NUPATHE INC.
Form 10-Q
November 14, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from _____ to_____

Commission file number 001-34836

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 R No £

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

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

Large accelerated filer £	Accelerated filer £	Non-accelerated filer R (Do not check if a smaller reporting company)	Smaller reporting company £

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

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

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NUPATHE INC.

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

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

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

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NUPATHE INC.

(A Development-Stage Company)

Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	September 30, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 29,991	$ 38,918
Prepaid expenses and other current assets	610	1,008
Total current assets	30,601	39,926
Property and equipment, net	230	98
Other assets	547	319
Other assets-equipment funding (Note 3(d))	6,763	3,410
Total assets	$ 38,141	$ 43,753
Liabilities and Stockholders Equity		
Current liabilities:		
Current portion of long-term debt	$ 7,174	$ 1,513
Accounts payable	2,679	1,198
Accrued expenses	2,608	3,073
Total current liabilities	12,461	5,784
Long-term debt	7,537	3,704
Total liabilities	19,998	9,488
Stockholders equity:		
Preferred stock, $0.001 par value. Authorized 10,000,000 shares. None issued and outstanding	-	-
	15	15

Common stock, $0.001 par value. Authorized 90,000,000 shares; issued and outstanding 14,748,582 and 14,549,461 shares at September 30, 2011 and December 31, 2010, respectively					
Additional paid-in capital		115,554			114,047
Deficit accumulated during the development stage		(97,426)			(79,797)
Total stockholders equity		18,143			34,265
Total liabilities and stockholders equity		$ 38,141			$ 43,753

See accompanying notes to unaudited financial statements.

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NUPATHE INC.

(A Development-Stage Company)

Statements of Operations

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from January 7, 2005 (inception) through
	2011	2010	2011	2010	September 30, 2011
Grant Revenue	$	$	$	$	$ 650
Operating expenses:					
Research and development	3,927	5,191	9,204	11,849	58,055
Acquired in-process research and development					5,500
Selling, general and administrative	3,010	1,320	7,510	3,138	22,109
Total operating expenses	(6,937)	(6,511)	(16,714)	(14,987)	(85,664)
Loss from operations	(6,937)	(6,511)	(16,714)	(14,987)	(85,014)
Interest income	17	19	58	24	632
Interest expense	(522)	(2,093)	(974)	(3,539)	(7,314)
Loss before tax benefit	(7,442)	(8,585)	(17,630)	(18,502)	(91,696)
Income tax benefit				320	651
Net loss	(7,442)	(8,585)	(17,630)	(18,182)	$ (91,045)
Accretion of redeemable convertible preferred stock	( )	(467)	( )	(2,533)	
Net loss available to common stockholders	$ (7,442)	$ (9,052)	$ (17,630)	$ (20,715)	
Basic and diluted net loss per common share	$ (0.51)	$ (1.01)	$ (1.21)	$ (6.30)	
Weighted average basic and diluted common shares outstanding	14,670,247	9,003,135	14,595,598	3,287,694	

See accompanying notes to unaudited financial statements.

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NUPATHE INC.

(A Development-Stage Company)

Statements of Cash Flows

(Unaudited)

(in thousands, except share and per share data)

	Nine Months Ended September 30,		Period from January 7, 2005 (inception) through
	2011	**2010**	**September 30, 2011**
Cash flows from operating activities:			
Net loss	$ (17,630)	$ (18,182)	$ (91,045)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	53	34	229
Loss on asset disposal			24
Acquired in-process research and development			5,500
Stock-based compensation	831	343	1,963
Noncash interest expense	194	3,310	5,419
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	922	526	499
Accounts payable	1,481	(121)	2,679
Accrued expenses	(534)	2,516	2,618
Net cash used in operating activities	(14,683)	(11,574)	(72,114)
Cash flows from investing activities:			
Purchase of in-process research and development			(5,500)
Payments under equipment funding agreement	(3,352)	(2,531)	(6,763)
Purchases of property and equipment	(185)	(33)	(484)
Net cash used in investing activities	(3,537)	(2,564)	(12,747)
Cash flows from financing activities:			
Proceeds from issuance of debt	10,000	5,000	17,500
Payment of debt issuance costs	(76)	(174)	(324)
Repayment of debt	(1,036)	(860)	(3,960)
Proceeds from sale of preferred stock, net			43,576
Proceeds from sale of common stock, net	405	42,975	43,593
Proceeds from sale of convertible notes, net		10,063	14,467
Net cash provided by financing activities	9,293	57,004	114,852
Net increase (decrease) in cash and cash equivalents	(8,927)	42,866	29,991
Cash and cash equivalents, beginning of period	38,918	3,927	
Cash and cash equivalents, end of period	$ 29,991	$ 46,793	$ 29,991
Supplemental cash flow disclosures:			
Noncash investing and financing activities:			
	$	$	$ 4,547

Conversion of note principal and accrued interest to redeemable convertible preferred stock					
Conversion of note principal and accrued interest to common stock				10,337	10,337
Conversion of redeemable convertible preferred stock into common stock				58,071	58,071
Reclassification of warrant liability				1,113	1,113
Fair value of warrants issued in connection with loan facility	272				272
Accretion of redeemable convertible preferred stock				2,533	9,948
Financing arrangement with third party vendors	532			386	1,121
Cash paid for interest	643			229	1,627

See accompanying notes to unaudited financial statements.

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NuPathe Inc.

(A Development-stage Company)

Notes to Unaudited Financial Statements

Amounts are in thousands, except share and per share data

(1) Background

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

(2) Development-Stage Risks and Liquidity

The Company has incurred losses and negative cash flows from operations since inception and has accumulated a deficit during its development-stage of $97,426 as of September 30, 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 $29,991 as of September 30, 2011 will be sufficient to sustain operations into the second 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 emerging biopharmaceutical 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, 2010 filed 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.

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(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 equivalents of $29,676 and $38,770 at September 30, 2011 and December 31, 2010, respectively. The Company had no Level 2 or Level 3 fair value instruments at September 30, 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 the Company s primary product candidate, NP101 (also known as Zelrix and our migraine patch). The Company agreed to make 14 monthly installments to LTS that commenced in June 2010, according to an agreed upon payment schedule. As of September 30, 2011, 4,970, or $6,763 based on exchange rates in effect at the time the payments were made, has been recorded as a noncurrent asset in the accompanying balance sheet. All amounts owed under this funding agreement have been paid in full as of September 30, 2011. Amounts capitalized under the LTS funding agreement will be amortized to cost of goods sold upon the commencement of commercial sales of NP101. If the Company were ever to cease development of NP101, amounts capitalized under this agreement would be immediately expensed.

LTS owns the purchased equipment and is responsible for its routine and scheduled maintenance and repair and is required to use the purchased equipment solely to manufacture NP101. 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, if any. 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, 2011 and 2010, as they would be anti-dilutive to the computations of net loss per common share:

	September 30,	
	2011	**2010**
Shares underlying outstanding options to purchase common stock	1,604,426	1,323,063
Shares of unvested restricted stock	16,000	----
Shares underlying outstanding warrants to purchase common stock	200,268	140,520

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(f) Recently Issued Accounting Standards

In June 2011, the FASB issued Accounting Standards Update 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05), which amends the presentation requirements of Comprehensive Income. Specifically, the FASB has decided to eliminate the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The amendment requires that all non-owner changes in stockholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 is effective for interim and annual reporting periods ending after December 15, 2011. The provisions of ASU 2011-05 should be applied retrospectively and early adoption is permitted. The Company does not expect the adoption of ASU 2011-05 to have a significant impact on the Company s financial statements.

(4) Credit Facility and Vendor Debt

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 prohibiting the granting of liens thereon to any third party. Upon execution of the May 2010 Loan Facility, the Company received $5,000 of loan proceeds (Term A Loans). The Company was required to make interest-only payments for the first twelve months of the Term A Loan s 39-month term; therefore at September 30, 2011, the balance of the Term A Loans was $4,259, with $2,222 of that amount being classified as current. The Term A Loans originally bore interest at an annual rate of LIBOR plus 8.75%, subject to a LIBOR floor of 3.00%. In June 2011, the interest rate was reduced to an annual rate of LIBOR plus 8.50%, subject to a LIBOR floor of 3.00%, in accordance with the amendment discussed below. In connection with the Term A Loans, 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 has been recorded as deferred financing costs and will be amortized to interest expense through the maturity date of the Term A Loans. As a result of the completion of the Company s IPO in August 2010, an additional $6,000 of funding became available to the Company under the May 2010 Loan Facility (Term B Loans).

In June 2011, the Company and the lenders amended the May 2010 Facility to:

- increase the amount of Term B Loans available to the Company from $6,000 to $10,000;

- require the Company to maintain at least $3,000 of unrestricted cash, which cash requirement shall expire after the occurrence of an equity event resulting in unrestricted cash proceeds to the Company of at least $15,000; and

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

Concurrently with the amendment, the Company received $10,000 of Term B Loans (representing the total amount of Term B Loans available to the Company under the amended facility). The Company is required to make interest-only payments for the first six months of the Term B

Loan s 26-month term; therefore at September 30, 2011, the balance of the Term B Loans was $10,000 with $4,500 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%. In connection with the Term B Loans, the lenders received warrants to purchase 59,748 shares of common stock at $7.95 per share. The fair value of the warrants at the date of issuance of $272 has been recorded as deferred financing costs and is being amortized to interest expense through the maturity date of the Term B Loans.

In August 2011, the Company entered into two short-term loan agreements with third party vendors to finance insurance premiums. The amount financed under the agreements was $532. As of September 30, 2011 the balance of these short-term loans was $452, which are required to be repaid by May 2012.

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(5) Stockholders Equity

(a) Warrants

As of September 30, 2011, the following warrants to purchase common stock were outstanding:

	Number of Shares		Exercise Price	Expiration
Common Stock Warrants	200,268	$	7.45 - $7.95	2016 through 2020

(b) Stock Options

Under the Company s 2010 Omnibus Incentive Compensation Plan, as amended and restated effective April 11, 2011 (the 2010 Plan), 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 September 30, 2011, the Company has granted incentive and non-qualified stock options and restricted stock under this plan. At September 30, 2011 there were 523,677 shares available for future grants under the 2010 Plan.

The following is a summary of stock option activity for the nine months ended September 30, 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	231,745	5.50		
Exercised	(27,534)	1.85		
Cancelled/forfeited	(14,891)	4.32		
Outstanding at September 30, 2011	1,604,426	4.45	7.79	$ 191
Vested and expected to vest at September 30, 2011	1,604,426	4.45	7.79	$ 191
Exercisable at September 30, 2011	866,860	2.52	7.01	$ 175

The aggregate intrinsic value is based on the Company s stock closing price of $2.02 as of September 30, 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 nine months ended September 30, 2011 and 2010 was $819 and $335, respectively. As of September 30, 2011, there was $2,658 of unrecognized compensation expense related to unvested stock options which is expected to be recognized over the remaining vesting period of such options, the weighted average period of which is 2.4 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 nine months ended September 30, 2011.

Weighted- average fair value of stock options granted	$3.86
Assumptions Used:	
Weighted average risk-free interest rate	1.76 %
Weighted average expected life in years	5.8 years
Weighted average expected volatility	82.5%
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

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companies as a basis for the expected volatility assumption. The Company intends to continue to consistently apply this process using comparable companies until a sufficient amount of historical information regarding the volatility 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 table summarizes the aggregate restricted stock activity for the nine months ended September 30, 2011:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested shares at January 1, 2011		$
Granted	16,000	7.73
Vested		
Forfeited/repurchased		
Nonvested shares at September 30, 2011	16,000	$ 7.73

Stock-based compensation expense related to restricted stock for the nine months ended September 30, 2011 and 2010 was $12 and $9, respectively. As of September 30, 2011, there was $111 of unrecognized compensation expense related to unvested restricted stock which is expected to be recognized over the remaining vesting period of such restricted stock, the weighted average period of which is 3.6 years.

(d) Equity Financing

On August 2, 2011, the Company entered into a common stock purchase agreement (Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital), which provides that Aspire is committed to purchase up to an aggregate of $30,000 of the Company s common stock over the term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company issued 84,866 shares of common stock to Aspire as a commitment fee in consideration for entering into the Purchase Agreement (the Commitment Shares) and the Company sold 70,721 shares of common stock to Aspire at a per share purchase price of $7.07 resulting in gross proceeds to the Company of $500 (the Initial Purchase Shares).

The Company has registered under the Securities Act of 1933 Aspire Capital s sale of the Commitment Shares, the Initial Purchase Shares and 2,746,147 additional shares that the Company may elect to sell to Aspire Capital under the Purchase Agreement. The conditions to the commencement of sales under the Purchase Agreement were satisfied on August 15, 2011. As a result, on any trading day on which the closing sale price of common stock is not less than $4.00 per share, the Company may direct Aspire Capital to purchase shares of the Company s common stock at a known per share purchase price based on prevailing market prices, using a formula as set forth in the Purchase Agreement (a Regular Purchase). The maximum number of shares that the Company may direct Aspire Capital to purchase on any trading day pursuant to a Regular Purchase is 100,000 shares or such lesser number of shares that results in an aggregate purchase price of not greater than $500.

In addition, on any trading day on which the Company directs Aspire Capital to make a Regular Purchase for the maximum number of shares set forth above, the Company may also direct Aspire Capital to purchase a number of shares of common stock equal to up to 30% of the aggregate shares of the Company s common stock traded on the NASDAQ Global Market on the next trading day (a VWAP Purchase), subject to a maximum number of shares the Company may determine and a minimum trading price, which is equal to the greater of (a) 90% of the closing price of the Company s common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set by the Company in the VWAP Purchase Notice. The per share purchase price of common stock sold to Aspire pursuant to a VWAP Purchase is equal to 95% of the volume weighted average price for such purchase date.

There are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of any sales stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as the Company directs in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties

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or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by the Company at any time, at our discretion, without any penalty or cost to the Company.

Other than the Commitment Shares and Initial Purchase Shares as referenced above, the Company did not make any sales to Aspire Capital during the three months ended September 30, 2011.

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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,*

- *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 an emerging biopharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system, including neurological and psychiatric disorders. Our most advanced product candidate, NP101 (also referred to as Zelrix and our migraine patch), is an active, single-use transdermal sumatriptan patch that we are developing for the treatment of migraine. NP101 uses our proprietary SmartRelief technology. If approved, NP101 will be the first transdermal patch indicated for the treatment of migraine. Following approval, we plan to build our own specialty sales force to launch NP101 in the U.S. and intend to seek a partner to develop and market NP101 outside the U.S.

We have two other proprietary product candidates in preclinical development that address large market opportunities, NP201 for the continuous symptomatic treatment of Parkinson s disease, which we are seeking to partner, and NP202 for the long-term treatment of schizophrenia and bipolar disorder. To accelerate the resubmission of our New Drug Application (NDA), we are shifting resources from NP202 to NP101. As a result, we expect to submit an Investigational New Drug Application (IND) for NP202 in 2013 instead of 2012, as previously planned.

We were incorporated in the State of Delaware in January 2005 and are a development stage company. Since our inception, we have invested a significant portion of our efforts and financial resources in the development of NP101. NP101 is the only product candidate for which we have conducted clinical trials, and to date we have not marketed, distributed or sold any products. As a result, we have generated no product revenue and have never been profitable. Our net loss for the nine months ended September 30, 2011 and September 30, 2010 was $17.6 million and $18.2 million respectively. As of September 30, 2011, we had an accumulated deficit of $97.4 million.

We have funded our operations to date primarily with the proceeds of the sale of common stock, convertible preferred stock, preferred and common stock warrants, convertible notes and borrowings under credit facilities. From inception through September 30, 2011, we have received net proceeds of $101.6 million from the sale of common stock, convertible preferred stock, preferred and common stock warrants and convertible notes. Since inception, we have also received $17.5 million of proceeds from venture debt.

Recent Developments

We submitted a NDA for NP101 to the FDA in October 2010. On August 29, 2011, we received a complete response letter (CRL) from the FDA regarding the NDA. A CRL is issued by the FDA when the review of an NDA is complete and questions remain that preclude the FDA from approving the NDA in its present form. On November 9, 2011, we had an End-of-Review meeting with the FDA to discuss certain questions outlined in the CRL and our approach for addressing such questions.

In the CRL, the FDA acknowledged that the efficacy of the migraine patch in the overall migraine population was established. The CRL primarily contained chemistry, manufacturing and safety questions. To address the questions raised by the FDA, we intend to complete two small Phase I trials, perform tests to collect additional chemistry data and implement a planned device enhancement to prevent NP101 from turning on in the rare event that it is applied incorrectly. At the request of the FDA, we are also developing an *in vitro* testing method that is more closely correlated to clinical data than the method that we previously submitted to the FDA. The *in vitro* test will be used to qualify newly manufactured product. See Item 1A. Risk Factors of this Form 10-Q for further discussion of the CRL.

We expect to resubmit the NDA for NP101 in the first half of 2012. We believe our resubmission will result in a six month review period under the Prescription Drug User Fee Act, which will be the target date for the FDA to complete its review of the NDA.

Liquidity and Capital Resources

Our principal sources of liquidity are cash and cash equivalents of $30.0 million as of September 30, 2011, of which $3.0 million is required to be maintained under the terms of our May 2010 Loan Facility. 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 NP101 and our other product candidates. If we obtain marketing approval for NP101, we will incur significant sales, marketing, manufacturing and distribution 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.

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We believe that our existing cash and cash equivalents will be sufficient to fund our operations and capital requirements beyond the planned resubmission of our NDA for NP101 and into the second half of 2012. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. Our future capital needs and the adequacy of our existing cash and cash equivalents will depend on many factors, including:

- our ability to successfully complete the additional trials, tests, device enhancement and other activities to support the resubmission of our NDA for NP101;

- the timing and outcome of the FDA s review of our NDA resubmission for NP101, including the extent to which the FDA may request or require us to provide additional information or undertake additional trials or studies;

- the cost, scope and timing of activities undertaken to prepare for commercialization of NP101;

- the scope, progress, results and costs of development for our 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.

We plan to raise additional funds through one or more public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives, including through sales of common stock to Aspire Capital under the Purchase Agreement discussed below. The covenants under the May 2010 Loan Facility and the pledge of our assets as collateral limit our ability to obtain additional debt financing. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms when needed, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would 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 financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Aspire Capital Purchase Agreement

On August 2, 2011, we 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 $30.0 million of our common stock over the term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 84,866 shares of common stock to Aspire Capital as a commitment fee in consideration for entering into the Purchase Agreement (the Commitment Shares and we sold 70,721 shares of common stock to Aspire Capital at a per share purchase price of $7.07 resulting in gross proceeds to us of $500,000 (the Initial Purchase Shares).

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We have registered under the Securities Act of 1933 Aspire Capital s sale of the Commitment Shares, the Initial Purchase Shares, and 2,746,147 additional shares that we may elect to sell to Aspire Capital under the Purchase Agreement. The conditions to the commencement of sales under the Purchase Agreement were satisfied on August 15, 2011. As a result, on any trading day on which the closing sale price of common stock is not less than $4.00 per share, we may direct Aspire Capital to purchase shares of Company common stock at a known per share purchase price based on prevailing market prices, using a formula as set forth in the Purchase Agreement (a Regular Purchase). The maximum number of shares that we may direct Aspire to purchase on any trading day pursuant to a Regular Purchase is 100,000 shares or such lesser number of shares that results in an aggregate purchase price of not greater than $500,000.

In addition, on any trading day on which we direct Aspire Capital to make a Regular Purchase for the maximum number of shares set forth above, we may also direct Aspire Capital to purchase a number of shares of common stock equal to up to 30% of the aggregate shares of our common stock traded on the NASDAQ Global Market on the next trading day (a VWAP Purchase), subject to a maximum number of shares as we may determine and a minimum trading price, which is equal to the greater of (a) 90% of the closing price of our common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as we may set in the VWAP Purchase Notice. The per share purchase price of common stock sold to Aspire Capital pursuant to a VWAP Purchase is equal to 95% of the volume weighted average price for such purchase date.

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any stock sales to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

Other than the Commitment Shares and Initial Purchase Shares as referenced above, we did not make any sales to Aspire Capital during the three months ended September 30, 2011.The extent to which we may utilize the Purchase Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources.

For additional information regarding the Aspire Capital Purchase Agreement, you are urged to read the Form 8-K we filed with the SEC on August 2, 2011.

Results of Operations

Three Months Ended September 30, 2011 compared to the Three Months Ended September 30, 2010

Research and Development Expense

Research and development expense for the three months ended September 30, 2011 and 2010 were comprised of the following:

	Three Months Ended September 30,			
	2011	2010	Increase/(Decrease)	
	(in thousands)			
Clinical development	$ 699	$ 1,753	$(1,054)	(60)%
Manufacturing	1,533	2,045	(512)	(25)
Regulatory and quality assurance	70	322	(252)	(78)
Medical affairs	191		191	n/a
Compensation and related	1,176	904	272	30
Facilities and related	258	167	91	54
	$ 3,927	$ 5,191	$(1,264)	(24)%

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Research and development expenses decreased by $1.3 million to $3.9 million in the three months ended September 30, 2011 from $5.2 million in the three months ended September 30, 2010. Clinical development expenses decreased by $1.1 million during the 2011 period as a result of two long-term, open label NP101 clinical trials that were both ongoing during the three months ended September 30, 2010, but had completed prior to the third quarter of 2011. 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 NP101 that were ongoing during the three months ended September 30, 2010, but had completed by the end of 2010. Partially offsetting these decreases in clinical development was the initiation of a Phase I trial to assess the pharmacokinetics of NP101 during the three months ended September 30, 2011. Manufacturing expenses decreased by $0.5 million to $1.5 million during the three months ended September 30, 2011 compared to $2.0 million during the same period in 2010. Approximately $0.3 million of this decrease was due to lower spend in formulation development for NP201. Also contributing to this decrease was manufacturing costs related to NP101 Phase III clinical supplies during the three months ended September 30, 2010 which did not exist during the same period of 2011. Partially offsetting these manufacturing decreases are increased costs incurred related to the manufacturing scale up for NP101. Regulatory and quality assurance expenses during the third quarter of 2010 were $0.3 million higher than in the third quarter of 2011. This was due to higher spend during the 2010 period for expenses related to the preparation of the NDA that we filed in 2010. Towards the end of 2010, we began to expand our medical affairs function, which resulted in $0.2 million of expense in the three months ended September 30, 2011. The $0.3 million increase during the 2011 period for compensation and related expenses is driven by incremental headcount, annual salary increases for research and development personnel, and increased stock compensation expense.

Research and development expenses by program for the three months ended September 30, 2011 and 2010 were as follows:

	Three Months Ended September 30,			
	2011	2010	Increase/(Decrease)	
	(in thousands)			
NP101	$ 2,371	$ 3,658	$(1,287)	(35)%
NP201	37	438	(401)	(92)
NP202	186	88	98	1,500
General development	1,333	1007	326	32
	$ 3,927	$ 5,191	$(1,264)	(24)%

NP101 expenses decreased by $1.3 million for the three months ended September 30, 2011 from $3.7 million for the three months ended September 30, 2010. As discussed above, the 2010 period included NP101 costs for two pharmacokinetic trials and a tolerability trial that the 2011 period did not include, as well as the 2010 expenses incurred for the manufacture of clinical supplies. Partially offsetting this savings in the third quarter of 2011 were expenses incurred for the initiation of a Phase I trial to assess the pharmacokinetics of NP101 and the continued work on NP101 manufacturing scale up. For the three months ended September 30, 2011, increased NP101 medical affairs expenses were partially offset by lower regulatory expenses related to NP101. The third quarter 2011 decrease in NP201 expenses relates to lower spend, particularly in the areas of preclinical and formulation development. The NP202 increase in 2011 relates to the expansion of development activities for this program. 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, annual salary increases for research and development personnel, and increased stock compensation expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $3.0 million in the three months ended September 30, 2011 from $1.3 million for the three months ended September 30, 2010. This higher expense during the 2011 period resulted from the increased infrastructure and expenses related to being a public company, such as increased personnel, board of director s fees and higher stock-based compensation expense. Additionally, during the third quarter of 2011 we incurred significantly more expense, as compared to the third quarter of 2010, related to the

growth of our commercial operations as we continued to prepare for the launch of NP101, such as personnel, market research expenses and consulting fees.

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Interest Expense

Interest expense decreased by $1.6 million in the three months ended September 30, 2011 from $2.1 million in the three months ended September 30, 2010. The 2010 period included $1.8 million of non-cash interest expense due to the amortization of the beneficial conversion feature related to our April 2010 Convertible Notes. By the third quarter of 2011, we no longer had outstanding convertible notes, therefore this non-cash interest item was not recurring in the 2011 period. Interest expense for the 2011 period relates to our borrowings under the May 2010 Loan Facility (Term A and Term B Loans) as well as non-cash interest expense for the amortization of the fair value of the warrants issued under these loans.***Nine Months Ended September 30, 2011 compared to the Nine Months Ended September 30, 2010***

Research and Development Expense

Research and development expense for the nine months ended September 30, 2011 and 2010 were comprised of the following:

	Nine Months Ended September 30,			
	2011	2010	Increase/(Decrease)	
	(in thousands)			
Clinical development	$ 1,806	$ 4,652	$ (2,846)	(61)%
Manufacturing	4,491	3,814	677	18
Regulatory and quality assurance	(1,301)	616	(1,917)	(311)
Medical affairs	593		593	n/a
Compensation and related	2,912	2,275	637	28
Facilities and related	703	492	211	43
	$9,204	$ 11,849	$ (2,645)	(22)%

Research and development expenses decreased by $2.6 million to $9.2 million in the nine months ended September 30, 2011 from $11.9 million in the nine months ended September 30, 2010. The primary reason for the decrease was 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 $1.5 million for the filing fee. 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. As a result, in March 2011, we reversed the previously expensed amount of $1.5 million which is classified as regulatory expense in the table above. Exclusive of this one-time expense reduction, research and development expenses would have been $10.7 million, which is a $1.1 million decrease from the 2010 period. Clinical development expenses were higher during the 2010 period as a result of a long-term, open label trial initiated in the third quarter of 2009 for NP101 as well as two pharmacokinetic trials and a tolerability trial initiated in early 2010, most of which had concluded by the beginning of 2011. These higher clinical development expenses in 2010 were offset by the initiation of a Phase I trial to assess the pharmacokinetics of NP101 during the third quarter of 2011 as well as higher nonclinical consulting expenses during the 2011 period for NP201 ($0.1 million) and NP202 ($0.1 million). Manufacturing expense increased by $0.7 million to $4.5 million during the nine months ended September 30, 2011 compared to $3.8 million during the same period in 2010. This increase mainly relates to manufacturing scale up expenses for NP101 as well as $0.2 million that had been incurred for manufacturing development of our NP202 candidate. Offsetting these 2011 increases in manufacturing are lower costs incurred during the 2011 period for the manufacture of NP101 Phase III clinical supplies. Excluding the impact of the $1.5 million NDA filing fee credit, regulatory and quality assurance expense for the first nine months of 2011 would have been $0.2 million, a decrease of $0.4 million from the 2010 period. This 2011 decrease can be attributed to the fact that the 2010 period included extensive work for the filing of our NP101 NDA, which was filed during the second half of 2010. The $0.6 million of expense for medical affairs resulted from the expansion of our medical affairs function during the first nine months of 2011. We did not have medical affairs activities during that same period in 2010 as these activities began in earnest in late 2010. The $0.6 million increase during the 2011 period for compensation and related expenses is driven by incremental research and development headcount, annual salary increases for research and development personnel, and increased stock compensation expense.

Research and development expenses by program for the nine months ended September 30, 2011 and 2010 are presented below:

	Nine Months Ended September 30,			
	2011	2010	Increase/(Decrease)	
	(in thousands)			
NP101	$ 4,887	$ 8,416	$(3,529)	(42)%
NP201	552	734	(182)	(25)
NP202	437	97	340	3,507
General development	3,328	2,602	726	28
	$ 9,204	$ 11,849	$(2,645)	(22)%

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NP101 expenses for the first nine months of 2011 decreased by $3.5 million from the first nine months of 2010. As discussed above, this decrease was due largely to one-time credit of $1.5 million resulting from the waiver by the FDA of the company s NDA submission fee. Exclusive of this $1.5 million credit, NP101 expenses would have been $6.4 million for the nine months ended September 30, 2011, a decrease of $2.0 million from the same period in 2010. As more fully explained above, the $2.0 million reduction in 2011 results from significantly lower clinical development expenses for NP101 during the 2011 period as well as lower manufacturing expenses for NP101 Phase III clinical supplies. These decreases were partially offset by higher manufacturing scale-up expenses for NP101 during the first nine months of 2011 as well as the initiation of a Phase I trial to assess the pharmacokinetics of NP101 in clinical development during the third quarter of 2011. NP201 expenses decreased to $0.6 million during the first nine months of 2011 compared to $0.7 million for the same period in 2010, primarily due to decreased formulation activities for this product offset by higher nonclinical consulting expenses. NP202 expenses increased by $0.3 million during the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 as a result of increased consultant expenses and formulation development work for this product candidate. 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 research and development headcount, annual salary increases for research and development personnel, and increased stock compensation expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $7.5 million in the nine months ended September 30, 2011 from $3.1 million for the nine months ended September 30, 2010. This increase resulted from increased expenses related to being a public company, such as increased personnel, independent auditor fees, board of director s fees and higher stock-based compensation expense. Additionally, during the first nine months of 2011 we incurred significantly more expense, as compared to the first nine months of 2010, related to the growth of our commercial operations as we continued to prepare for the launch of NP101, such as personnel, market research expenses, and consulting fees.

Interest Expense

Interest expense decreased by $2.6 million in the nine months ended September 30, 2011 from $3.5 million in the nine months ended September 30, 2010. The 2010 period included $2.6 million of non-cash interest expense due to the amortization of the beneficial conversion feature related to our April 2010 Convertible Notes and $0.3 million of non-cash interest expense for the increase in fair value of our warrant liability during the nine months ended September 30, 2010. In 2011 we no longer had outstanding convertible notes or liability classified warrants, therefore these non-cash interest items were not recurring in the 2011 period. Interest expense for the 2011 period relates to our borrowings under the May 2010 Loan Facility (Term A and Term B Loans) as well as non-cash interest expense for the amortization of the fair value of the warrants issued under these loans.

Income Tax Benefit

We recognized an income tax benefit of $320,000 in the nine months ended September 30, 2010 related to the sale of Pennsylvania research and development tax credits to a third party buyer. This benefit was not recurring in the first nine months of 2011.

Cash Flow Analysis

Net cash used in operating activities for the nine months ended September 30, 2011 was $14.7 million, primarily the result of spending for our continued development and scale up of NP101, related activities for commercial operations as we prepare for the launch of NP101, and our continued operation as a public company, such as increased headcount and higher consulting and professional fees. Cash used for investing activities during the nine months ended September 30, 2011was $3.5 million, almost solely for the purchase of equipment related to the commercial manufacture of NP101. 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.

Net cash used in operating activities for the nine months ended September 30, 2010 was $11.6 million primarily related to the progress of our Phase III clinical program for NP101 during the first nine months of 2010. Cash used in investing activities was $2.6 million in the nine months ended September 30, 2010, primarily for the purchase of equipment related to the commercial manufacture of NP101. Cash provided by financing activities during the nine months ended September 30, 2010 was $57.0 million, primarily

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related to $43.0 million of net proceeds received from our IPO as well as debt proceeds of $15.0 million. These financing activities were both partially offset by offering costs of $0.2 million and contractual debt repayments of $0.9 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 2010 Annual Report. There have been no changes to our critical accounting policies during the nine months ended September 30, 2011.

Future Payments Under Contractual Obligations

In June 2011, the Company borrowed an additional $10.0 million under the May 2010 Loan Facility (the Term B Loans). The Company is required to make interest-only payments for the first six months of the Term B Loan s 26-month term. The Term B Loans bear interest at an annual rate of LIBOR plus 8.50%, subject to a LIBOR floor of 3.00% and matures in August 2013. Principal payments on the Term B Loans are expected to be $0.0 million, $6.0 million and $4.0 million in the years ended December 31, 2011, 2012 and 2013, respectively. Interest payments on the Term B Loans are expected to be $0.5 million, $0.8 million and $0.4 million in the years ended December 31, 2011, 2012 and 2013, respectively.

In August 2011, the Company entered into two short-term loan agreements with third party vendors to finance insurance premiums. The amount financed under the agreements was $0.5 million, which is required to be repaid by May 2012.

Other than our obligations under the Term B Loans and short-term loans mentioned above, during the nine month period ended September 30, 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.

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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 September 30, 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.

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PART II. OTHER INFORMATION

Item 1A. Risk Factors.

The information presented below updates and supplements the risk factors contained in Part I, Item 1.A Risk Factors of our 2010 Annual Report and should be read in conjunction therewith. Any of the risks and uncertainties described in Part I, Item 1.A of our 2010 Annual Report, as updated below, could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, such risks and uncertainties could cause actual results to differ materially from those expressed or implied by forward-looking statements that we may make from time to time.

Our success in obtaining regulatory approval to market NP101 (also referred to as Zelrix and the migraine patch) in the U.S. depends on our ability to address the issues raised by the FDA in its complete response letter regarding our new drug application for NP101.

We are seeking to obtain regulatory approval to market NP101 in the U.S. for the treatment of migraine. We submitted a new drug application (NDA) for NP101 to the FDA in October 2010. On August 29, 2011, we received a complete response letter (CRL) from the FDA regarding the NDA. A CRL is issued by the FDA when the review of an NDA is complete and questions remain that preclude the FDA from approving the NDA in its present form. The CRL primarily contained chemistry, manufacturing and safety questions. On November 9, 2011, we had an End-of-Review meeting with the FDA to discuss certain issues outlined in the CRL and our approach for resolving such issues. Based on the End-of-Review meeting, we believe the primary outstanding issues are:

- additional characterization of the NP101 drug product to confirm uniformity of dosage. We plan to address this matter by performing tests to collect additional chemistry data;

- the development and validation of an *in vitro* testing method that is more closely correlated to clinical data than the method that we previously submitted to the FDA. The *in vitro* test will be used to qualify newly manufactured product;

- the potential for NP101 to cause administration site adverse events that result in permanent skin effects. In our Phase III clinical program, consisting of 796 patients applying approximately 10,000 NP101 patches, three subjects (0.4%) experienced significant skin irritation that resulted in a small mark on the skin. These marks occurred because the patients did not apply the patch correctly. To address this issue we have revised the NP101 patient instructions, developed patient training materials and intend to implement a device enhancement to prevent NP101 from turning on in the rare event that it is applied incorrectly;

- demonstrating that NP101 can be used correctly by patients;

- the completion of two Phase I trials, one of which is to verify the performance of our planned device enhancement and the other is a repeat of a Phase I trial that assessed the pharmacokinetics of NP101 compared to oral Imitrex because the clinical site that performed the original trial did not retain sufficient samples; and

- justification for waiver of a dermal carcinogenicity study.

We expect to resubmit the NDA for NP101 in the first half of 2012, however, the timing of such resubmission is dependent upon our ability to successfully complete the trials, tests and device enhancement discussed above and to address the other questions contained in the CRL. If we do not timely complete such trials, tests or device enhancement, or if we obtain unexpected results, our NDA resubmission may be delayed and we may incur substantial additional costs which could have a material adverse effect on our business and financial condition.

The FDA will review our resubmission to determine whether to approve NP101 for the treatment of migraine. If the FDA is not satisfied with the information we provide, the FDA may require the addition of labeling statements or other warnings or contraindications, require us to perform additional trials or studies or provide additional information in order to secure approval of NP101 or may refuse to approve our NDA. Any such requirement or refusal could have a material adverse effect on our business and financial condition.

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The FDA may require us to address additional issues which may delay, limit or preclude approval of NP101.

While we may continue our efforts to obtain and to follow FDA guidance in order to receive approval of NP101, the FDA may not agree that any new trial results or information we submit will be sufficient to support NP101 approval, or may reconsider its guidance, require more trials or studies or otherwise require additional information to justify approval. Additionally, despite the FDA s acknowledgment that the efficacy of NP101 in the overall migraine population had been established, there can be no assurance that the FDA will not come to a different interpretation of our previously submitted clinical trial data, or otherwise alter its view and conclude that NP101 is not sufficiently effective, or safe, to warrant approval.

If we fail to obtain additional financing, we may not be able to complete development of and commercialize NP101 or any other product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- seek marketing approval for NP101 and complete any additional development activities that may be required by the FDA;

- launch and commercialize NP101 and any other product candidates for which we obtain marketing approval; and

- continue our development programs to advance our internal product pipeline, which currently consists of two preclinical product candidates.

We will need substantial additional funding and may be unable to raise capital when needed or on attractive terms, which would force us to significantly delay, scale back or discontinue the development or commercialization of NP101 or our other product candidates.

We believe that our existing cash and cash equivalents will be sufficient to fund our operations and capital requirements beyond the planned resubmission of our NDA for NP101 and into the second half of 2012. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. Our future cash needs and the adequacy of our existing cash and cash equivalents will depend on many factors, including:

- our ability to successfully complete the additional trials, tests, device enhancement and other activities to support the resubmission of our NDA for NP101;

- the extent to which the FDA may request or require us to provide additional information or undertake additional trials or studies;

- the cost, scope and timing of activities undertaken to prepare for commercialization of NP101;

- our ability to establish and effectively manage our supply chain;

- 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.

We plan to raise additional funds through one or more public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives, including through sales of common stock to Aspire Capital under the Purchase Agreement. The covenants under our secured loan facility with MidCap Funding III, LLC and Silicon Valley Bank and the pledge of our assets as collateral limit our ability to obtain additional debt financing.

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Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms when needed, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing acquisition, licensing, development and commercialization efforts and our ability to generate revenues and achieve or sustain profitability will be substantially harmed.

The extent to which we utilize the Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than $4.00 per share. Even if we are able to access the full $30.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would 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 financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations.

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We have registered 2,901,734 shares of common stock that we may sell to Aspire Capital under the Purchase Agreement, of which 84,866 shares have been issued to Aspire Capital as a commitment fee in consideration for entering into the Purchase Agreement (the Commitment Shares), 70,721 shares were sold to Aspire Capital upon execution of the Purchase Agreement (the Initial Purchase Shares) and 2,746,147 shares that we may elect to sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered will be sold over the term of the Purchase Agreement, which ends on August 15, 2013. The number of shares ultimately offered for sale by Aspire Capital is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

In addition, sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

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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 September 30, 2011, we have used the net proceeds from the IPO as follows:

- approximately $16.2 million for further clinical development, manufacturing development, and preparation and submission of an NDA for NP101;

- approximately $1.9 million for further preclinical development of NP201 and NP202; and

- approximately $8.9 million for salaries and related personnel expenses for research and development and administrative personnel and approximately $6.1 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 has 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.

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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 14, 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)

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
4.1	Registration Rights Agreement, dated as of August 2, 2011, between NuPathe Inc. and Aspire Capital Fund, LLC	8-K	001-34836	4.1	August 2, 2011	
10.1	Common Stock Purchase Agreement, dated August 2, 2011 between NuPathe Inc. and Aspire Capital Fund, LLC	S-1	001-34836	10.31	August 2, 2011	
10.2	Employment Agreement, dated November 1, 2011, by and between NuPathe Inc. and Bart J. Dunn					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 (a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification by Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					*
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Link Base 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	*

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* Furnished herewith.