NUPATHE INC.
Form 10-Q
September 14, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

þ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended June 30, 2010
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 o No þ*****

*** The registrant has not been subject to the filing requirements for the past 90 days as it commenced trading following its initial public offering on August 6, 2010, but has filed all reports required to be filed by**

Section 13 or 15(d) of the Securities Exchange Act of 1934 since such time.

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 þ (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 þ

As of September 13, 2010, the number of shares outstanding of the registrant s common stock, $0.001 par value, was 14,546,161.

NUPATHE INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2010
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PART I. FINANCIAL INFORMATION

Item 1. ***Unaudited Financial Statements***

NUPATHE INC.
(A Development-Stage Company)
Balance Sheets
(Unaudited)

	June 30, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$ 8,494,528	$ 3,926,574
Prepaid expenses and other	2,235,164	918,878
Total current assets	10,729,692	4,845,452
Property and equipment, net	72,353	70,628
Other assets	365,662	93,053
Other assets- equipment funding	1,921,782	
Total assets	$ 13,089,489	$ 5,009,133
Liabilities and Stockholders Deficit		
Current liabilities:		
Current portion of long-term debt	$ 8,460,523	$ 818,139
Accounts payable	1,949,482	1,464,106
Accrued expenses	2,523,375	1,035,826
Total current liabilities	12,933,380	3,318,071
Long-term debt	4,814,815	
Warrant liability	1,112,820	626,492
Total liabilities	18,861,015	3,944,563
Redeemable convertible preferred stock, $0.001 par value. Authorized 71,745,055 shares, issued and outstanding 53,096,340 shares (liquidation value of $58,154,823 at June 30, 2010)	57,604,990	55,538,191
Stockholders deficit:		
Common stock, $0.001 par value. Authorized 28,254,945 shares, issued and outstanding 392,254 and 390,676 shares at June 30, 2010 and December 31, 2009, respectively	392	390
Additional paid-in capital	1,658,382	
Deficit accumulated during the development stage	(65,035,290)	(54,474,011)
Total stockholders deficit	(63,376,516)	(54,473,621)
Total liabilities and stockholders deficit	$ 13,089,489	$ 5,009,133

See accompanying notes to unaudited financial statements.

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NUPATHE INC.
(A Development-Stage Company)
Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six months Ended June 30,		Period from January 7, 2005 (inception) through
	2010	2009	2010	2009	June 30, 2010
Operating expenses:					
Research and development	$ 3,267,814	$ 3,198,797	$ 6,657,731	$ 6,194,673	$ 38,445,300
Acquired in-process research and development					5,500,000
General and administrative	945,339	753,914	1,818,357	1,550,229	11,645,739
Total operating expenses	(4,213,153)	(3,952,711)	(8,476,088)	(7,744,902)	(55,591,039)
Interest income	3,700	5,453	4,467	24,385	530,940
Interest expense	(1,435,001)	(49,722)	(1,446,255)	(105,761)	(4,068,792)
Loss before income tax benefit	(5,644,454)	(3,996,980)	(9,917,876)	(7,826,278)	(59,128,891)
Income tax benefit			320,381	151,012	471,393
Net loss	(5,644,454)	(3,996,980)	(9,597,495)	(7,675,266)	$ (58,657,498)
Accretion of redeemable convertible preferred stock	(1,033,399)	(829,766)	(2,066,798)	(1,659,531)	
Net loss available to common stockholders	$ (6,677,853)	$ (4,826,746)	$ (11,664,293)	$ (9,334,797)	
Basic and diluted net loss per common share	$ (17.42)	$ (12.64)	$ (30.49)	$ (24.45)	
Weighted average basic and diluted common shares outstanding	383,368	381,789	382,609	381,789	

See accompanying notes to unaudited financial statements.

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NUPATHE INC.
(A Development-Stage Company)
Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2009	Period from January 7, 2005 (inception) through June 30, 2010
Cash flows from operating activities:			
Net loss	$ (9,597,495)	$ (7,675,266)	$ (58,657,498)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	22,798	28,637	153,623
Loss on asset disposal			23,508
Acquired in-process research and development			5,500,000
Stock-based compensation	174,745	92,882	764,091
Noncash interest expense	1,327,760	25,734	3,216,152
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	102,040	140,730	(730,416)
Accounts payable	(343,195)	688,802	1,120,911
Accrued expenses	641,692	762,839	1,801,888
Net cash used in operating activities	(7,671,655)	(5,935,642)	(46,807,741)
Cash flows from investing activities:			
Purchase of in-process research and development			(5,500,000)
Payments under equipment funding agreement	(1,921,782)		(1,921,782)
Purchases of property and equipment	(24,524)	(15,303)	(249,484)
Net cash used in investing activities	(1,946,306)	(15,303)	(7,671,266)
Cash flows from financing activities:			
Proceeds from issuance of debt	5,000,000		7,608,741
Payment of debt issuance costs	(61,484)		(135,518)
Repayment of debt	(818,139)	(456,076)	(2,753,641)
Proceeds from sale of preferred stock, net			43,576,007
Proceeds from sale of common stock	3,038		211,263
Proceeds from convertible notes	10,062,500		14,466,683
Net cash provided by (used in) financing activities	14,185,915	(456,076)	62,973,535
Net increase (decrease) in cash and cash equivalents	4,567,954	(6,407,021)	8,494,528
Cash and cash equivalents, beginning of period	3,926,574	8,368,460	
Cash and cash equivalents, end of period	$ 8,494,528	$ 1,961,439	$ 8,494,528
Supplemental cash flow disclosures:			

Noncash investing and financing activities:			
Conversion of note principal and accrued interest to redeemable convertible preferred stock	$	$	$ 4,547,366
Accretion of redeemable convertible preferred stock	2,066,798	1,659,531	9,481,616
Cash paid for interest	45,986	83,944	648,791

See accompanying notes to unaudited financial statements.

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

(1) Background

NuPathe Inc. (the Company) is a development-stage company incorporated in Delaware on January 7, 2005 (inception). 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 operates in one segment and has its principal office in Conshohocken, Pennsylvania.

(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 $65,035,290 as of June 30, 2010. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development.

In August 2010 the Company completed its initial public offering of common stock (the IPO), selling 5,000,000 shares at an offering price of $10.00 per share, resulting in gross proceeds of $50,000,000. Net proceeds received after underwriting fees and offering expenses were $43,000,000. Management estimates that current cash and cash equivalents and the proceeds of our August 2010 IPO will be sufficient to sustain planned operations into the first half of 2012. Additional financing will be needed by the Company to fund the continued operations and commercialization of its products beyond the first half of 2012. 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.

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 final prospectus dated August 5, 2010 filed with the Securities and Exchange Commission, which includes annual financial statements as of and for the year ended December 31, 2009.

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

(b) Use of Estimates

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

(c) Fair Value of Financial Instruments

Management believes that the carrying amounts of the Company s 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 following fair value hierarchy table presents information about each major category of the Company s financial assets and liability measured at fair value on a recurring basis as of December 31, 2009 and June 30, 2010:

	Fair Value Measurement at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
At December 31, 2009				
Assets				
Cash equivalents	$ 3,654,831	$	$	$ 3,654,831
Liabilities				
Warrant liability	$	$	$ 626,492	$ 626,492
At June 30, 2010				
Assets				
Cash equivalents	$ 8,271,316	$	$	$ 8,271,316
Liabilities				
Warrant liability	$	$	$ 1,112,820	$ 1,112,820

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

The reconciliation of warrant liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Warrant Liability
Balance at December 31, 2009	$ 626,492
Issuance of additional warrants	204,224
Change in fair value of warrant liability	282,104
Balance at June 30, 2010	$ 1,112,820

The fair value of the warrant liability is based on Level 3 inputs. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See Note 6(b) for further discussion of the warrant liability.

(d) Deferred IPO Costs

As of June 30, 2010, the Company had incurred $1,600,000 of legal and accounting costs in connection with our IPO. These costs have been deferred and are reflected as a prepaid expense in the accompanying balance sheet. These costs will be recorded as a reduction of the proceeds from the IPO.

(e) Reverse Stock Split

On July 14, 2010, the board of directors of the Company approved a reverse stock split of the Company s common stock at a ratio of one share of common stock for every 8.0149 shares previously held. The stockholders approved the reverse stock split on July 19, 2010, and it was effected on July 20, 2010. All common stock share and per-share data included in these unaudited financial statements reflects the reverse stock split.

(f) 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 June 30, 2010, the first installment payment of 1,566,500, or $1,921,782 based on exchange rates in effect as of June 30, 2010, 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 a commercial manufacturing agreement with LTS for the production 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.

(g) 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 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 preferred 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.

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of June 30, 2010 and 2009, as they would be anti-dilutive:

	June 30,	
	2010	**2009**
Shares of redeemable convertible preferred stock	6,624,704	5,265,825
Shares issuable pursuant to redeemable convertible preferred stock accretion	1,177,273	661,866
Shares underlying outstanding options	938,222	956,799
Shares of unvested restricted stock	8,887	8,887
Shares underlying outstanding warrants to purchase preferred stock	140,526	16,769

(h) 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) Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2010	**December 31, 2009**
Accrued compensation and benefits	$ 508,071	$ 504,091
Accrued professional fees	94,555	112,301
Accrued fees relating to initial public offering	640,328	
Accrued research and development expenses	829,188	238,401
Accrued interest and other	451,233	181,033
	$ 2,523,375	$ 1,035,826

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

(5) Debt

(a) Convertible Notes

In July 2009, the Company issued convertible promissory notes for cash proceeds of $1,934,000 to existing investors, including two officers of the Company, (the 2009 Notes). The 2009 Notes bore interest of 10% per year and were due on June 30, 2010, if not converted prior to such date, and were mandatorily convertible into preferred stock upon the occurrence of the Second Tranche Closing, as defined. The holders of the 2009 Notes were entitled to receive warrants to purchase shares of Series B upon the conversion of the 2009 Notes. The fair value of the warrants of $556,042 was recorded as a reduction in the carrying value of the 2009 Notes as original issue discount and recognized as interest expense. After the allocation of the original issue discount, the 2009 Notes contained a beneficial conversion feature (BCF) of $556,042, which was also recognized as additional interest expense.

In August 2009, the holders of the 2009 Notes converted their notes, including accrued interest of $22,840, into 2,104,326 shares of Series B at a conversion price of $0.93 per share. Upon conversion, the investors received warrants to purchase 736,514 shares of Series B at $0.93 per share which, upon the IPO, converted into warrants to purchase 91,890 shares of common at $7.45 per share that are exercisable for a term of up to seven years.

In April 2010, the Company issued convertible promissory notes for cash proceeds of $10,062,500 to existing investors, including three officers of the Company (the April 2010 Convertible Notes). The April 2010 Convertible Notes bore interest of 8% per year and were due on December 31, 2010, if not converted prior to that date. The April 2010 Convertible Notes and related accrued interest were mandatorily convertible into common stock at a conversion price equal to 80% of the IPO price per share upon the occurrence of an IPO, as defined therein. Upon the close of our IPO in August 2010, the April 2010 Convertible Notes and related accrued interest converted into 1,292,122 shares of common stock, based on our initial offering price of $10.00 per common share. The Company recorded the April 2010 Convertible Notes net of a $2,583,615 BCF which is being recognized as interest expense through the due date of the April 2010 Convertible Notes. As of June 30, 2010, the balance of the April 2010 Convertible Notes net of the BCF was $8,275,338.

(b) Credit Facilities and Vendor Debt

In May 2010, the Company executed a term loan facility with lenders to fund working capital needs (the May 2010 Loan Facility). The loan is secured by a lien on all of the Company s assets, excluding intellectual property, which is subject to a negative pledge. The Company received proceeds of $5,000,000 at closing. The May 2010 Loan Facility is interest-only payments for the first twelve months of the loan, therefore at June 30, 2010, the balance of this note is $5,000,000, with $185,185 of that amount being classified as current. As a result of the successful completion of our IPO in August 2010, there is an additional $6,000,000 of proceeds available to the Company, subject to final approval from the lenders. The loan bears interest at an annual rate of LIBOR plus 8.75%, subject to a LIBOR floor of 3.00%. The loan is repayable over 39 months with interest only payments for the first twelve months. 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 IPO, converted into warrants to purchase 31,861 shares of common 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. The Company is required to issue additional warrants to purchase up to 38,235 shares of common stock in the event that additional proceeds are received from the lenders.

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

(6) Capital Structure

(a) Redeemable Convertible Preferred Stock

As of June 30, 2010, the shares of authorized and outstanding redeemable convertible preferred stock were as follows:

Convertible Preferred Stock	Shares Authorized	Shares Outstanding	Carrying Amount	Liquidation Value
Series A	17,056,914	16,922,506	$ 19,749,334	$ 20,103,513
Series B	54,688,141	36,173,834	37,855,656	38,051,310

Series A and Series B holders are entitled to receive dividends of 8% per year as and when declared by the board of directors. Series A and Series B dividends accrue cumulatively and no dividends have been declared through June 30, 2010. Dividends are accrued and are payable in the event of sale or liquidation of the Company or qualified public offering, as defined, or upon conversion or redemption of the Series A or Series B. As of June 30, 2010, there was $4,365,583 of unpaid Series A dividends. As of June 30, 2010, there was $4,409,644 of unpaid Series B dividends.

Series A and Series B holders are entitled to a liquidation preference in an amount equal to $0.93 per share, plus any accumulated but unpaid dividends, in the event of a liquidation, dissolution, or winding-up of the Company, or in the event the Company merges with or is acquired by another entity.

The carrying value of the Series A and Series B are accreted to their redemption value by a charge to additional paid-in capital, if any, then to accumulated deficit. The accretion of Series A and Series B includes dividends and accretion of issuance costs and of the BCF recorded in connection with the conversion of the Series A notes. The carrying value of the preferred stock differs from the current liquidation value due to the issuance costs and BCF.

In August 2010, the Company completed its IPO, selling 5,000,000 shares of common stock at an offering price of $10.00 per share, resulting in gross proceeds of $50,000,000. Net proceeds received after underwriting fees and offering expenses were $43,000,000. In connection with the closing of the IPO, all outstanding shares of the Company s redeemable convertible preferred stock, plus accrued dividends thereon, were converted into 7,861,785 shares of common stock.

(b) Warrants

In connection with a term loan from 2007, the Company issued warrants to purchase shares of Series A. In connection with the 2009 Notes and the May 2010 Loan Facility, the Company issued warrants to purchase shares of Series B (Note 5). As of June 30, 2010, the following warrants to purchase Preferred Stock were outstanding:

Convertible Preferred Stock	Number of Shares	Exercise Price	Expiration
Series A	134,408	$ 0.93	2017
Series B	991,890	0.93	2016 and 2020

The warrants were classified as a warrant liability on the accompanying balance sheet in accordance with FASB accounting guidance, as the warrants entitled the holder to purchase preferred stock, which could have been redeemed at the option of the holder.

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

The Company records the warrant liability at its fair value using the Black-Scholes option-pricing model and revalues the warrant at each reporting date. The following tables summarize the fair value and the assumptions used for the Black-Scholes option-pricing model for the warrants:

Series A Warrants	June 30, 2010	December 31, 2009
Fair value	$ 131,855	$ 99,664
Expected dividend yield	%	%
Expected volatility	84.72%	89.17%
Risk-free interest rate	2.3%	3.4%
Remaining contractual term	6.75 years	7.25 years

Series B Warrants expiring May 2016	June 30, 2010	December 31, 2009
Fair value	$ 701,706	$ 526,828
Expected dividend yield	%	%
Expected volatility	84.4%	87.8%
Risk-free interest rate	2.2%	3.3%
Remaining contractual term	6.1 years	6.6 years

Series B Warrants expiring May 2020	June 30, 2010	Date of Issuance (May 13, 2010)
Fair value	$ 279,259	$ 202,224
Expected dividend yield	%	%
Expected volatility	87.8%	87.16%
Risk-free interest rate	3.0%	3.6%
Remaining contractual term	9.8 years	10 years

In conjunction with the completion of our IPO, all outstanding warrants to purchase preferred stock were converted into warrants to purchase 140,520 shares of common stock at $7.45 per share.

(7) Stock-Based Compensation

In 2005, the Company adopted the 2005 Equity Compensation Plan (as amended from time to time, the 2005 Plan) that authorized the Company to grant up to 474,116 shares of common stock to eligible employees, directors, and consultants to the Company in the form of restricted stock and stock options. In 2008, the Company authorized an additional 623,838 shares, for a total of 1,097,954 shares, available for grant. The amount, terms of grants, and exercisability provisions are determined by the board of directors. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors.

As of June 30, 2010, there were 105,555 shares of common stock available for future grants under the 2005 Plan.

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NuPathe Inc.
(A Development-stage Company)
Notes to Unaudited Financial Statements

In June 2010, the Company adopted the 2010 Omnibus Incentive Compensation Plan (the 2010 Plan), subject to stockholder approval and effective upon the effective date of the IPO. The stockholders approved the 2010 Plan on July 19, 2010 and the 2010 Plan became effective on August 5, 2010. The 2010 Plan authorizes the Company to grant up to 1,738,886 shares of common stock, which includes the number of shares that are subject to outstanding grants under the 2005 Plan and shares that remain available for issuance under the 2005 Plan, to eligible employees, directors, consultants and advisors to the Company in the form of restricted stock, stock options, stock appreciation rights, stock units, performance units and other stock-based awards.

(a) Stock Options

The following is a summary of stock option activity for the six months ended June 30, 2010:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2009	950,693	$ 1.84		
Granted				
Exercised	(1,578)	1.92		
Cancelled/forfeited	(10,893)	1.74		
Outstanding at June 30, 2010	938,222	1.81	7.94	$ 7,684,038
Vested and expected to vest at June 30, 2010	936,731	1.81	7.82	$ 7,671,831
Exercisable at June 30, 2010	527,975	1.75	7.75	$ 4,358,059

Stock-based compensation expense for the six months ended June 30, 2010 and 2009 was $174,745 and $92,882, respectively. As of June 30, 2010, there was $521,144 of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2 years.

(b) Restricted Stock

As of June 30, 2010, there were 8,887 unvested shares subject to vesting upon the achievement of certain corporate performance goals. There was no restricted stock granted during the six months ended June 30, 2010. As of June 30, 2010, there was $8,550 of unrecognized compensation expense related to the unvested restricted stock awards that will vest upon the achievement of a certain defined milestone. We expect these milestones to be met in the third quarter of 2010.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included in our final prospectus dated August 5, 2010 filed with the Securities and Exchange Commission, which includes annual financial statements as of and for the year ended December 31, 2009. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this document, including information with respect to our plans and strategy for our business and related financing, contains forward-looking statements that involve risks, uncertainties and assumptions. All statements that express expectations, estimates, forecasts or projections are forward-looking statements. Words such as expects , anticipates , intends , plans , believes , seeks , estimates , projects , forecasts , may , should , variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future results and our actual results may differ materially from those anticipated or implied in these forward-looking statements as a result of important factors described in the cautionary statements included in this document, particularly those discussed under the heading Risk Factors in Item 1A of Part II. We undertake no obligation to revise or update any forward-looking statements, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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 acute migraine. Zelrix uses our proprietary SmartRelief technology. We successfully completed a pivotal Phase III clinical trial for Zelrix in July 2009 and expect to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2010. 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 hold exclusive worldwide rights to two proprietary drug delivery technologies: SmartRelief and LAD. Zelrix uses SmartRelief, while NP201 and NP202 both use our long-acting delivery (LAD) technology. SmartRelief is our proprietary transdermal delivery technology based on iontophoresis, a non-invasive method of transporting a molecule through the skin by applying a mild electrical current. Unlike passive transdermal technologies, which rely on diffusion for medication delivery, SmartRelief controls the amount and rate of medication delivery. The SmartRelief technology facilitates active transdermal delivery, which is important for molecules, such as sumatriptan, that are not able to be delivered passively through the skin. LAD is comprised of a biodegradable polymer matrix using commonly available medical polymers and an active drug. It is formed into a small implant for injection just below the skin. We designed LAD to improve the control, consistency and convenience of medication delivery.

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 revenue and have never been profitable. Our net loss was $9.6 million for the six months ended June 30, 2010 and $7.7 million for the six months ended June 30, 2009. As of June 30, 2010, we had an accumulated deficit of $65.0 million.

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 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 outsourced 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.

We have funded our operations to date primarily with the proceeds of the sale of convertible preferred stock, convertible notes and borrowings under debt facilities. From inception through June 30, 2010, we have received net proceeds of $58.1 million from the sale of convertible preferred stock and convertible notes, including gross proceeds of $10.1 million from the sale of the April 2010 Convertible Notes. In August 2010, we completed our IPO and obtained equity financing, after underwriting fees and offering expenses, of $43.0 million which is expected to fund our operations into the first half of 2012.

In May 2010, we entered into the May 2010 Loan Facility under which $5.0 million was advanced on the closing date. We used a portion of the proceeds from the May 2010 Loan Facility to repay all outstanding amounts under a term loan that we entered into in 2007. The April 2010 Convertible Notes and the May 2010 Loan Facility are described in more detail under Liquidity and Capital Resources.

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Financial Overview

Research and Development Expenses

Our research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including:

- Expenses associated with regulatory submissions, preclinical development, clinical trials and manufacturing;
- Personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation;
- Payments made to third party investigators who perform research and development on our behalf;
- Payments to third party contract research organizations, contractor laboratories and independent contractors;
- Expenses incurred to obtain technology licenses if the technology licensed has not reached technological feasibility and has no alternative future use; and
- Facility, maintenance and other related expenses.

We expense all research and development costs as incurred. Preclinical development expenses and clinical trial expenses for our product candidates are a significant component of our current research and development expenses. Product candidates in later stage clinical development, such as Zelrix, generally have higher research and development expenses than those in earlier stages of development, primarily due to the increased size and duration of the clinical trials. We track and record information regarding external research and development expenses for each study or trial that we conduct. From time to time, we use third party contract research organizations, contractor laboratories and independent contractors in preclinical studies. We recognize the expenses associated with third parties performing these services for us in our preclinical studies based on the percentage of each study completed at the end of each reporting period. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

From our inception in January 2005 through June 30, 2010, we incurred research and development expenses of $38.4 million, of which $32.6 million were allocated to the development of Zelrix and $2.0 million was allocated to the development of NP201. The remaining research and development expenses are for amounts incurred that we do not allocate to specific programs, such as personnel related expenses, including salaries and benefits, as well as general fixed costs for our facility and related expenses.

We expect that our research and development expenses in 2010 will be higher than in 2009 as a result of the full enrollment of the long term, open label Phase III clinical studies for Zelrix and the increased regulatory work related to the NDA that we expect to submit for Zelrix during the fourth quarter of 2010. We also expect to incur additional research and development expenses in 2010 as we continue the development of NP201 and NP202. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our preclinical development and clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- The number of sites included in the trials;
- The length of time required to enroll suitable subjects;
- The size of subject populations participating in the trials;
- The duration of subject follow-ups;

The development stage of the product candidates; and

The efficacy and safety profile of the product candidates.

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Neither Zelrix nor any of our other product candidates has received FDA approval. In order for the FDA to approve a product candidate, the FDA must conclude that the data establishes the safety and efficacy of such product candidate. We currently anticipate submitting an NDA for Zelrix in the fourth quarter of 2010. We also expect to incur additional costs relating to post-marketing studies to gather additional information regarding Zelrix s risks, benefits and optimal use.

We currently anticipate submitting an IND for NP201 in the first half of 2011 and for NP202 in 2012. Due to their early stages of development, we are unable to determine the duration and completion costs of our NP201 and NP202 development projects. As a result of the difficulties forecasting NP201 and NP202 development costs, as well as the other uncertainties discussed above, we are unable to determine when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal, market research and human resource functions. Our general and administrative expenses also include facility and related costs not included in research and development expenses, professional fees for legal, including patent-related expenses, consulting, tax and accounting services, insurance, depreciation and general corporate expenses. We expect that our general and administrative expenses will increase with the continued development and commercialization of our product candidates.

We expect that our general and administrative expenses in 2010 will be higher than in 2009 as a result of greater expenses relating to our operations as a public company, including increased costs for the hiring of additional personnel, and for payment to outside consultants, including lawyers and accountants, to comply with additional regulations, corporate governance, internal control and similar requirements applicable to public companies, as well as increased costs for insurance. Additionally, we plan to increase spending related to building a commercial infrastructure for the anticipated launch of Zelrix in the U.S. in the first half of 2012. Sales representatives will be hired only if Zelrix is approved by the FDA.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists primarily of cash and non-cash interest costs related to our outstanding debt. Additionally, in connection with some of our debt financings, we issued warrants, the fair value of which we recorded as deferred financing costs. We amortize these deferred financing costs over the lives of the loans as interest expense in our statement of operations. On a quarterly basis these warrants are marked-to-market, in accordance with GAAP, and any change in market value is also recorded as interest expense in our statement of operations. We expect interest expense to increase in 2010 compared with 2009 as a result of the April 2010 Convertible Notes and the May 2010 Loan Facility.

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Results of Operations

Three Months Ended June 30, 2010 compared to the Three Months Ended June 30, 2009

Research and Development Expense

Research and development expense for the three months ended June 30, 2010 and 2009 were comprised of the following:

	Three Months Ended June 30,			
	2010	2009	Increase/(Decrease)	
	(in thousands)			
Clinical development	$ 1,334	$ 1,492	$ (158)	(11)%
Manufacturing	874	740	134	18
Research and preclinical expenses		196	(196)	(100)
Regulatory and quality assurance	191	61	130	214
Compensation and related expenses	697	584	113	19
Facilities and related expenses	172	126	46	36
	$ 3,268	$ 3,199	$ 69	2

In the aggregate, research and development expenses for the three months ended June 30, 2010 were comparable to those in the three months ended June 30, 2009; however, there were fluctuations within specific expense categories between such periods. The decrease of $0.2 million in preclinical expenses from the three months ended June 30, 2009 as compared to the same period in 2010 was due to various preclinical studies in 2009 that were concluded late in the year. In the second quarter of 2010, we did not conduct preclinical studies as we focused on the clinical program for Zelrix. The decrease of $0.2 million in clinical development expenses from the three months ended June 30, 2009 to the three months ended June 30, 2010 resulted from the conclusion of our pivotal phase III clinical study for Zelrix, which was ongoing during the three months ended June 30, 2009. Long term, open label clinical studies have been initiated for Zelrix and the costs incurred for these studies in the three months ended June 30, 2010 partially offset this decrease from 2009. The increase in manufacturing expenses for the 2010 period was primarily driven by NP201 manufacturing activity. Increased regulatory and quality assurance expenses were the result of work in 2010 for the anticipated filing of our Zelrix NDA. Higher compensation and related expenses were attributable to incremental headcount.

Research and development expenses by program for the three months ended June 30, 2010 and 2009 were as follows:

	Three Months Ended June 30,			
	2010	2009	Increase/(Decrease)	
	(in thousands)			
Zelrix	$ 2,217	$ 2,453	$ (235)	(10)%
NP201	226	36	190	528
NP202	8		8	
General development expenses	817	710	106	15
	$ 3,268	$ 3,199	$ 69	2

Zelrix expenses decreased in the three months ended June 30, 2010 due to the inclusion in the 2009 period of significant expenses for our pivotal phase III clinical trial. This trial was competed later in 2009, therefore no expenses related to that study were included in the three months ended June 30, 2010. Other clinical studies were ongoing, but they are smaller in scale and therefore do not fully offset that decrease. In addition, the second quarter of

2009 included preclinical studies for Zelrix which did not occur in the second quarter of 2010. The 2010 increase in NP201 expenses relates to the initiation of a research agreement for this program which had minimal activity during 2009. 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 2010 increase shown for general development expenses is primarily related to increased research and development headcount.

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General and Administrative Expenses

General and administrative expenses increased to $0.9 million in the three months ended June 30, 2010 from $0.8 million for the three months ended June 30, 2009. This increase resulted primarily from higher market research expenses and annual increases in salaries, bonuses and benefit premiums.

Interest Expense

Interest expense increased by $1.4 million in the three months ended June 30, 2010 from $50,000 in the three months ended June 30, 2009 as a result of $0.8 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 three months ended June 30, 2010.

Six Months Ended June 30, 2010 compared to the Six Months Ended June 30, 2009

Research and Development Expense

Research and development expense for the six months ended June 30, 2010 and 2009 were comprised of the following:

	Six Months Ended June 30,			
	2010	2009	Increase/(Decrease)	
	(in thousands)			
Clinical development	$ 2,899	$ 2,621	$ 278	11%
Manufacturing	1,768	1,337	431	32
Research and preclinical expenses		698	(698)	(100)
Regulatory and quality assurance	294	110	184	167
Compensation and related expenses	1,371	1,183	188	16
Facilities and related expenses	326	246	80	32
	$ 6,658	$ 6,195	$ 463	7

Research and development expenses increased by $0.5 million to $6.7 million in the six months ended June 30, 2010 from $6.2 million in the six months ended June 30, 2009. Increased clinical development expenses during the 2010 period were the result of a new long term, open label clinical study initiated in the third quarter of 2009 for Zelrix. This new study more than offset the decrease in clinical development expense that resulted from concluding our pivotal phase III study in 2009. Also contributing to the increase in clinical development during the 2010 period was $0.2 million of clinical consulting related to NP201. Manufacturing expense increased by $0.4 million to $1.8 million during the six months ended June 30, 2010 compared to $1.4 million during the same period in 2009. Approximately $0.3 million of this increase related to Zelrix, as we incurred higher consulting, process development and phase III clinical supply manufacturing costs during the 2010 period for our ongoing long term, open label Zelrix clinical trials. Also contributing to the higher manufacturing expenses during the 2010 period was $0.1 million of expense incurred for the initial phase of manufacturing development of our NP201 candidate during the second quarter of 2010. We incurred no preclinical expenses for the six months ended June 30, 2010 as the preclinical studies were completed in 2009 for Zelrix, and these costs did not recur in 2010. The $0.2 million increase in regulatory and quality assurance results from our work in 2010 in anticipation of our expected NDA filing later this year. The $0.2 million increase in compensation and related expenses during the 2010 period results from slightly higher research and development headcount as well as annual increases in salaries, bonuses and benefit premiums.

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Research and development expenses by program for the six months ended June 30, 2010 and 2009 are presented below:

	Six Months Ended June 30,			
	2010	2009	Increase/(Decrease)	
	(in thousands)			
Zelrix	$ 4,758	$ 4,658	$ 100	2%
NP201	296	106	190	179
NP202	10		10	
General development expenses	1,594	1,431	163	11
	$ 6,658	$ 6,195	$ 463	7

As discussed earlier, the increase in spending on Zelrix in the six months ended June 30, 2010 results from costs incurred during the 2010 period for ongoing clinical studies, higher manufacturing related expenses for clinical supplies, and efforts toward completing the filing of our NDA, anticipated later this year. These costs were partially offset by the completion in 2009 of preclinical Zelrix activities. Spending on NP201 increased during the six months ended June 30, 2010 as compared to the six months ended June 30, 2009 as a result of consultant expenses and additional development work on NP201. 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 2010 increase in general development expenses results from slightly higher research and development headcount as well as annual increases in salaries, bonuses and benefit premiums.

General and Administrative Expenses

General and administrative expenses increased to $1.8 million in the six months ended June 30, 2010 from $1.6 million for the six months ended June 30, 2009. This increase resulted primarily from a $0.1 million increase in marketing expenses due to higher grant sponsorship and additional market research and a $0.1 million increase in compensation expenses due to annual increases in salaries, bonuses and benefit premiums.

Interest Expense

Interest expense increased by $1.3 million in the six months ended June 30, 2010 from $106,000 in the six months ended June 30, 2009. The primary reason for the increase is $0.8 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 six months ended June 30, 2010.

Income Tax Benefit

We recognized an income tax benefit of $320,000 in the six months ended June 30, 2010 and $151,000 in the six months ended June 30, 2009 related to the sale of Pennsylvania research and development tax credits to a third party buyer.

Liquidity and Capital Resources

Since our inception in 2005, we have devoted most of our cash resources to research and development and general and administrative activities primarily related to the development of Zelrix. We have financed our operations primarily with the proceeds of the sale of convertible preferred stock and convertible notes and borrowings under debt facilities. To date, we have not generated any revenues from the sale of products, and we do not anticipate generating any revenues from the sale of Zelrix until at least 2012. We have incurred losses and generated negative cash flows from operations since inception. As of June 30, 2010, our principal sources of liquidity were our cash and cash equivalents, which totaled $8.5 million. Our working capital was $(2.2) million as of June 30, 2010.

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Equity Financings

From inception through June 30, 2010, we have received net proceeds of $58.1 million from the sale of convertible preferred stock and convertible notes. The various issuances of our preferred stock are described in more detail under Note 6 to our unaudited financial statements.

In August 2010 we completed our IPO, selling 5,000,000 shares of common stock at an offering price of $10.00 per share, resulting in gross proceeds of $50.0 million. Net proceeds received after underwriting fees and offering expenses were $43.0 million.

Debt Facilities

In April 2010 we received gross proceeds of $10.1 million from the sale of the April 2010 Convertible Notes. These notes bore interest at 8% per year and were due on December 31, 2010, if not converted prior to such date. The outstanding principal balance and accrued interest on the April 2010 Convertible Notes converted into shares of common stock upon the closing of our IPO at a conversion price equal to 80% of the offering price to the public. At June 30, 2010 there was accrued but unpaid interest on these notes of $0.2 million and unamortized BCF related to these notes of $1.8 million. Upon the close of our IPO in August 2010, the April 2010 Convertible Notes converted into 1,292,122 shares of common stock, based on our offering price of $10.00 per common share.

In May 2010, we entered into the May 2010 Loan Facility to fund our working capital requirements, under which we were advanced $5.0 million on the closing date. The May 2010 Loan 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 used $0.4 million of the proceeds from the May 2010 Loan Facility to repay all outstanding amounts owed under a March 2007 loan facility. Amounts outstanding under the May 2010 Loan Facility bear interest at LIBOR plus 8.75% per year, with a LIBOR floor of 3%. Until June 2011, the May 2010 Loan Facility only requires monthly payments of interest. Thereafter, that loan will amortize on a straight line basis, and we will be required to pay 27 equal monthly installments of principal and interest through the maturity date.

Equipment Funding Agreement

We expect to incur aggregate costs of approximately 5.4 million relating to the funding of commercial manufacturing equipment for Zelrix. As of June 30, 2010, 3.8 million, or approximately $4.7 million based on exchange rates in effect as of June 30, 2010, remain to be paid in monthly installments under the LTS equipment funding agreement.

Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities for the six months ended June 30, 2010 and 2009:

	Six Months Ended June 30,	
	2010	2009
	(in thousands)	
Statement of cash flows data:		
Total cash provided by (used in):		
Operating activities	$ (7,672)	$ (5,936)
Investing activities	(1,946)	(15)
Financing activities	14,186	(456)
Increase (decrease) in cash and cash equivalents	$ 4,568	$ (6,407)

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Operating Activities

Cash used in operating activities increased $1.7 million for the six months ended June 30, 2010, compared to the six months ended June 30, 2009, primarily driven by our higher operating expenses for the 2010 period which included $0.5 million in higher research and development expenses and a $0.3 million increase in general and administrative expenses. Additionally, due to more conservative cash management in the first half of 2009, accounts payable and accrued expenses increased by $1.2 million during the six months ended June 30, 2009. During the same period of 2010, the increase in accounts payable and accrued expenses was only $0.2 million.

Investing Activities

Cash used in investing activities increased $1.9 million for the six months ended June 30, 2010, compared to the six months ended June 30, 2009, due to a June 2010 payment of $1.9 million for equipment related to the commercial manufacture of Zelrix. This payment was the first of fourteen scheduled payments to be made for this equipment that total $6.6 million based on exchange rates in effect at June 30, 2010.

Financing Activities

Cash provided by financing activities increased $13.6 million for the six months ended June 30, 2010, compared to the six months ended June 30, 2009, primarily due to net proceeds received in 2010 from the April 2010 Convertible Notes and the May 2010 Loan Facility, as discussed more fully in the notes to our unaudited financial statements. The proceeds from the 2010 issuances of debt were partially offset by contractual loan repayments. The use of cash during the 2009 period was for the contractual loan repayments of a term loan that we entered into in 2007 which was fully repaid in May 2010.

Initial Public Offering

In August 2010 we completed our IPO, selling 5,000,000 shares at an offering price of $10.00 per share resulting in gross proceeds of $50.0 million. Net proceeds received after underwriting fees and offering expenses were approximately $43.0 million. In connection with the closing of the IPO, all outstanding shares of our redeemable convertible preferred stock, plus accrued dividends thereon, were converted into an aggregate of 7,861,785 shares of common stock, and all outstanding warrants to purchase preferred stock were converted into aggregate of 140,520 warrants to purchase common stock. Additionally, upon the closing of the IPO, the April 2010 Convertible Notes, plus accrued interest thereon, were converted into 1,292,122 shares of common stock. For more information related to the debt conversion, refer to Note 5 in the notes to the accompanying unaudited financial statements. Based on our current operating plans, we expect to use the proceeds received from our IPO to complete the development of, seek marketing approval for, initiate the commercial manufacture of and, if approved, commercially launch Zelrix in the U.S. We also expect to use the proceeds to continue preclinical and clinical development of NP201 and NP202, as well as for working capital and other general corporate purposes.

Future Payments Under Contractual Obligations

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our final prospectus filed pursuant to Rule 424(b) under the Securities Act with the Securities and Exchange Commission on August 6, 2010.

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 Securities and Exchange Commission.

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Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk from changes in interest rates is primarily related to interest earned on our cash and cash equivalents and interest expense on our outstanding debt. We do not engage in any hedging activities against changes in interest rates. We believe that changes in interest rates will not be a material risk for the Company.

We have no operations outside the U.S. We have, however, entered into two agreements with a manufacturer in Germany. Under one of these agreements, the manufacturer provides services to us related to the development and manufacture of clinical supplies for Zelrix. Under this agreement, we paid $2.1 million in 2008, $1.2 million in 2009 and $0.6 million in the six months ended June 30, 2010 to this manufacturer. Under the other agreement, we have agreed to pay the manufacturer an aggregate of 5.4 million in 14 monthly installments that commenced in June 2010, for the purchase of manufacturing equipment for Zelrix, which will be installed in the U.S. As of June 30, 2010, 3.8 million, or approximately $4.7 million based on exchange rates in effect as of June 30, 2010, are to be paid in the remaining monthly installments under this agreement.

Because of these agreements, we are subject to fluctuations in exchange rates. We believe that the risk from exposure to foreign currency fluctuations under these agreements will not have a material impact on the Company. Additionally, we are currently in the process of transferring our existing manufacturing activities with this manufacturer to the U.S., thereby substantially eliminating our exposure to fluctuation in the relative values of the U.S. dollar and the Euro.

Item 4. 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 on Form 10-Q, 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 1. Legal Proceedings.

None.

Item 1A. ***Risk Factors.***

Our business is subject to numerous risks. In addition to the other information included in this Quarterly Report on Form 10-Q, the following factors should be considered in evaluating our business and future prospects. Any of the following risks, either alone or taken together, could materially and adversely affect our business, financial position or results of operations. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, our actual results may vary materially from what we projected. There may be additional risks that we do not presently know or that we currently believe are immaterial which could also impair our business or financial position.

Risks Related to Development and Commercialization of Our Product Candidates

We are heavily dependent on the success of Zelrix. If we fail to obtain marketing approval for and commercialize Zelrix, or experience delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, 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. Our ability to generate revenues in the near term is substantially dependent on our ability to develop and commercialize Zelrix. In the fourth quarter of 2010, we plan to submit an NDA seeking approval to commercialize Zelrix for treatment of acute migraine. We cannot commercialize Zelrix prior to obtaining FDA approval. Even though Zelrix has completed its pivotal Phase III clinical trial with positive results, Zelrix is still, nonetheless, susceptible to the risks of failure inherent at any stage of drug development, including the appearance of unexpected adverse events, manufacturing and testing failures, and the FDA s determination Zelrix is not approvable. As a company, we have never obtained marketing approval for or commercialized a drug. It is possible that the FDA may refuse to accept our NDA for substantive review or may review our data and conclude that our application is insufficient to obtain marketing approval of Zelrix. If we do not receive FDA approval for and commercialize Zelrix, we will not be able to generate product revenues in the foreseeable future, or at all.

If, following submission, our NDA is not accepted for substantive review or approved, the FDA may require that we conduct additional clinical or preclinical trials or manufacture additional validation batches before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider sufficient any additional required trials that we perform and complete.

Even if we believe that the data from our clinical trials support marketing approval of Zelrix in the U.S., the FDA may not agree with our analysis and approve our NDA. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing Zelrix, generating revenues and achieving profitability.

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The commercial success of Zelrix and any other product candidates that we develop, if approved in the future, will depend upon significant market acceptance of these products among physicians, patients and third party payors.

As a company, we have never commercialized a product candidate for any indication. Even if any product candidate that we develop, including Zelrix, is approved by the appropriate regulatory authorities for marketing and sale, it may not gain acceptance among physicians, patients and third party payors. If our products for which we obtain marketing approval do not gain an adequate level of acceptance, we may not generate significant product revenues or become profitable. Market acceptance of Zelrix, and any other product candidates that we develop, by physicians, patients and third party payors will depend on a number of factors, some of which are beyond our control, including:

- The efficacy, safety and other potential advantages in relation to alternative treatments;
- The relative convenience and ease of administration;
- The availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- The prevalence and severity of adverse events;
- The cost of treatment in relation to alternative treatments, including generic products;
- The extent and strength of marketing and distribution support;
- The limitations or warnings contained in a product s FDA approved labeling; and
- Distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan.

For example, even if the medical community accepts that Zelrix is safe and effective for its approved indications, physicians and patients may not immediately be receptive to Zelrix and may be slow to adopt it as an accepted treatment for acute migraine. In addition, even though we believe Zelrix has significant advantages, because no head-to-head trials comparing Zelrix to competing products have been conducted, it is unlikely that any labeling approved by the FDA will contain claims that Zelrix is safer or more effective than competitive products or will permit us to promote Zelrix as being superior to competing products. Further, the availability of numerous inexpensive generic forms of migraine therapy products may also limit acceptance of Zelrix among physicians, patients and third party payors. If Zelrix is approved but does not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate meaningful revenues from Zelrix and we may not become profitable.

It will be difficult for us to profitably sell any of our product candidates that the FDA approves, including Zelrix, if reimbursement for such product candidate is limited.

Market acceptance and sales of Zelrix or any other product candidates that we develop will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for Zelrix or any other product candidates that we develop and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, our products for which we obtain marketing approval. Numerous generic products may be available at lower prices than branded therapy products, such as Zelrix, if it is approved, which may also reduce the likelihood and level of reimbursement for our product candidates, including Zelrix. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize Zelrix or any other product candidates that we develop.

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If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates after they are approved, we may be unable to generate product revenues.

We currently do not have a commercial infrastructure for the marketing, sales and distribution of pharmaceutical products. In order to commercialize our products, we must build our marketing, sales and distribution capabilities or make arrangements with third parties to perform these services. If Zelrix is approved by the FDA, we plan to build a commercial infrastructure to launch Zelrix in the U.S., including a specialty sales force of approximately 100 people. We may seek to further penetrate the U.S. market in the future by expanding our sales force or through collaborations with other pharmaceutical or biotechnology companies. We may also seek to commercialize Zelrix outside the U.S., although we currently plan to do so only with a collaborator.

The establishment and development of our own sales force and related compliance plans to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We, or our future collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to develop a marketing and sales infrastructure, we would not be able to commercialize Zelrix or any other product candidates that we develop, which would limit our ability to generate product revenues.

Companies such as ours often expand their sales force and marketing capabilities for a product prior to it being approved by the FDA so that the drug can be commercialized upon approval. Although our current plan is to hire most of our sales and marketing personnel only if Zelrix is approved by the FDA, we will incur expenses prior to product launch in recruiting this sales force and developing a marketing and sales infrastructure. If the commercial launch of Zelrix is delayed as a result of FDA requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from product sales. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing Zelrix or any other product candidates that we develop.

To the extent we rely on third parties to commercialize any products for which we obtain marketing approval, we may receive less revenues than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts. In the event we are unable to collaborate with a third party marketing and sales organization, our ability to generate product revenues may be limited either in the U.S. or internationally.

We face significant competition from other pharmaceutical and biotechnology companies. Our operating results will suffer if we fail to compete effectively.

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our major competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies and specialty pharmaceutical and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as larger research and development staff and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than Zelrix or any other drug candidate that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

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The competition in the market for acute migraine medication is intense. The majority of marketed prescription products for treatment of acute migraine in the U.S. are in the triptan class in tablet, orally-disintegrating tablet, nasal spray and injectable therapies. The largest selling triptan is sumatriptan, with 2009 sales of approximately $800 million in the U.S., including approximately $200 million attributable to GlaxoSmithKline plc s, or GlaxoSmithKline, branded sumatriptan, Imitrex. There are at least eight other branded triptan therapies being sold by pharmaceutical and biotechnology companies, including Maxalt from Merck & Co., Inc. (Merck) and Treximet from GlaxoSmithKline. In July 2009, the FDA approved Zogenix, Inc. s Sumavel DosePro needle-free sumatriptan injection for the treatment of acute migraine and cluster headache, and in June 2010, the FDA approved King Pharmaceuticals, Inc. s Alsuma subcutaneous sumatriptan injection.

If approved, Zelrix will face competition from inexpensive generic versions of sumatriptan and generic versions of other branded products of competitors that have lost or will lose their patent exclusivity. For example, Amerge, the branded version of naratriptan, lost patent protection in July 2010. In addition, we expect other triptan patents to expire between 2012 and 2025. Many of these products are manufactured and marketed by large pharmaceutical companies and are well accepted by physicians, patients and third party payors. Because of the low cost, health insurers likely would require or encourage use of, and consumers likely would use, a generic triptan prior to trying Zelrix.

In addition to marketed migraine medications, if approved, Zelrix may face competition from migraine product candidates in various stages of clinical development by both large and small companies. These include Merck s telcagepant, an orally administered calcitonin gene related peptide antagonist, and Levadex from MAP Pharmaceuticals, Inc., an inhaled formulation of dihydroergotamine, both for acute migraine, and Allergan, Inc. s Botox for chronic migraine. Each of these has either completed or is in Phase III clinical development. Zelrix may also compete with other drug candidates that receive marketing approval before Zelrix. If we are unable to demonstrate the advantages of Zelrix over competing drugs and drug candidates, we will not be able to successfully commercialize Zelrix and our results of operations will suffer.

As with Zelrix, if approved, each of NP201 and NP202 will face competition from generic and branded products. Specifically, NP201, a biodegradable, subcutaneous, injectable polymer implant combined with ropinirole, will face competition from generic immediate release and extended release versions of ropinirole and the dopamine agonist pramiprexole, as well as from two continuous delivery medications, a levadopa gel and an injectable apomorphine. NP202, a biodegradable, subcutaneous, injectable polymer implant combined with an atypical antipsychotic medication, will face competition from a variety of branded and generic versions of antipsychotic medications, in addition to several other sustained delivery depot formulations of atypical antipsychotics.

As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA approval or discovering, developing and commercializing migraine and other therapies before we do.

Any failure or delay in preclinical studies or clinical trials for our product candidates may cause us to incur additional costs or delay or prevent the commercialization of our product candidates and could severely harm our business.

Before obtaining marketing approval for the sale of our product candidates, we must conduct, at our own expense, extensive preclinical tests and then clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing, in particular, is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Even if preclinical studies and early phase clinical trials succeed, it is necessary to conduct additional clinical trials in larger numbers of subjects taking the medication for longer periods before seeking FDA approval to market and sell a medication in the U.S. Clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. A failure of one or more of our clinical trials can occur at any stage of testing.

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We may experience numerous unforeseen events during, or as a result of, the clinical trial process, which could delay or prevent us from receiving marketing approval or commercializing our product candidates, including the following:

- Regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or we may abandon projects that we expect to be promising;
- The number of subjects required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate;
- We might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- Regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or our clinical protocols;
- Regulators may refuse to accept or consider data from clinical trials for various reasons, including noncompliance with regulatory requirements or our clinical protocols;
- The cost of our preclinical or clinical trials may be greater than we anticipate;
- The supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate; and
- The effects of our product candidates may not be the desired effects or the desired level of effect or may include undesirable side effects or the product candidates may have other unexpected characteristics.

A number of these risks remain applicable to our trials required for our NDA submission for Zelrix.

Subject enrollment, which is a significant factor in the timing of clinical trials, is affected by a variety of factors, including the following:

- The size and nature of the subject population;
- The proximity of subjects to clinical sites;
- The eligibility criteria for the trial;
- The design of the clinical trial;
- Competing clinical trials; and
- Clinicians and subjects perceptions as to the potential advantages of the medication being studied in relation to other available therapies, including any new medications that may be approved for the indications we are investigating.

Furthermore, we plan to rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Any delays or unanticipated problems during clinical testing, such as enrollment in our clinical trials being slower than we anticipate or participants dropping out of our clinical trials at a higher rate than we anticipate, could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues.

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Serious adverse events or other safety risks could require us to abandon development and preclude or limit approval of our product candidates.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies or institutional review boards may at any time order the temporary or permanent discontinuation of our clinical trials or of investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial of any product candidates, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates, if at all, will be delayed or eliminated.

Clinical trials for our product candidates involve testing in large subject populations, which could reveal a high prevalence of adverse events. If these effects include undesirable serious adverse events or have unexpected characteristics, we may need to abandon our development of these product candidates. Alternatively, the identification of serious adverse events or other significant safety risks could result in the imposition of approval requirements, such as labeling or distribution and use restrictions that limit the available market for our product candidates.

Even if Zelrix receives FDA marketing approval, we may not be able to secure marketing exclusivity in the U.S.

Although we plan to seek three years marketing exclusivity in the U.S. if we receive FDA approval for Zelrix, we may not be entitled to such marketing exclusivity if the FDA determines that our clinical investigations were not essential to the approval of the Zelrix NDA. This three year marketing exclusivity period, if granted, would be coterminous with any patent coverage for Zelrix. We also intend to seek an additional period of six months pediatric exclusivity in the U.S., but may not be able to secure such exclusivity if the FDA does not request pediatric trials for Zelrix or we are unable to complete the trials that the FDA requests. The six month pediatric exclusivity period, if granted, would be in addition to the term of any existing regulatory exclusivity or listed patent term. If we are unable to secure marketing exclusivity and any patents that we are issued do not provide sufficient protection, our business and ability to generate revenues may be harmed significantly.

If we fail to acquire, develop and commercialize product candidates other than Zelrix, our prospects for future growth and our ability to sustain profitability may be limited.

A key element of our strategy is to develop and commercialize a portfolio of product candidates in addition to Zelrix. To do so, we plan to obtain additional product candidates or technologies primarily through acquisitions or licenses. We may not be successful in our efforts to identify and develop additional product candidates, and any product candidates we do identify may not produce commercially viable drugs that safely and effectively treat their indicated conditions. To date, our efforts have yielded two product candidates in addition to Zelrix, both of which are currently in preclinical development.

Our development programs may initially show promise in identifying potential product leads, yet fail to produce product candidates for clinical development. In addition, identifying new treatment needs and product candidates requires substantial technical, financial and human resources on our part. If we are unable to maintain or secure additional development program funding or continue to devote substantial technical and human resources to such programs, we may have to delay or abandon these programs. Any product candidate that we successfully identify may require substantial additional development efforts prior to commercial sale, including preclinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development.

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We may be unable to license or acquire suitable product candidates or technologies from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, we expect competition in acquiring product candidates to increase, which may lead to fewer suitable acquisition opportunities for us as well as higher acquisition prices.

Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates include the following:

- We may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from such product;
- Companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or
- We may be unable to identify suitable products or product candidates within our areas of expertise.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of any products that we may successfully develop.

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We will face an even greater risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates, or any products we may commercialize, cause injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, these lawsuits may:

- Expose us to adverse publicity;
- Decrease demand for any products that we successfully develop;
- Cause clinical trial participants to withdraw from clinical trials or be reluctant to enroll;
- Divert our management from pursuing our business strategy;
- Increase warnings on our product label;
- Be costly to defend; and
- Force us to limit or forgo further development and commercialization of these products.

Although we maintain general liability and product liability insurance with limits, subject to deductibles, of $2.0 million in the aggregate for general liability, $1.0 million in the aggregate for umbrella liability coverage for payments that exceed the general liability limits and $2.0 million in the aggregate for product liability, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, operating results and financial condition.

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A variety of risks associated with our planned international business relationships could materially adversely affect our business.

We may enter into agreements with third parties for the development and commercialization of Zelrix and possibly other products in international markets. If we do so, we would be subject to additional risks related to entering into international business relationships, including:

- Differing regulatory requirements for drug approvals in foreign countries;
- Potentially reduced protection for intellectual property rights;
- The potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market, with low or lower prices, rather than buying them locally;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- Foreign taxes;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- Workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- Business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future. We may never become profitable.

As of June 30, 2010, we had an accumulated deficit of approximately $65.0 million. We are a development stage specialty pharmaceutical company with no products approved for commercial sale and, to date, have not generated any revenues. We have funded our operations to date primarily with the proceeds of the sale of convertible preferred stock, convertible notes and borrowings under debt facilities, and with the proceeds from our August 2010 IPO. 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 and, subject to obtaining such approval, the eventual commercialization of Zelrix and our other product candidates. In addition, we will incur additional costs of operating as a public company and, if we obtain marketing approval for Zelrix, will incur significant sales, marketing and outsourced manufacturing expenses. As a result, we expect to continue to incur significant and increasing losses for the foreseeable future.

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To achieve and maintain profitability, we need to generate significant revenues from future product sales. This will require us to be successful in a range of challenging activities, including:

- Obtaining marketing approval for the marketing of Zelrix and possibly other product candidates;
- Commercializing Zelrix and any other product candidates for which we obtain marketing approval; and
- Achieving market acceptance of Zelrix and any other product candidates for which we obtain marketing approval in the medical community and with patients and third party payors.

Zelrix will require additional clinical trials and evaluation, marketing approval and investment in commercial capabilities, including manufacturing and sales and marketing efforts, before its product sales generate any revenues for us. Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to predict the extent of any future losses. We may never successfully commercialize any products, generate significant future revenues or achieve and sustain profitability.

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

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

- Complete development of and seek marketing approval for Zelrix;
- Launch and commercialize Zelrix 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 Zelrix or our other product candidates.

We believe that our existing cash and cash equivalents, including the proceeds from our IPO, will be sufficient to fund our operations and capital requirements and to complete the development of Zelrix through FDA approval and to fund the expected commercial launch of Zelrix in the U.S. in the first half of 2012. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

Our future capital requirements will depend on many factors, including the following:

- The timing of our submission to the FDA and outcome of the FDA s review of the NDA for Zelrix;
- The extent to which the FDA may require us to perform additional clinical trials for Zelrix;
- The costs of our commercialization activities for Zelrix, if it is approved by the FDA;
- The cost of purchasing manufacturing and other capital equipment for our potential products;
- The scope, progress, results and costs of development for our other product candidates;
- The cost, timing and outcome of regulatory review of our other product candidates;

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- The extent to which we acquire or invest in products, businesses and technologies;
- The extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for product candidates; and
- The costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. The covenants under the $5.0 million May 2010 Loan Facility and the pledge of our assets as collateral limit our ability to obtain additional debt financing. We have no committed external sources of funds. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, 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.

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.

Our indebtedness may limit cash flow available to invest in the ongoing needs of our business.

As of June 30, 2010 we had $5.0 million principal amount of indebtedness outstanding under the May 2010 Loan Facility. We may incur additional indebtedness beyond this amount, including, subject to our satisfaction of specified conditions and approval by the lenders in their sole discretion, up to $6.0 million under the May 2010 Loan Facility. Our indebtedness combined with our other financial obligations and contractual commitments, including amounts due under an equipment funding agreement with LTS could have significant adverse consequences, including:

- Requiring us to dedicate a substantial portion of our cash resources to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- Increasing our vulnerability to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;
- Limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- Placing us at a competitive disadvantage compared to our competitors that have less debt.

In addition, we are vulnerable to increases in the market rate of interest because amounts outstanding under the May 2010 Loan Facility bear interest at a variable rate. If the market rate of interest increases, we may have to pay additional interest on our outstanding debt, which would reduce cash available for our other business needs. Further, we are subject to fluctuations in exchange rates because amounts due under the equipment funding agreement with LTS are in Euros. If the U.S. dollar weakens against the Euro, our costs in U.S. dollars will increase, which would also reduce cash available for our other business needs.

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We may need external sources of funds to repay our indebtedness as it matures. We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under the May 2010 Loan Facility or any other borrowings. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under the May 2010 Loan Facility or future indebtedness could result in an event of default. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default or the occurrence of a mandatory prepayment event, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness.

We have a limited operating history, which makes it difficult to evaluate our business and growth prospects.

We were incorporated in Delaware in January 2005. Our operations to date have been limited to organizing and staffing our company, conducting product development activities for Zelrix and performing preclinical development of our other product candidates. As a company, we have not yet demonstrated an ability to obtain marketing approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products as a company.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to Our Dependence on Third Parties

We use third parties to manufacture all of our product candidates, including Zelrix, and the machinery to produce the commercial supply of Zelrix must be designed, built and validated. This may increase the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could result in clinical development and commercialization of our product candidates being delayed, prevented or impaired.

We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale.

We currently outsource all manufacturing of our preclinical and clinical product candidates to third parties, including sumatriptan and key components of Zelrix, typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our preclinical and clinical product candidates may delay the development or commercialization of Zelrix or our other product candidates.

In addition, we do not currently have any agreements with third party manufacturers for the long-term commercial supply of our product candidates. We may be unable to enter agreements for commercial supply with third party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time.

In particular, LTS manufactures Zelrix using sumatriptan and components that we purchase from third parties. Although LTS has considerable experience in the manufacturer of passive transdermal drug patches, it does not have such experience in manufacturing active transdermal patches such as Zelrix. In order for LTS to produce our commercial supply of Zelrix, LTS must successfully complete the following:

- Transfer technology and production capabilities from its German facility where our clinical supply has been produced to its manufacturing facility in New Jersey;
- Assemble the commercial scale manufacturing equipment for Zelrix using components purchased from third party suppliers; and
- Test and validate the newly-assembled machinery and production process.

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The machinery that LTS will use to produce the commercial supply of Zelrix will be customized to the particular manufacturing specifications of Zelrix and does not exist currently. In June 2010, we entered into an equipment funding agreement with LTS, under which we agreed to fund the purchase by LTS of the manufacturing equipment for Zelrix. If LTS is unable to assemble and validate this equipment, or to validate the production process at its New Jersey facility, in each case in a timely manner, our ability to launch and commercialize Zelrix will be compromised significantly. If this customized equipment malfunctions at any time during the production process, the time it may take LTS to secure replacement parts, to undertake repairs and to revalidate the equipment and process could limit our ability to meet the commercial demand for Zelrix.

Reliance on third party manufacturers subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

- Reliance on the third parties for regulatory compliance and quality assurance;
- The possible breach of the manufacturing agreements by the third parties because of factors beyond our control;
- The possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities; and
- The disruption and costs associated with changing suppliers.

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under current good manufacturing practice (cGMP) regulations and that are both capable of manufacturing for us and willing to do so. If our existing third party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control, manufacturing, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements.

We may rely on third parties to conduct aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining or ultimately not be able to obtain marketing approval to commercialize Zelrix or any other product candidates.

We currently rely on contract research organizations (CROs) for some aspects of our clinical trials, including data management, statistical analysis and electronic compilation of our NDA. We may enter into additional agreements with CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to ongoing clinical and preclinical programs. Entering into relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period when a CRO commences work. As a result, delays may occur, which may materially impact our ability to meet our desired clinical development timelines and ultimately have a material adverse impact on our operating results, financial condition or future prospects.

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As CROs are not our employees, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs in which they are engaged to perform. If the CROs we engage do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the data they provide is compromised due to the failure to adhere to regulatory requirements, or for other reasons, our development programs may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize Zelrix or any other product candidates that we develop. As a result, our financial results and the commercial prospects for Zelrix and any other product candidates that we develop would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our product candidates in the future. We may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each product candidate, both in the U.S. and internationally. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Regulatory Matters

If we are unable to obtain marketing approval for Zelrix or our other product candidates, we will not be able to commercialize our product candidates and our business will be substantially harmed.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. As a company, we have not received approval from the FDA or demonstrated our ability to obtain marketing approval for any drugs that we have developed or are developing. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish the product candidate s safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Our other product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

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The process of obtaining marketing approvals is expensive and often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the nature of the disease or condition to be treated. We intend to seek approval of Zelrix and likely other product candidates pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) in the U.S., which enables an NDA applicant to rely in part on findings of safety and efficacy of a product already approved by the FDA. We may fail to obtain marketing approval for Zelrix or any other product candidates for many reasons, including the following:

- We may not be able to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;
- The results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- The FDA or comparable foreign regulatory authorities may disagree with the number, design, conduct or implementation of our clinical trials;
- We may not be able to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- We may not be able to demonstrate that a product candidate provides an advantage over current standard of care or future competitive therapies in development;
- The FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- The FDA or comparable foreign regulatory authorities may not accept data generated at our clinical trial sites;
- The data collected from clinical trials of any product candidates that we develop may not be sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the U.S. or elsewhere;
- The FDA may determine that we have identified the wrong reference listed drug or drugs or that approval of our 505(b)(2) application for Zelrix or any other product candidate is blocked by patent or non-patent exclusivity of the reference listed drug or drugs; and
- The FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing or testing processes or facilities of third party manufacturers with which we enter into agreements for clinical and commercial supplies.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain marketing approval to market Zelrix or any future product candidates, which would significantly harm our business, results of operations and prospects.

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Even if we obtain marketing approval for Zelrix or any of our other product candidates, we will continue to face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if marketing approval in the U.S. is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing, including risk evaluation and mitigation strategies, or impose ongoing requirements, including with respect to:

- Post-market surveillance, post-market studies or post-market clinical trials;
- Labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information;
- Monitoring and reporting adverse events and instances of the failure of a product to meet the specifications in the NDA;
- Changes to the approved product, product labeling or manufacturing process;
- Advertising and other promotional material; and
- Disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. The distribution, sale and marketing of our products are subject to a number of additional requirements, including:

- State wholesale drug distribution laws and the distribution of our product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act;
- Sales, marketing and scientific or educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, the transparency provision of the Patient Protection and Affordable Care Act and an associated reconciliation bill that became law in March 2010, which we refer to collectively as the Health Care Reform Law, the False Claims Act and similar state laws;
- Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran s Health Care Act of 1992; and
- If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or any third parties involved in our commercialization efforts fail to comply with applicable regulatory requirements, a regulatory agency may:

- Issue warning letters or untitled letters asserting that we are in violation of the law;
- Seek an injunction or impose civil or criminal penalties or monetary fines;
- Suspend or withdraw marketing approval;
- Suspend any ongoing clinical trials;
- Refuse to approve pending applications or supplements to applications submitted by us;

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- Suspend or impose restrictions on operations, including costly new manufacturing requirements;
- Seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall;
- Refuse to allow us to enter into supply contracts, including government contracts;
- Impose civil monetary penalties; or
- Pursue civil or criminal prosecutions and fines against our company or responsible officers.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenues.

Even if we obtain marketing approval for Zelrix or any of our other product candidates, adverse effects discovered after approval could limit the commercial profile of any approved product.

If we obtain marketing approval for Zelrix or any other product candidate that we develop, we or others may later discover, after use in a larger number of subjects for longer periods of time than in clinical trials, that our products could have adverse effect profiles that limit their usefulness or require their withdrawal. This discovery could have a number of potentially significant negative consequences, including:

- Regulatory authorities may withdraw their approval of the product;
- Regulatory authorities may require the addition of labeling statements, such as black box or other warnings or contraindications;
- Regulatory authorities may require us to issue specific communications to healthcare professionals, such as Dear Doctor Letters;
- Regulatory authorities may impose additional restrictions on marketing and distribution of the products;
- Regulatory authorities may issue negative publicity regarding the product, including safety communications;
- We may be required to change the way the product is administered, conduct additional clinical studies or restrict the distribution of the product;
- We could be sued and held liable for harm caused to subjects; and
- Our reputation may suffer.

Any of these events could prevent us from maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

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We will need FDA approval of our proposed trade name, Zelrix, and any failure or delay associated with such approval may delay the commercialization of Zelrix.

Any trade name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office (USPTO). The FDA typically conducts a rigorous review of proposed trade names, including an evaluation of potential for confusion with other trade names and medical error. The FDA may also object to a trade name if it believes the name inappropriately implies medical claims. We intend to submit the proposed trade name Zelrix to the FDA for approval. If the FDA objects to our proposed trade name, we may be required to adopt an alternative name for our product candidate. Even after approval, the FDA may request that we adopt an alternative name for the product if adverse event reports indicate a potential for confusion with other trade names and medical error. If we are required to adopt an alternative name, the commercialization of Zelrix could be delayed or interrupted, which would limit our ability to commercialize Zelrix and generate revenues.

If the FDA does not approve the manufacturing facilities of LTS or any future third party manufacturers for commercial production, we may not be able to commercialize Zelrix or any of our other product candidates.

The facilities used by LTS and any of our future manufacturers to manufacture Zelrix must be approved by the FDA after we submit our NDA to the FDA and before approval of Zelrix. W e do not control the manufacturing process of Zelrix and are completely dependent on third party manufacturers for compliance with the FDA s requirements for manufacture of Zelrix. If our manufacturers cannot successfully manufacture material components and finished products that conform to our specifications and the FDA s strict regulatory requirements, they will not be able to secure FDA approval for their manufacturing facilities. If the FDA does not approve these facilities for the commercial manufacture of Zelrix, or the facilities of any of our other product candidates, we may need to find alternative manufacturing facilities, which would result in significant delays of up to several years in obtaining FDA approval for Zelrix, or any of our other product candidates. We would incur substantial additional costs as a result of any such delays, including with respect to finding alternative manufacturing facilities.

Even if our product candidates receive marketing approval in the U.S., we may never receive marketing approval or commercialize our products outside the U.S.

In order to market Zelrix or any other product candidate outside the U.S., we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the U.S., as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FDCA in the U.S., which relates to the ability of an NDA applicant to use published data not developed by such applicant, does not exist in other countries. In territories where data is not freely available, we may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. Further, we may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety and effectiveness dossiers. In addition, in many countries outside the U.S., it is required that a product receives pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries.

Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we fail to comply with applicable foreign regulatory requirements. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third party payors and customers will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- The federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities conducted by our sales team in the sale of Zelrix, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products for which we obtain marketing approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Risks Related to Intellectual Property

We may not be able to rely on our intellectual property to protect our products in the marketplace.

Our success depends, in large part, on our ability to protect our competitive position through patents, trade secrets, trademarks and other intellectual property rights. The patent positions of pharmaceutical and biotechnology companies, including our company, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved or may change. As a result of recent court decisions, the requirements for patentability of inventions in the U.S. have become more stringent, including stricter requirements that inventions be non-obvious and that patent applications provide an adequate written description of the invention. These court decisions may have the effect of narrowing the types of medical treatments that are patentable.

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The patent we have licensed and patents that may be licensed by or issued to us in the future may not provide us with any competitive advantage. Our patents may be challenged by third parties in patent litigation, or in patent reexamination or opposition proceedings, which are becoming widespread in the pharmaceutical industry. In particular, it is not uncommon for potential competitors to challenge the validity of patents protecting new pharmaceutical products shortly after the products receive FDA approval. Alternatively, it is possible that third parties with products that are very similar to ours will circumvent our issued patents by purposely developing products or processes that avoid our patent claims. Our patent protection may be limited because of any of the following:

- Our patents may not be broad or strong enough to prevent competition from identical or similar products;
- We may be required to disclaim part of the term of some patents;
- There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- There may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a claim, but which, nonetheless ultimately may be found to affect the validity or enforceability of a claim;
- If challenged, a court could determine that our issued patents are not valid or enforceable;
- A court could determine that a competitor s technology or product does not infringe our patents; and
- Our patents and patent applications could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing.

We do not currently own any issued U.S. or foreign patents covering any of our product candidates or technology. We have licensed one issued U.S. patent that relates to an iontophoresis drug delivery system. We and our licensors have filed and are actively pursuing applications for patents in the U.S. and in foreign jurisdictions. However, pending patent applications may not result in the issuance of patents or the scope of patent protection that we have requested, and we may not develop additional proprietary products which are patentable. Further, if we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

Because the composition of matter patent covering the active pharmaceutical ingredient of Zelrix has expired, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as Zelrix so long as these competitors do not infringe any other patents that may be issued to or licensed by us, including any product, formulation and method of use patents, or violate any marketing exclusivity period that may be granted. Similarly, the composition of matter patents covering the active ingredients of our NP201 and NP202 product candidates have expired, and competitors will be able to offer and sell products with the same active pharmaceutical ingredients as these product candidates products so long as these competitors do not infringe any other patents that we hold or may obtain in the future, including any product, formulation and method of use patents, or violate any marketing exclusivity period that may be granted.

Patents covering new products or formulations incorporating a generic active pharmaceutical ingredient cannot prevent competitors from commercializing the original products and formulations. In addition, method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product s labeling. Although off label prescriptions may infringe our method of use patents, if issued, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off label sales would limit our ability to generate revenue from the sale of our product candidates, if approved for commercial sale. In addition, if a third party were able to design around any issued product, method, formulation or other patent and create a different product not covered by our patents, if issued, we would likely be unable to prevent that third party from manufacturing and marketing its product.

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We rely on third parties to protect the intellectual property we license, including trade secrets, patents, and know-how, and we may not have any input or control over the filing, prosecution or enforcement of such intellectual property rights. Any resulting patents may be invalid or unenforceable. Any enforcement of intellectual property rights, or defense of any claims asserting the invalidity thereof, may be subject to the cooperation of the third parties.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements and may enter into additional licenses in the future. If we fail to comply with the obligations under a license agreement or otherwise breach the license agreement, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by any previously licensed patents.

For example, we are party to a license agreement with the University of Pennsylvania (Penn), pursuant to which we license from Penn patent applications and other intellectual property related to the LAD technology to develop and commercialize licensed products, including NP201 and NP202, and a license agreement with SurModics Pharmaceuticals, Inc. (SurModics), pursuant to which we license from SurModics intellectual property to make, have made, use, sell, import and export NP201. We are obligated to pay milestone and royalty payments under each agreement in addition to other obligations. The triggering of milestone payments to Penn or SurModics depends on factors relating to the clinical and regulatory development and commercialization of NP201 and NP202, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization and marketing efforts or seek additional capital to meet these obligations on terms unfavorable to us.

Our failure to comply with the requirements of these license agreements, including our milestone payment obligations, could result in the termination of such agreements, in which case we might not be able to develop or market any product that is covered by the license. Even if we contest any such termination and are ultimately successful, our results of operations and stock price could suffer.

Our ability to pursue the development and commercialization of Zelrix is significantly dependent upon obtaining a license of LTS s intellectual property.

Our development and license agreement with LTS provides that if we enter into a commercial manufacturing agreement with LTS, LTS will have the exclusive right to manufacture Zelrix and LTS will grant us an exclusive, worldwide, royalty-free license under LTS s intellectual property to use, import, sell, market and distribute Zelrix. We may not enter into a commercial manufacturing agreement with LTS on commercially reasonable terms, if at all. If we do not enter into a commercial manufacturing agreement with LTS, we may not have access to LTS s proprietary technology and know-how to manufacturer Zelrix. In this situation, we would need to develop equivalent or alternative intellectual property, which will significantly delay our commercialization of Zelrix and entail significant additional cost.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. There could be issued patents of which we are not aware that our products infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes.

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Third parties may assert that we are employing their proprietary technology without authorization. If a court held that any third party patents cover our products, the holders of any such patents may be able to block our ability to commercialize our products unless we obtained a license under the applicable patent or patents, or until such patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be significantly diminished.

In addition to patents, we rely on trade secrets and proprietary know-how to protect our intellectual property. We generally require our employees, consultants, outside scientific collaborators and sponsored researchers and other advisors to enter into confidentiality agreements. These agreements provide that all confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment are our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions.

These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of our proprietary information. Involuntary disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position. In addition, it is possible that third parties could independently develop proprietary information and techniques substantially similar to ours or otherwise gain access to our trade secrets.

Risks Related to Employee Matters and Managing Growth

If we are not successful in attracting and retaining highly qualified personnel, including our current senior executive team, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceutical and biotechnology industries depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Competition for skilled personnel in our market is very intense because of the numerous pharmaceutical and biotechnology companies that seek similar personnel. These companies may have greater financial and other resources, offer a greater opportunity for career advancement and have a longer history in the industry than we do. We also experience competition for the hiring of our scientific and clinical personnel from universities and research institutions.

We are highly dependent on Jane H. Hollingsworth, our Chief Executive Officer, and Terri B. Sebree, our President. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have formal employment agreements with Ms. Hollingsworth and Ms. Sebree, as well as all of our other executive officers, that each include reasonable notice periods for terminations of such individual s employment. Besides these agreements, all other employees employment is at-will, which means that any of these employees could leave our employment at any time. We maintain key person insurance for each of Ms. Hollingsworth and Ms. Sebree. The total death benefit under each policy is $2.0 million and we are the only named beneficiary and owner of the policies. The policies have an initial term of ten years and are subject to renewal annually thereafter. We do not maintain key person insurance for any of our other employees. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition.

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We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of June 30, 2010, we employed 22 full-time employees. We expect to expand our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the anticipated commercialization of Zelrix or development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize Zelrix and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been, and may continue to be, highly volatile.

The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including the following:

- Any delay in submitting our NDA for Zelrix and any adverse development or perceived adverse development with respect to the FDA s review of such NDA, including the FDA s refusal to accept the NDA for substantive review or a request for additional information;
- The commercial success of Zelrix, if approved by the FDA;
- Results of clinical trials of our product candidates or those of our competitors;
- Changes or developments in laws or regulations applicable to our product candidates;
- Introduction of competitive products or technologies;
- Failure to meet or exceed financial projections we provide to the public;
- Actual or anticipated variations in quarterly operating results;
- Failure to meet or exceed the estimates and projections of the investment community;
- The perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- General economic and market conditions and overall fluctuations in U.S. equity markets;
- Developments concerning our sources of manufacturing supply;
- Disputes or other developments relating to patents or other proprietary rights;
- Additions or departures of key scientific or management personnel;
- Issuances of debt, equity or convertible securities;

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Changes in the market valuations of similar companies; and

The other factors described in this Risk Factors section.

In addition, the stock market in general, and the market for small pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management s attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

To our knowledge, upon the closing of our initial public offering on August 11, 2010, our executive officers, directors and 5% stockholders and their affiliates owned approximately 78% of our outstanding voting stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after August 11, 2010. As a result, these stockholders will have significant influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership could delay or prevent any acquisition of our company on terms that other stockholders may desire.

Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options and warrants could negatively affect our stock price.

A substantial portion of our outstanding common stock can be traded without restriction at any time. Some of these shares are currently restricted as a result of securities laws or lock-up agreements that were entered into with the underwriters of our public offering, but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and warrants. The exercise of these options and warrants and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Because we do not intend to pay dividends on our common stock, your returns will be limited to any increase in the value of our stock.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our bylaws that will become effective following the closing of our IPO, as well as provisions of the Delaware General Corporation Law (DGCL) could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- Authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- Prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- Eliminating the ability of stockholders to call a special meeting of stockholders; and
- Establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the pharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully respond to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

- Responding to proxy contests and other actions by activist stockholders may be costly and time-consuming, and may disrupt our operations and divert the attention of management and our employees;
- Perceived uncertainties as to the potential outcome of any proxy contest may result in our inability to consummate potential acquisitions, collaborations or licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and
- If individuals that have a specific agenda different from that of our management or other members of our board of directors are elected to our board as a result of any proxy contest, such an election may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

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

Unregistered Sales of Equity Securities

During the period from April 1, 2010 until June 30, 2010, we:

- Received gross proceeds of $10.1 million from the sale of the convertible promissory notes in a private placement to certain of our existing investors. The convertible promissory notes accrued interest at a rate equal to 8% per year, compounding monthly, and had a maturity date of December 31, 2010, unless converted prior thereto. The convertible promissory notes automatically converted into common stock upon the closing of our IPO at a conversion price equal to 80% of the offering price to the public; and

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Entered into the May 2010 Loan Facility for $5.0 million. In connection with such loan we issued the lenders warrants to purchase 255,376 shares of Series B preferred stock at an exercise price of $0.93 per share. Upon the closing of our IPO, in accordance with their terms, the warrants automatically became exercisable for 31,861 shares of common stock at an exercise price of $7.45 per share of common stock.

We deemed the offers, sales and issuances of the securities described above to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, relative to transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

Use of Proceeds from Registered Securities

Our IPO of common stock was effected through Registration Statements on Form S-1 (File No. 333- 166825), that was declared effective by the SEC on August 5, 2010, which registered an aggregate of 5,000,000 shares of our common stock at an aggregate price of $50,000,000. All of the 5,000,000 shares of common stock registered under the Registration Statement were sold at a price to the public of $10.00 per share. The offering commenced on August 5, 2010 and closed on August 11, 2010. Leerink Swann, LLC and Lazard Capital Markets, LLC acted as joint book-running managers for the offering. Needham & Company, LLC acted as co-manager. There were no selling stockholders in the offering.

We paid $3.5 million in underwriting discounts and commissions to the underwriters in connection with the offering. In addition, we incurred additional costs of approximately $3.5 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $7.0 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately $43.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We expect to use the net proceeds from our IPO as follows: approximately $36.0 million to complete the clinical development of, seek marketing approval for, initiate the commercial manufacture of and, if approved, commercially launch Zelrix in the U.S, approximately $5.0 million to continue preclinical and clinical development of NP201 and NP202 and the balance for other working capital and other general corporate purposes. 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: September 14, 2010

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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INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation of NuPathe Inc.	8-K		3.1	August 12, 2010	
3.2	Bylaws of NuPathe Inc.	8-K		3.2	August 12, 2010	
4.1	Amended and Restated Investor Rights Agreement, dated as of July 8, 2008, as amended	S-1/A	333-166825	4.1	August 5, 2010	
4.2	Preferred Stock Warrant, dated as of March 29, 2007, as amended, issued to Oxford Finance Corp.	S-1/A	333-166825	4.2	June 15, 2010	
4.3	Form of Warrant to Purchase Shares of Series B Preferred Stock, as amended	S-1/A	333-166825	4.3	June 15, 2010	
4.4	Series B Preferred Stock Warrant, dated May 13, 2010, issued to MidCap Funding III, LLC	S-1/A	333-166825	4.4	June 15, 2010	
4.5	Series B Preferred Stock Warrant, dated May 13, 2010, issued to Silicon Valley Bank	S-1/A	333-166825	4.5	June 15, 2010	
10.1#	Feasibility Evaluation Agreement, dated March 19, 2007, as amended, between NuPathe Inc. and SurModics Pharmaceuticals, Inc. (f/k/a Brookwood Pharmaceuticals, Inc.)	S-1/A	333-166825	10.4	July 27, 2010	
10.2	Secured Subordinated Convertible Note and Warrant Purchase Agreement, dated April 9, 2010, between NuPathe Inc. and the Purchasers named therein	S-1/A	333-166825	10.6	June 15, 2010	
10.3	Loan and Security Agreement, effective as of May 13, 2010, by and among MidCap Funding III, LLC, Silicon Valley Bank and NuPathe Inc.	S-1/A	333-166825	10.7	June 15, 2010	
10.4	Secured Promissory Note, dated May 13, 2010, made by NuPathe Inc. in favor of MidCap Funding III, LLC	S-1/A	333-166825	10.8	June 15, 2010	

10.5	Secured Promissory Note, dated May 13, 2010, made by NuPathe Inc. in favor of Silicon Valley Bank	S-1/A	333-166825	10.9	June 15, 2010
10.6#	Equipment Funding Agreement, dated June 1, 2010, between NuPathe Inc. and LTS Lohmann Therapie-Systeme AG	S-1/A	333-166825	10.11	July 27, 2010

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.7	2010 Omnibus Incentive Compensation Plan, including forms of Incentive Stock Option Grant Agreements, Nonqualified Stock Option Grant Agreements and Restricted Stock Grant Agreement thereunder	S-1/A	333-166825	10.13	July 21, 2010	
10.8	2010 Employee Stock Purchase Plan	S-1/A	333-166825	10.14	July 21, 2010	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 (a) under the Securities Exchange Act of 1934					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934					X
32.1*	Certification by Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					X

Certain information in this exhibit has been omitted pursuant to an Order Granting Confidential Treatment issued by the Securities and Exchange Commission.

* Furnished herewith.