additional warrants to purchase up to 38,235 shares of common stock in the event that such additional loan proceeds are received from the lenders.

Table of Contents

(5) Stockholders Equity

(a) Warrants

All outstanding warrants to purchase shares of preferred stock converted into warrants to purchase an equal number of shares of common stock, subject to the Company s reverse stock split, upon completion of the IPO in August 2010. As of March 31, 2011, the following warrants to purchase common stock were outstanding:

	Number of Shares	Exercise Price	Expiration
Common Stock	140,520	$ 7.45	2016 through 2020

(b) Stock Options

Under the Company s 2010 Omnibus Incentive Compensation Plan (the 2010 Plan), as approved by the stockholders of the Company, qualified and nonqualified stock options and stock awards may be granted to employees, non-employee directors and consultants and advisors who provide services to the Company. On January 3, 2011, an additional 499,070 shares were made available under the plan pursuant to its evergreen provision bringing the total shares authorized under the 2010 Plan to 2,237,956. As of March 31, 2011, the Company has granted incentive and non-qualified stock options and restricted stock under this plan. At March 31, 2011 there were 704,932 shares available for future grants under the 2010 Plan.

The following is a summary of stock option activity for the three months ended March 31, 2011:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2011	1,415,106	$ 4.22		
Granted	51,599	7.76		
Exercised	(10,871)	1.92		
Cancelled/forfeited				
Outstanding at March 31, 2011	1,455,834	4.36	7.83	$ 5,702,662
Vested and expected to vest at March 31, 2011	1,455,834	4.36	7.83	$ 5,702,662
Exercisable at March 31, 2011	674,154	1.85	7.11	$ 4,014,711

The aggregate intrinsic value is based on the Company s stock closing price of $7.81, as of March 31, 2011, that would have been received by the option holders had all option holders exercised their options as of that date.

Stock-based compensation expense related to stock options for the three months ended March 31, 2011 and 2010 was $254,035 and $66,580, respectively. As of March 31, 2011, there was $3,287,519 of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.5 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, 2011.

Weighted- average fair value of stock options granted	$	5.50
Assumptions Used:		
Risk-free interest rate		2.24 2.65%
Expected life in Years		5 6 years
Expected volatility		83.7- 84.1%
Dividend Yield		0%

Table of Contents

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 and dividend yield 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.

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 2010 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 2010 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, Zelrix, is an active, single-use transdermal sumatriptan patch that we are developing for the treatment of migraine. Zelrix uses our proprietary SmartRelief technology. We submitted a New Drug Application (NDA) for Zelrix to the U.S. Food and Drug Administration (FDA) on October 29, 2010. The NDA s Prescription Drug User Fee Act (PDUFA) date, the target date for the FDA to complete its review of the NDA, is August 29, 2011. Subject to the approval of our NDA, we plan to build our own specialty sales force in the U.S. to launch Zelrix. 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 expect to submit an Investigational New Drug Application (IND) to the FDA in the first half of 2011 for NP201 and in 2012 for NP202.

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 Zelrix. Zelrix 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, 2011 and March 31, 2010 was $3.7 million and $5.0 million, respectively. As of March 31, 2011, we had an accumulated deficit of $83.5 million.

We have funded our operations to date primarily with the proceeds of the sale of common stock, convertible preferred stock, preferred stock warrants, convertible notes and borrowings under credit facilities. From inception through March 31, 2011, we have received net proceeds of $101.3 million from the sale of common stock, convertible preferred stock, preferred stock warrants and convertible notes.

Liquidity and Capital Resources

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval for, and the eventual commercialization of, Zelrix and our other products candidates. If we obtain marketing approval for Zelrix, we will incur significant sales, marketing and manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

Our principal sources of liquidity are cash and cash equivalents of $32.8 million as of March 31, 2011. In addition, we may request an additional $6.0 million in funding through May 2011 under the credit facility we entered into in May 2010 (the May 2010 Loan Facility). Any such request for additional funding would be subject to our compliance with the terms of the May 2010 Loan Facility, including the continued accuracy of our representations and warranties contained therein, and is at the lenders sole discretion. This facility has a scheduled maturity date in August 2013 and is secured by substantially all of our assets, excluding intellectual property, which is subject to a negative pledge prohibiting the granting of liens thereon to any third party.

We believe that our existing cash and cash equivalents will be sufficient to fund our operations and capital requirements into the expected commercial launch of Zelrix in the U.S. in the first half of 2012. However, changing circumstances may cause us to spend

Table of Contents

more cash than currently expected. We will require additional financing to fund our operations and the commercialization of Zelrix beyond the first half of 2012.

Our future capital needs and the adequacy of our available funds will depend on many factors, including:

- The outcome of the FDA s review of the NDA for Zelrix;
- The cost, scope and timing of activities undertaken to prepare for commercialization of Zelrix;
- The extent to which the FDA may require us to perform additional clinical trials for Zelrix;
- The cost of purchasing manufacturing and other capital equipment for our product candidates;
- The scope, progress, results and costs of development for our other 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 product candidates.

When additional funds are required or we elect to raise additional funds, we may raise such funds from time to time through public or private sales of equity or debt securities or from bank or other loans. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially and adversely impact our growth plans and our financial condition or results of operations. The terms of any such financing may involve significant cash payment obligations and covenants that restrict our ability to operate our business. Additionally, equity financing, if available, may be dilutive to the holders of our common stock.

Results of Operations

Three Months Ended March 31, 2011 compared to the Three Months Ended March 31, 2010

Research and Development Expense

Research and development expense for the three months ended March 31, 2011 and 2010 were comprised of the following:

Clinical development	$ 644	$ 1,565	$ (921)	(59)%
Regulatory and quality assurance	(1,469)	104	(1,573)	(1,512)
Compensation and related	800	673	127	19
	$ 1,574	$ 3,390	$ (1,816)	(54)

Research and development expenses decreased by $1.8 million to $1.6 million in the three months ended March 31, 2011 from $3.4 million in the three months ended March 31, 2010. The primary reason for the decrease is a $1.5 million reduction related to a waiver of the NDA filing fee that we had paid to the FDA in the fourth quarter of 2010. At the time of payment, we expensed the full amount of the filing fee, $1.5 million. In March 2011, we received notice from the FDA that we qualified for a one-time waiver and that we would be receiving a refund of the $1.5 million filing fee during the second quarter of 2011. As a result, we reversed the previously expensed amount of $1.5 million and have classified the amount due back from the FDA as a current asset on our balance sheet as of March 2011. Exclusive of this one-time expense reduction, our research and development expenses for the three months ended March 31, 2011 were $3.1 million, a 9% decrease from the three months ended March 31, 2010. Clinical development expenses decreased by $0.9 million during the 2011 period as a result of two long-term, open label Zelrix clinical studies that were both ongoing during the three months ended March 31, 2010, but had either completed or were nearing completion during the three months ended March 31, 2011.

Table of Contents

Also contributing to the decrease in clinical development expenses was the initiation, during the first half of 2010, of two pharmacokinetic trials and a tolerability trial for Zelrix that were ongoing during the three months ended March 31, 2010, but had completed by the end of 2010. Reduced spending on our Zelrix clinical development program was partially offset by higher development expenses incurred in the first quarter of 2011for our product candidate NP201. Manufacturing expense increased by $0.3 million to $1.2 million during the three months ended March 31, 2011 compared to $0.9 million during the same period in 2010. Approximately $0.2 million of this increase related to formulation development activities for NP201 and NP202. The balance of the increase for manufacturing expenses relates to our manufacturing scale up for Zelrix. Towards the end of 2010, we began to expand the medical affairs function within the Company, which resulted in $0.2 million of expense in the three months ended March 31, 2011. Higher compensation and related expenses were attributable to incremental headcount as well as annual salary increases for research and development personnel and higher healthcare benefit premiums.

Research and development expenses by program for the three months ended March 31, 2011 and 2010 were as follows:

	Three Months Ended March 31,			
	2011	2010	Increase/(Decrease)	
	(in thousands)			
Zelrix	$ 244	$ 2,541	$ (2,297)	(90)%
NP201	268	70	198	283
NP202	123		123	n/a
General development	939	779	160	21
	$ 1,574	$ 3,390	$ (1,816)	(54)

Zelrix expenses for the three months ended March 31, 2011 were $0.2 million, compared to $2.5 million for the same period in 2010. As discussed above, the decrease is due primarily to the reversal of $1.5 million of Zelrix-related expense for the refund of the NDA filing fee. Exclusive of the $1.5 million reduction, Zelrix expenses were $1.8 million for the three months ended March 31, 2011, compared to $2.5 million for the same period in 2010. The decrease from 2010 to 2011, as explained above, results primarily from the fact that our clinical development program for Zelrix was much more active in the first quarter of 2010 compared to the same period in 2011. The lower clinical development expenses in 2011 were partially offset by higher medical affairs and manufacturing expenses during the three months ended March 31, 2011. The 2011 increase in NP201 and NP202 expenses relates to the expansion of development activities for these programs. 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 2011 increase shown for general development expenses is primarily related to incremental headcount as well as annual salary increases for research and development personnel and higher healthcare benefit premiums.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $2.0 million in the three months ended March 31, 2011 from $0.9 million for the three months ended March 31, 2010. In part this increase resulted from the continued building of the infrastructure needed as a public company and increased expenses related to being a public company, such as increased public accounting expense, board of directors fees and higher stock-based compensation expense. Additionally, during the first quarter of 2011 we incurred significantly more expense, as compared to the first quarter of 2010, related to the growth of our commercial operations as we continue to prepare for the launch of Zelrix, such as public relations, market research and other consulting. We also incurred higher personnel costs in the three months ended March 31, 2011 resulting from increased headcount, salary increases and higher healthcare benefit premiums compared to the 2010 period.

Interest Expense

Interest expense increased by $0.2 million in the three months ended March 31, 2011 from $11,000 in the three months ended March 31, 2010. The increase results primarily from our borrowings under the May 2010 Loan Facility.

Income Tax Benefit

We recognized an income tax benefit of $0.3 million in the three months ended March 31, 2010 related to the sale of Pennsylvania research and development tax credits to third party buyers. There was no income tax benefit recognized during the 2011 period.

Table of Contents

Cash Flow Analysis

Net cash used in operating activities for the three months ended March 31, 2011 was $5.5 million, primarily the result of spending for our continued development of Zelrix and the related activities for commercial operations as we prepare for the launch of Zelrix. Also significantly contributing to the first quarter operating expenses are the higher expenses incurred to operate as a public company, such as higher general and administrative headcount and higher consulting and professional fees. 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 Zelrix. For the three months ended March 31, 2011, we made contractual debt repayments of $0.1 million, which was partially offset by approximately $21,000 in proceeds from the exercise of stock options during the first quarter of 2011.

Net cash used in operating activities for the three months ended March 31, 2010 was $3.1 million primarily related to the progress of our Phase III clinical program for Zelrix during the first quarter of 2010. Cash used in investing activities for the purchase of property and equipment was $20,000 in the three months ended March 31, 2010 and cash used in financing activities was $0.3 million for the three months ended March 31, 2010 for scheduled debt repayments.

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, 2010. There have been no changes to our critical accounting policies during the three months ended March 31, 2011.

Future Payments Under Contractual Obligations

During the three month period ended on March 31, 2011, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those specified in our 2010 Annual Report.

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 3. Quantitative and Qualitative Disclosures About Market Risk

There have not been any material changes to the Company s market risk during the quarter ended March 31, 2011. For additional information regarding the Company s market risk, refer to Item 7A. Quantitative and Qualitative Disclosure About Market Risk of our 2010 Annual Report.

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 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 1A. Risk Factors.

There have been no material changes in our risk factors as previously disclosed in Item 1.A of our 2010 Annual Report.

Table of Contents

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. From the Effective Date through March 31, 2011, we have used the net proceeds from the IPO as follows:

- approximately $8.8 million for further clinical development, manufacturing development, and preparation and submission of an NDA for Zelrix;

- approximately $1.3 million for the further preclinical development of NP201 and NP202; and

- approximately $4.5 million for salaries and related personnel expenses for research and development and administrative personnel and approximately $2.5 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. The remainder of the net proceeds have been invested into money market accounts. 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, 2011

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	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.1	NuPathe Inc. Non-employee Director Compensation Policy	10-K	001-34836	10.26	March 18,2011	
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					*

* Furnished herewith.