
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2009

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 000-31719

POZEN Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

62-1657552
(I.R.S. Employer
Identification No.)

**1414 Raleigh Road
Suite 400
Chapel Hill, North Carolina 27517**
(Address of principal executive offices, including zip code)

(919) 913-1030
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934. (Check one):

☐ Large Accelerated Filer ☒ Accelerated Filer
☐ Non-Accelerated Filer ☐ Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ Yes ☒ No

The number of shares outstanding of the registrant's common stock as of July 24, 2009 was 29,825,365.

POZEN Inc.
FORM 10-Q

For the Three Months Ended June 30, 2009

INDEX

	<u>Page</u>
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements (unaudited)	
Balance Sheets as of June 30, 2009 and December 31, 2008	1
Statements of Operations for the Three and Six Months Ended June 30, 2009 and 2008	2
Statements of Cash Flows for the Six Months Ended June 30, 2009 and 2008	3
Notes to Financial Statements	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	11
Item 3. Quantitative and Qualitative Disclosures About Market Risk	22
Item 4. Controls and Procedures	22
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	23
Item 1A. Risk Factors	23
Item 4. Submission of Matters to a Vote of Security Holders	36
Item 6. Exhibits	36
Signature and Certifications	37
Exhibit Page	38

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc. BALANCE SHEETS (Unaudited)

	<u>June 30, 2009</u>	<u>December 31, 2008</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,867,053	\$ 26,119,249
Short-term investments	31,155,163	35,562,723
Accounts receivable	948,512	8,119,435
Prepaid expenses and other current assets	<u>232,645</u>	<u>562,161</u>
Total current assets	49,203,373	70,363,568
Property and equipment, net of accumulated depreciation	<u>51,063</u>	<u>72,563</u>
Total assets	<u>\$ 49,254,436</u>	<u>\$ 70,436,131</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,107,416	\$ 7,328,428
Accrued compensation	1,101,678	2,172,314
Accrued expenses	2,193,633	5,737,254
Deferred revenue	<u>12,344,708</u>	<u>12,344,708</u>
Total current liabilities	17,747,435	27,582,704
Long-term liabilities:		
Deferred revenue	<u>1,028,726</u>	<u>7,201,080</u>
Total liabilities	18,776,161	34,783,784
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, issuable in series, of which 90,000 shares are designated Series A Junior Participating Preferred Stock, none outstanding	—	—
Common stock, \$0.001 par value, 90,000,000 shares authorized; 29,825,365 and 29,778,310 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	29,825	29,778
Additional paid-in capital	171,250,310	168,541,451
Accumulated other comprehensive income	72,220	221,520
Accumulated deficit	<u>(140,874,080)</u>	<u>(133,140,402)</u>
Total stockholders' equity	<u>30,478,275</u>	<u>35,652,347</u>
Total liabilities and stockholders' equity	<u>\$ 49,254,436</u>	<u>\$ 70,436,131</u>

See accompanying Notes to Financial Statements.

POZEN Inc.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Revenue:				
Licensing revenue	\$ 4,034,689	\$ 24,519,015	\$ 8,138,309	\$ 28,370,096
Development revenue	881,290	8,605,038	5,536,053	12,582,946
Total revenue	4,915,979	33,124,053	13,674,362	40,953,042
Operating expenses:				
General and administrative	4,783,168	3,142,869	9,211,160	5,991,842
Research and development	4,559,256	17,144,221	12,584,613	30,256,753
Total operating expenses	9,342,424	20,287,090	21,795,773	36,248,595
Interest and other income	156,025	497,140	387,732	1,258,404
Income (loss) before income tax expense	(4,270,420)	13,334,103	(7,733,679)	5,962,851
Income tax expense	-	-	-	-
Net income (loss) attributable to common stockholders	\$ (4,270,420)	\$ 13,334,103	\$ (7,733,679)	\$ 5,962,851
Basic net income (loss) per common share	\$ (0.14)	\$ 0.45	\$ (0.26)	\$ 0.20
Shares used in computing basic net income (loss) per common share	29,815,228	29,759,250	29,802,015	29,741,406
Diluted net income (loss) per common share	\$ (0.14)	\$ 0.43	\$ (0.26)	\$ 0.19
Shares used in computing diluted net income (loss) per common share	29,815,228	30,707,710	29,802,015	30,636,529

See accompanying Notes to Financial Statements.

POZEN Inc.
STATEMENTS OF CASH FLOWS
(Unaudited)

	Six months ended June 30,	
	2009	2008
Operating activities		
Net (loss) income	\$ (7,733,679)	\$ 5,962,851
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation	20,001	39,310
Loss on sale of fixed assets	1,498	—
Bond amortization income	(241,255)	(574,798)
Noncash compensation expense	2,676,205	2,693,056
Changes in operating assets and liabilities:		
Accounts receivable	7,170,923	(7,300,035)
Prepaid expenses and other current assets	329,517	536,377
Accounts payable and accrued expenses	(9,835,269)	3,778,735
Deferred revenue	(6,172,354)	(7,546,097)
Net cash used in operating activities	(13,784,413)	(2,410,601)
Investment activities		
Purchase of equipment	—	(6,493)
Purchase of investments	(18,081,096)	(43,020,061)
Sale of investments	22,580,611	38,819,288
Net cash provided by (used in) investing activities	4,499,515	(4,207,266)
Financing activities		
Proceeds from issuance of common stock	32,702	160,296
Net cash provided by financing activities	32,702	160,296
Net decrease in cash and cash equivalents	(9,252,196)	(6,457,571)
Cash and cash equivalents at beginning of period	26,119,249	37,660,068
Cash and cash equivalents at end of period	<u>\$ 16,867,053</u>	<u>\$ 31,202,497</u>

See accompanying Notes to Financial Statements.

POZEN Inc.
NOTES TO FINANCIAL STATEMENTS
(Unaudited)

1. Significant Accounting Policies

General

POZEN Inc. (“we” or “POZEN” or the “Company”) was incorporated in the State of Delaware on September 25, 1996 and is operating in a single reportable segment. The Company is a pharmaceutical company focused primarily on products for the treatment of acute and chronic pain and other pain-related conditions. Since inception, the Company has focused its efforts on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions. The Company may enter into collaboration agreements to commercialize its product candidates, and has entered into, and may continue to enter into such collaborations. The Company’s licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product’s development or commercialization are reached, and the eventual royalty payments based on product sales. Additionally, the Company’s development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under its collaboration agreements.

2. Summary of Significant Accounting Policies

Use of Estimates—The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from the estimates and assumptions used.

Revenue Recognition—The Company records revenue under two categories: licensing revenues and development revenues. With regard to the licensing revenues, the Company’s licensing agreements have terms that include upfront payments upon contract signing, additional payments if and when certain milestones in the product’s development or commercialization are reached, and royalty payments based on product sales. These agreements are accounted for in accordance with SEC Staff Accounting Bulletin No. 101, “Revenue Recognition”, as amended by SAB 104, “Revenue Recognition” (“SAB 104”), and Emerging Issues Task Force 00-21 (“EITF 00-21”), “Revenue Arrangements with Multiple Deliverables.” The non-refundable portion of upfront payments received under the Company’s existing agreements is deferred by the Company upon receipt and recognized on a straight-line basis over the period ending on the anticipated date of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on the part of the Company. For the Company’s current agreements, these periods are estimated to be as follows:

- The September 2006 \$40.0 million licensing fee received from AstraZeneca AB, or AstraZeneca, related to the August 2006 Collaboration and License Agreement with AstraZeneca has been deferred and was initially being amortized over 40 months. The AstraZeneca licensing fee relates to the Company’s proprietary fixed dose combinations of the proton pump inhibitor, or PPI, esomeprazole magnesium with the non-steroidal anti-inflammatory drug, or NSAID, naproxen, in a single tablet. As a result of the revised development timeline agreed upon in the September 2007 amendment to the AstraZeneca agreement, we extended the amortization period by 3 months. The September 2007 amendment included a \$10 million payment in connection with execution of the amendment. This payment was deferred to be amortized over 31 months. In 2008, we subsequently extended the amortization periods by 4 months, as a result of revisions to the development timeline. We recognized \$6.2 million and \$7.4 million of licensing revenue from the amortization of the AstraZeneca licensing fee and September 2007 amendment for the six months ended June 30, 2009 and 2008, respectively, and we recognized \$3.1 million and \$3.7 million for the three months ended June 30, 2009 and 2008.
- The June 2003 initial licensing and patent-issuance milestone payments totaling \$25.0 million for MT 400 received from GlaxoSmithKline, or GSK, have been deferred and were amortized over the expected period of development. During 2005 the amortization period was decreased to 39 months based upon the August 2005 submission to the U.S. Food and Drug Administration (“FDA”) of the Treximet[®] new drug application (“NDA”) which occurred earlier than previously anticipated. The 2005 change in the amortization period resulted in a \$0.7 million increase in the 2005 full-year amortization. During 2006, based upon the June 2006 receipt of an approvable letter from the FDA related to the Treximet NDA and the December 2006 receipt of a notice from the FDA that it had requested additional analyses and supporting information relating to submitted data, \$1.9 million of the \$25 million initial licensing and patent-issuance milestone payments was deferred to 2007. With the receipt of a second approvable letter in August 2007, unamortized deferred revenue was amortized through March 2008. We recognized \$0.2 million of licensing revenue from the amortization of GSK milestone payments during the six months ended June 30, 2008 and no revenue was recognized

during the three months ended June 30, 2008 and the three and six months ended June 30, 2009. The GSK upfront payments are now fully amortized.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Treximet royalty revenue is recognized when earned as will any future royalty revenues with respect to the manufacture, sale or use of the Company's products or technology. For Treximet or those future arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties. During the three and six months ended June 30, 2009, the Company recognized \$0.9 and \$2.0 million of royalty revenue which is included within licensing revenue in the accompanying statements of operations. During the three and six months ended June 30, 2008, the Company recognized \$0.8 million and \$0.8 million of royalty revenue which is included within licensing revenue in the accompanying statements of operations.

With regards to the development revenues, the Company's licensing agreements may include payment for development services provided by the Company on an hourly rate and direct expense basis. The Company records such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project. In accordance with EITF 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent", under the collaboration agreements with AstraZeneca and GSK, the Company recognizes as development revenue the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described within the related agreements. We recognize development revenue for development activities performed pursuant to the AstraZeneca and GSK agreements. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Development revenue and direct billed costs for the three and six months ended June 30, 2009 and 2008 were the following:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Development Revenue	\$ 881,290	\$ 8,605,038	\$ 5,536,053	\$ 12,582,946
Direct Costs	\$ 227,415	\$ 7,955,144	\$ 3,966,802	\$ 11,003,063

Investments—Investments consist primarily of United States government and government agency obligations, and corporate fixed income securities. The Company invests in high-credit quality investments in accordance with its investment policy, which minimizes the possibility of loss; however, given the recent disruption in the credit markets and the downgrades of previous high-credit companies, the possibility of a loss is increased. Under the Company's investment policy, investments that have a maturity of greater than three months and less than one year are classified as short-term, are considered to be available-for-sale and are carried at fair value with unrealized gains and losses recognized in other comprehensive income (loss). Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis. Generally, investments with maturities beyond twelve months are classified as long-term. Marketable and non-marketable equity investments are evaluated, on an on-going basis, for market impairment. If it is determined that a decline of any investment is other-than-temporary, the investment would be written down to fair value and the write-down would be permanent. For the three month periods ended June 30, 2009 and 2008, the Company had \$49,000 and \$214,000, respectively, of interest income and \$107,000 and \$283,000, respectively, of bond amortization income included in other income for the period. For the six month periods ended June 30, 2009 and 2008, the Company had \$147,000 and \$683,000, respectively, of interest income and \$241,000 and \$575,000, respectively, of bond amortization income included in other income for the period. The Company has considered the impact of the current economic environment on its evaluation of the fair value of its investments. We have no investments in debt securities with maturities of greater than one year. As of June 30, 2009 and December 31, 2008, there were no investments in a significant unrealized loss position.

Short-term investments consisted of the following as of June 30, 2009:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Market
Short-term investments:				
U.S. treasury and agency securities	\$ 31,080,702	\$ 72,161	\$ (107)	\$ 31,152,756
Corporate notes	2,241	275	(109)	2,407
Total short-term investments	\$ 31,082,943	\$ 72,436	\$ (216)	\$ 31,155,163

Short-term investments consisted of the following as of December 31, 2008:

	<u>Amortized Cost</u>	<u>Unrealized Gain</u>	<u>Unrealized Loss</u>	<u>Market</u>
Short-term investments:				
U.S. treasury and agency securities	\$ 30,429,208	\$ 213,830	\$ -	\$ 30,643,038
Corporate notes	4,911,995	12,584	(4,894)	4,919,685
Total short-term investments	<u>\$ 35,341,203</u>	<u>\$ 226,414</u>	<u>\$ (4,894)</u>	<u>\$ 35,562,723</u>

Cash and Cash Equivalents and Concentration of Credit Risk

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash is invested in interest-bearing investment-grade securities. Cash is restricted to the extent of a \$94,684 letter of credit, maintained in compliance with the terms of the Company's office lease.

Cash and cash equivalents include financial instruments that potentially subject the Company to a concentration of credit risk. Cash and cash equivalents are of a highly liquid nature and are insured by the respective financial institutions up to \$250,000 per account. Any excess amounts are uninsured. Cash and cash equivalents are deposited with high credit quality financial institutions which invest primarily in U.S. Government securities, highly rated commercial paper and certificates of deposit guaranteed by banks which are members of the FDIC. The counterparties to the agreements relating to the Company's investments consist primarily of the U.S. Government and various major corporations with high credit standings.

Fair Value Measurement

On January 1, 2008, we adopted the provisions of SFAS 157 "Fair Value Measurements" ("SFAS 157"). SFAS 157 was issued in September 2006 and is effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the Financial Accounting Standards Board ("FASB") released FSP No. FAS 157-2 which deferred the effective date of SFAS 157 for one year for nonfinancial assets and nonfinancial liabilities. SFAS 157 was adopted for financial assets and financial liabilities or for nonfinancial assets and nonfinancial liabilities that are remeasured at least annually. Accordingly, as of January 1, 2009, we have fully adopted the provisions of SFAS 157.

The following table sets forth our financial instruments carried at fair value as of June 30, 2009 and December 31, 2008:

	Financial Instruments Carried at Fair Value	
	<u>June 30, 2009</u>	<u>December 31, 2008</u>
Assets:		
Cash and cash equivalents	\$ 16,867,053	\$ 26,119,249
Short-term investments	31,155,163	35,562,723
Total cash and investments	<u>\$ 48,022,216</u>	<u>\$ 61,681,972</u>

The following table sets forth our financial instruments carried at fair value within the SFAS 157 hierarchy and using the lowest level of input as of June 30, 2009:

	Financial Instruments Carried at Fair Value			
	<u>Quoted prices in active Markets for identical items (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>	<u>Total</u>
Assets:				
Cash and cash equivalents	\$ 13,069,882	3,797,171	—	16,867,053
Short-term investments	—	31,155,163	—	31,155,163
Total cash and investments	<u>\$ 13,069,882</u>	<u>34,952,334</u>	<u>—</u>	<u>48,022,216</u>

Realized gains and losses from sales of our investments are included in "Other income (expense), net" and unrealized gains and losses are included as a separate component of equity unless the loss is determined to be "other-than-temporary."

In determining whether a decline in fair value below the original cost is other-than-temporary, we use a systematic methodology that considers all available evidence, including the credit rating of the relevant trust, the parity score (a measure of the

trust's ability to meet its obligations as they come due), general market conditions, and industry and sector performance, among other factors. We also consider the duration and extent to which the fair value is less than cost, as well as our intent and ability to hold the investment until recovery or, if necessary, to the instrument's maturity. When determining whether an impairment is other-than-temporary we also consider the following information: (i) if the market value of the investment is below its current carrying value for an extended period, which we generally define as nine to twelve months; (ii) if the issuer has experienced significant financial declines; or (iii) if the issuer has experienced significant changes in its credit quality, among other factors. The Company did not have any other-than-temporary impairments during the periods presented.

Accumulated Other Comprehensive Income—The Company follows the provisions of SFAS 130, “Reporting Comprehensive Income.” SFAS 130 establishes standards for the reporting and display of comprehensive income (loss) and its components for general purpose financial statements. Accumulated other comprehensive income (loss) is comprised of unrealized gains and losses on marketable securities and is disclosed as a component of stockholders’ equity. The Company had \$72,220 of unrealized gains on its investments that are classified as accumulated other comprehensive income (loss) at June 30, 2009 and \$221,520 of unrealized gains at December 31, 2008.

Comprehensive income (loss) consists of the following components for the three and six months ended June 30, 2009 and 2008:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Net (loss) income	\$ (4,270,420)	\$ 13,334,103	\$ (7,733,679)	\$ 5,962,851
Unrealized (loss) gain on marketable securities	(73,684)	(47,065)	(149,299)	(32,560)
Total comprehensive (loss) income	<u>\$ (4,344,104)</u>	<u>\$ 13,287,038</u>	<u>\$ (7,882,978)</u>	<u>\$ 5,930,291</u>

Stock-based Compensation—We follow Statement of Financial Accounting Standards (“SFAS”) No. 123(R), “Share-Based Payment,” which requires us to account for share-based payment transactions using a fair value-based method and recognize the related expense in our results of operations.

Under the fair value recognition provisions of SFAS No. 123(R), stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. Consistent with the valuation method we used for disclosure-only purposes under the provisions of SFAS No. 123, we use the Black-Scholes model to value service condition and performance condition option awards under SFAS No. 123(R). For awards with only service conditions and graded-vesting features, we recognize compensation cost on a straight-line basis over the requisite service period. For awards with performance conditions granted subsequent to our adoption of SFAS No. 123(R), we recognize compensation cost over the expected period to achieve the performance conditions, provided achievement of the performance conditions are deemed probable.

Our consolidated statements of operations for the three and six months ended June 30, 2009 and 2008 includes the following stock-based compensation expense:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Research and development	\$ 431,587	\$ 590,770	\$ 849,629	\$ 922,676
General and administrative	1,041,940	1,062,547	1,826,576	1,770,380
Operating expense	1,473,527	1,653,317	2,676,205	2,693,056
Tax benefit	-	-	-	-
Net expense	<u>\$ 1,473,527</u>	<u>\$ 1,653,317</u>	<u>\$ 2,676,205</u>	<u>\$ 2,693,056</u>

Unrecognized stock-based compensation expense, including time-based options, performance-based options and restricted stock awards, expected to be recognized over an estimated weighted-average amortization period of 1.85 years was \$6.4 million at June 30, 2009 and, over an estimated weighted-average amortization period of 1.45 years was \$9.8 million at June 30, 2008. Unrecognized stock-based compensation expense expected to be recognized over the remaining period ending December 31, 2009 was \$2.2 million at June 30, 2009 and was \$3.1 million at June 30, 2008 for the remaining period ending December 31, 2008.

Time-Based Stock Awards

For the three and six months ended June 30, 2009, the Company recognized \$1.1 million and \$2.0 million, respectively, in compensation for time-based awards. For the three and six months ended June 30, 2008, the Company recognized \$1.4 million and \$2.4 million, respectively, in compensation for time-based awards. The fair value of each time-based award is estimated on the date of grant using the Black-Scholes option valuation model, which uses the assumptions described below. Our weighted-average assumptions used in the Black-Scholes valuation model for equity awards with time-based vesting provisions granted for the three and six months ended June 30, 2009 and 2008 are shown in the following table:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Expected volatility	73.3 %	72.9 %	73.3 – 77.8 %	72.9 – 73.2 %
Expected dividends	0 %	0 %	0 %	0 %
Expected terms	6.0 Years	5.3 – 6.3 Years	6.0 Years	5.3 – 6.3 Years
Risk-free interest rate	2.95 %	3.3 %	2.2 – 2.95 %	2.6 – 3.3 %

For the three and six months ended June 30, 2009 and 2008, the expected volatility rate was estimated based on an equal weighting of the historical volatility of POZEN common stock over approximately a six year period. For the three and six months ended June 30, 2009 and 2008, the expected term was based upon average historical terms to exercise. The risk-free interest rate for periods within the contractual life of the option is based on seven year U.S. Treasury securities. The pre-vesting forfeiture rate used for the three and six months ended June 30, 2009 and 2008 was based on historical rates. As required under SFAS No. 123(R), we adjust the estimated forfeiture rate based upon actual experience.

A summary of the time-based stock awards as of June 30, 2009, and changes during the three and six months ended June 30, 2009, is as follows:

<u>Time-Based Stock Awards</u>	<u>Underlying Shares (000s)</u>	<u>Weighted- Average Exercise Price</u>	<u>Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (000s)</u>
Outstanding at January 1, 2009	3,732	\$ 9.86	5.2	\$ 197
Granted	459	5.66		
Exercised	(34)	0.89		
Forfeited or expired	(61)	12.79		
Outstanding at March 31, 2009	4,096	\$ 9.49	5.5	\$ 816
Exercisable at March 31, 2009	2,839	\$ 8.93	4.9	\$ 607
Granted	48	7.75		
Exercised	(1)	2.02		
Forfeited or expired	(188)	9.46		
Outstanding at June 30, 2009	3,955	\$ 9.39	5.4	\$ 2,926
Exercisable at June 30, 2009	2,742	\$ 9.03	4.8	\$ 2,018

The aggregate intrinsic value of options outstanding represents the pretax value (the period's closing market price, less the exercise price, times the number of in-the-money options) that would have been received by all option holders had they exercised their options at the end of the period. The exercise price of stock options granted during the six month periods ended June 30, 2009 and 2008 was equal to the market price of the underlying common stock on the grant date. The total intrinsic value of stock options exercised during the three and six month period ended June 30, 2009 was less than \$0.1 million and \$0.2 million, respectively. The total intrinsic value of stock options exercised during the three and six month period ended June 30, 2008 was \$2.1 million and \$2.4 million, respectively.

Restricted Stock and Restricted Stock Units

For the three and six months ended June 30, 2009, the Company recognized \$29,000 and \$77,000, respectively, in compensation expense related to restricted stock units. For the three and six months ended June 30, 2008, the Company recognized \$49,000 and \$119,000, respectively, in compensation expense related to restricted stock units. As of June 30, 2009, there was an aggregate \$114,000 of unrecognized compensation expense related to unvested restricted stock units. Of the aggregate amount, \$36,000 unrecognized compensation expense related to unvested restricted stock units under the 2007 award of 20,200 restricted stock units with a grant-date per-share fair value of \$16.89 and \$78,000 unrecognized compensation expense related to unvested restricted

stock units under the June 3, 2009 award of 11,000 restricted stock units with a grant-date per-share fair value of \$7.75. During the second quarter of 2009, no restricted stock units were forfeited. There were 14,487 unvested restricted stock units outstanding at June 30, 2009.

Performance-Based Awards

On May 6, 2008, pursuant to an incentive program (the “PN incentive program”) approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company’s employees, including its executive officers, to purchase an aggregate of 281,433 shares of common stock. On September 10, 2008, additional stock options were granted under the PN incentive program, to purchase 11,700 shares of common stock. Twenty-five percent (25%) of the PN incentive program options granted will vest upon the acceptance by the FDA of the NDA for PN 400. The remaining seventy-five (75%) of the options granted will vest upon the receipt by the Company of an action letter from the FDA indicating approval of the NDA for PN 400. The options have a ten-year term. The May 6, 2008 and September 10, 2008 option grants have exercise prices of \$14.45 and \$10.82, respectively, which was equal to the NASDAQ reported market closing price of the common stock on the date of grant. The weighted average grant-date fair value of these performance-based options was \$9.66 and \$7.08 per share for the May 6, 2008 and September 1, 2008 option grants, respectively. The options also include provisions that require satisfactory employee performance prior to vesting. Additionally, 20,000 options were granted to an executive officer on May 6, 2008 under the PN incentive plan, with identical grant and exercise terms except that 100% of the options granted will vest upon the FDA indicating acceptance of the NDA for PN 400. The Company is recognizing compensation costs for these awards over the expected service period. Total expense related to these awards for the three and six months ended June 30, 2009 was \$0.3 million and \$0.6 million, respectively.

As of June 30, 2009, there was \$0.9 million in unrecognized compensation expense related to performance-based awards granted under the PN incentive program. The June 30, 2009 amount is expected to be recognized over the period ending July 31, 2010. There were 276,633 unvested performance-based options outstanding at June 30, 2009. There were 36,500 awards forfeited during the six months ended June 30, 2009. No awards were forfeited during the six months ended June 30, 2008. No performance-based awards were exercised during the six months ended June 30, 2009 and June 30, 2008. At June 30, 2009 the performance-based options had no intrinsic value and a remaining contractual life of 8.7 years.

The fair value of the performance-based options granted under the Plan was estimated as of the grant date using the Black-Scholes option valuation model without consideration of the performance measures.

Net Loss Per Share—Basic and diluted net loss per common share amounts are presented in conformity with SFAS 128, “Earnings per Share,” for all periods presented. In accordance with SFAS 128, basic and diluted net income or loss per common share amounts have been computed using the weighted-average number of shares of common stock outstanding for the six months ended June 30, 2009 and 2008. During the six months ended June 30, 2009 and 2008, the Company had potential common stock equivalents related to its outstanding stock options. These potential common stock equivalents were not included in diluted loss per share for the six months ended June 30, 2009 because the effect would have been antidilutive. Accordingly, basic and diluted net loss per share is the same for six months ended June 30, 2009. In accordance with SFAS 128, the Company has excluded the impact of any shares which might be issued under the Rights Plan, detailed below, from the earnings per share calculation because the Rights are not exercisable since the specified contingent future event has not occurred.

Reconciliation of denominators for basic and diluted earnings per share computations:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Basic weighted average shares outstanding	29,815,228	29,759,250	29,802,015	29,741,406
Effect of dilutive employee and director awards	-	948,460	-	895,123
Diluted weighted-average shares outstanding and assumed conversions	<u>29,815,228</u>	<u>30,707,710</u>	<u>29,802,015</u>	<u>30,636,529</u>

Rights Plan/Series A Junior Participating Preferred Stock—In January 2005, the Company approved a stockholder rights plan (the “Rights Plan”), pursuant to which the Company entered into a Rights Agreement dated January 12, 2005 with StockTrans, Inc., as Rights Agent, and the Company declared a dividend of a right to acquire one preferred share purchase right (a “Right”) for each outstanding share of the Company’s Common Stock, \$0.001 par value per share, to stockholders of record at the close of business on January 28, 2005. Generally, the Rights only are triggered and become exercisable if a person or group acquires beneficial ownership of 15 percent or more of the Company’s common stock or announces a tender offer for 15 percent or more of the Company’s common stock. The Rights Plan is similar to plans adopted by many other publicly-traded companies. The effect of the Rights Plan is to discourage any potential acquirer from triggering the Rights without first convincing POZEN’s Board of Directors that the proposed acquisition is fair to, and in the best interest of, the shareholders and the Company. The provisions of the Plan will

substantially dilute the equity and voting interest of any potential acquirer unless the Board of Directors determines that the proposed acquisition is in the best interest of the shareholders. In connection with the Plan, the Company designated 90,000 shares of its authorized Preferred Stock as Series A Junior Participating Preferred Stock. Each Right, if and when exercisable, will entitle the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, \$0.001 par value per share, at a purchase price of \$80.00 for each one one-thousandth of a share, subject to adjustment. Each holder of a Right (except for the Acquiring Person (as defined in the Rights Plan), whose Rights will be null and void upon such event) shall thereafter have the right to receive, upon exercise, that number of shares of Common Stock of the Company (or, in certain circumstances, cash, property or other securities of the Company) which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of Common Stock at the date of the occurrence of such event. The Rights can be terminated by POZEN's Board of Directors and are subject to optional redemption by the Company at \$0.001 per Right. The Rights Plan has a 10-year term and contains provisions requiring a periodic review and evaluation by the Board of Directors.

Leases—On February 16, 2009, the Company entered into a Lease Modification Agreement No. 1 (the “Modification Agreement”) modifying certain terms to our existing lease agreement, dated November 21, 2001, relating to approximately 17,009 square feet of office space located at Exchange Office Building, Chapel Hill, North Carolina. Under the terms of the Modification Agreement, the lease term is extended for an additional 5 years and 7 months, terminating on September 30, 2015. The Modification Agreement also provides the Company with a reduced notice period of 7 months for renewals of the lease. The Company is also entitled to a 3-year lease extension option available at the end of the term and a first offer right on available space located within the Exchange Office Building property. As a result of entering into the Modification Agreement, the Company's noncancellable future minimum lease payments for operating leases will increase by approximately \$2.7 million over the lease term.

New Accounting Pronouncements—In December 2007, the FASB ratified the consensus reached on Emerging Issues Task Force Issue No. 07-1, “Accounting for Collaborative Arrangements” (“EITF 07-1”). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 was effective beginning on January 1, 2009. The Company believes EITF 07-1 does not have a material impact on its financial statements.

In May 2009, the FASB issued Statement of Financial Accounting Standards No. 165, *Subsequent Events* which provides authoritative accounting literature for a topic that was previously addressed only in the auditing literature. Three modifications to the subsequent events guidance in AU Section 560 are: 1) to name the two types of subsequent events either as recognized subsequent events or non-recognized subsequent events; 2) to modify the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued; and 3) to require entities to disclose the date through which an entity has evaluated subsequent events and the basis for that date. SFAS 165 was adopted effective June 15, 2009.

In April 2009, the FASB issued FSP FAS 107-1, *Interim Disclosures About Fair Value of Financial Instruments* which requires disclosures of the fair value of all financial instruments (recognized or unrecognized), except for those specifically listed in paragraph 8 of Statement 107, when practicable to do so. These fair value disclosures must be presented together with the related carrying amount of the financial instruments in a manner that clearly distinguishes between assets and liabilities and indicates how the carrying amounts relate to amounts reported on the balance sheet. An entity must also disclose the method(s) and significant assumptions used to estimate the fair value of financial instruments. FSP FAS 107-1 was adopted effective June 15, 2009.

In April 2009, the FASB issued FSP FAS 115-2, *Recognition and Presentation of Other-Than-Temporary Impairment*. Statement 115 changes existing accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it is not more likely than not it will be required to sell the security before the recovery of its amortized cost basis. FSP FAS 115-2 was adopted effective June 15, 2009. The Company believes FSP FAS 115-2 does not have a material impact on its financial statements.

Contingencies—A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of its securities against the Company, its chairman and chief executive officer and one of its directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, the Company received the plaintiffs' amended and consolidated complaint which added two current officers of the Company as additional defendants. The Company and individual defendants filed motions to dismiss the amended and consolidated complaint with the Court on June 26, 2008. On August 27, 2008, the plaintiffs voluntarily dismissed their claims against one of the Company's directors. On February 19, 2009, Magistrate Judge Dixon, to whom the Court had referred the motion to dismiss, issued a Recommendation that the Court grant the Company and individual defendants' motion to dismiss without leave for plaintiffs to file another amended complaint. Plaintiffs filed objections to the recommendation on March 23, 2009 and a corrected version of the objections on March 26, 2009. Defendants' response to these

objections was filed on April 20, 2009. The matter is now awaiting a decision by the Court. The Company and the individual defendants intend to continue to defend these claims vigorously but there can be no assurance that the Court will accept the Recommendation of the Magistrate Judge.

The Company and GSK have received notices of Paragraph IV Notice Letters from Par Pharmaceuticals Inc., or Par, and Alphapharm Pty Ltd., or Alphapharm, and Alphapharm's designated agent, Mylan Pharmaceuticals Inc., and Teva Pharmaceuticals USA, or Teva, informing us that each company had filed an Abbreviated New Drug Application, or ANDA, with the Food and Drug Administration, or FDA, seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm and Teva have each indicated in their respective Notice Letters that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it has elected not to exercise its first right to bring infringement suits against Par, Alphapharm and Teva. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009 and Teva on April 14, 2009, all in the United States District Court for the Eastern District of Texas. All three actions have since been consolidated into one suit. The Company's filing of these patent infringement lawsuits within forty-five days of our receipt of the respective Notice Letters from Par, Alphapharm and Teva resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's and Teva's respective ANDAs for up to 30 months or until a final court decision is entered in the infringement suit in favor of the ANDA applicant, whichever occurs first. Treximet currently has regulatory exclusivity through April 15, 2011. Treximet may be eligible for an additional six months of exclusivity upon the completion of certain pediatric studies. Written and document discovery are at an early stage. The cases are set for trial in the fourth quarter of 2010.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above or a patent infringement lawsuit against Par, Alphapharm and Teva. Furthermore, we will have to incur expenses in connection with these lawsuits, which may be substantial. In the event of an adverse outcome or outcomes, our business could be materially harmed. Moreover, responding to and defending pending litigation will result in a significant diversion of management's attention and resources and an increase in professional fees.

Under its 2003 commercialization collaboration with Valeant NA, related to MT 300, if the Company chooses to withdraw the MT 300 NDA for commercial or financial reasons under the conditions specified in the agreement, it could be required to pay a withdrawal fee of \$1.0 million. As a result of this contingency, \$1.0 million of the \$2.0 million upfront payment received by the Company from Valeant NA pursuant to the agreement was not initially recognized as revenue.

In July 2005, we received a letter from Valeant NA, seeking payment of a \$1.0 million withdrawal fee required under certain conditions under the agreement. We do not believe that the withdrawal fee is payable under the circumstances of receipt of the not-approvable letter from the FDA. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement although the last written communication from Valeant NA was received in March 2006. In 2008, based upon our evaluation of the facts and circumstances, we recognized the remaining \$1.0 million licensing fee for MT 300. We can give no assurance that Valeant NA will agree to termination terms acceptable to us, or that we will not be required to pay Valeant NA the withdrawal fee described above.

Subsequent Events—The Company has evaluated subsequent events through July 31, 2009, which represents the date the Company's Form 10-Q for the quarter ended June 30, 2009 was filed with the Securities and Exchange Commission.

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

This discussion of our financial condition and the results of operations should be read together with the financial statements, including the notes contained elsewhere in this Form 10-Q, and the financial statements, including the notes thereto, contained in our Annual Report on Form 10-K for the year ended December 31, 2008, as filed on March 6, 2009.

This report includes "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The forward-looking statements are subject to a number of risks and uncertainties which are discussed below in the section entitled "Item 1A --Risk Factors." We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements, other than as is required under the federal securities laws.

Overview

We are a pharmaceutical company focused on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions. We operate a business model that focuses on the following:

- obtaining patents for innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas through proof of concept by working with strategic outsource partners;
- developing a regulatory pathway with the appropriate agency; and
- determining how best to commercialize our products, which may include licensing the resulting product or technology to a strong pharmaceutical partner to commercialize.

We hire experts with strong project management skills in the specific disciplines we believe are important to maintain within our company. We contract with and manage strong outsource partners as we complete the necessary development work, permitting us to avoid incurring the cost of buying or building laboratories, manufacturing facilities or clinical research operation sites. This allows us to control our annual expenses, but to utilize “best in class” resources as required.

After we establish the proof of concept for an innovative idea, we work with the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies to design a clear path forward to the filing of a new drug application, or NDA, or its foreign equivalent. We may then decide to seek a strong pharmaceutical partner to license the product or technology to collaborate with us in the remaining development and to commercialize the product or technology after approval. The success of our business is highly dependent on the marketplace value of our ideas and the related patents we obtain, our ability to obtain from the required regulatory agencies approval to sell the developed products and our ability to find strong commercial partners to successfully commercialize the products or to successfully commercialize the products ourselves.

We have developed Treximet® (formerly known as Trexima™) in collaboration with GlaxoSmithKline, or GSK. Treximet is the brand name for the product combining sumatriptan 85 mg, formulated with RT Technology™ and naproxen sodium 500 mg in a single tablet designed for the acute treatment of migraine. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. Upon receipt of FDA approval, GSK notified us of its intention to launch the product and Treximet was available in pharmacies in May 2008.

Treximet incorporates our MT 400 technology, which refers to our proprietary combinations of a triptan (5-HT_{1B/1D} agonist) and a non-steroidal anti-inflammatory drug, or NSAID. Under our MT 400 technology, we sought to develop product candidates that provide acute migraine therapy by combining the activity of two drugs that act by different mechanisms to reduce the pain and associated symptoms of migraine. We filed the NDA for Treximet with the FDA in August 2005, and in June 2006 we received an approvable letter requiring us to provide certain additional safety information relating to Treximet, some of which required new studies. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In early January 2007, we delivered a full response to this approvable letter that provided additional data and analyses and supporting information addressing the FDA’s safety concerns, including cardiovascular safety. On August 1, 2007, we received a second approvable letter from the FDA for Treximet in which the FDA requested that we further address the FDA’s concern about the product’s potential for genotoxicity. In response to this approvable letter, we submitted the results of three non-clinical (in vitro) studies that provided clarifying information about the Chinese Hamster Ovary, or CHO, assay and data from a clinical evaluation of the genotoxic potential of Treximet in human volunteers which indicated that no chromosomal aberrations were induced in peripheral blood lymphocytes when Treximet was administered to volunteers for seven days. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults.

We are also developing product candidates that combine a type of acid inhibitor, a proton pump inhibitor, or PPI, with an NSAID (our PN program). These product candidates are intended to provide management of pain and inflammation associated with conditions such as osteoarthritis, and are intended to have fewer gastrointestinal complications compared to an NSAID taken alone.

In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca AB, or AstraZeneca, to co-develop and commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet using our PN formulation technology, which agreement was amended in September 2007 and October 2008. We began the Phase 3 program in September 2007. As part of the program, we conducted two Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which was the reduction in

endoscopic gastric ulcers. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for POZEN's clinical programs. The two pivotal trials have been completed and met their primary endpoints. In both trials, patients taking PN 400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period. In addition to the Phase 3 pivotal trials, we have completed a long-term, open label safety study. We terminated a non-pivotal smaller study in patients at high risk of gastrointestinal related events from NSAIDs which we believe is not required for approval. We also conducted additional studies at AstraZeneca's expense. The NDA for PN 400 was submitted on June 30, 2009. Pending regulatory approval, the proposed trade name of PN 400 is VIMOVO™.

Another product candidate, PA, a combination of a PPI and aspirin, is currently in formulation and clinical development testing. Our PA product candidates are excluded from our agreement with AstraZeneca. We have met with the FDA to discuss the overall development program requirements. An investigational new drug application, or IND, was filed in the fourth quarter of 2007. We have completed a study which demonstrated the bioequivalence of the salicylic acid component of PA32540 as compared to 325 mg of enteric-coated aspirin which we believe will satisfy the FDA's bioequivalence requirement. We filed a Special Protocol Assessment, or SPA, with the FDA for the design of the Phase 3 studies for the product, the primary endpoint for which is the reduction in endoscopic gastric ulcers. The SPA is a process by which the FDA and a company reach agreement on the Phase 3 pivotal trial protocol design, clinical endpoints and statistical analyses that are acceptable to support regulatory approval. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. In February 2009, we received written confirmation from the FDA that endoscopic gastric ulcer incidence was an acceptable primary endpoint for the Phase 3 clinical studies we proposed in our SPA for PA32540. We are aware of publications that contain conflicting data regarding a possible interaction between clopidogrel (Plavix®) and certain enteric-coated proton pump inhibitor products. To determine whether an interaction occurs between clopidogrel and PA32540, we intend to undertake a Phase 1 drug-drug interaction study to evaluate the platelet aggregation effects of PA32540 plus clopidogrel compared to aspirin plus clopidogrel. We plan to begin Phase 3 studies for PA32540 in the second half of 2009. We are also continuing to evaluate how best to commercialize the PA product candidates and programs.

We are also conducting both formulation development and early stage clinical studies with new product concepts that are currently in the exploratory stage. If warranted, we may file U.S. and international patent applications with claims directed toward these novel combinations and formulations.

We have incurred significant losses since our inception and have not yet generated significant revenue from product sales. As of June 30, 2009, our accumulated deficit was approximately \$140.9 million. We record revenue under two categories: licensing revenues and development revenues. Our licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, and the royalty payments based on product sales. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented approximately 73% of our total operating expenses. For the six months ended June 30, 2009, our research and development expenses represented approximately 58% of our total operating expenses.

Operating losses may be incurred over the next several years as we complete the development and seek regulatory approval for our product candidates, develop other product candidates and acquire and develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of our PN and PA product candidates and our other product candidates in the clinical and regulatory process;
- The ability of GSK to successfully commercialize Treximet in the U.S. For example, Treximet was available in pharmacies within one month from the date of its approval, but promotional and professional materials for the product, including direct to consumer advertising, were not approved on a timely basis by the FDA. The lack of approved materials and delayed advertising launch may have had an adverse impact on uptake of the product, thus negatively impacting our royalty revenue;

- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates; and
- The acquisition and/or in-licensing, and development of our therapeutic product candidates.

We do not currently have commercialization or manufacturing capabilities. We have entered into collaborations and may enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. Our ability to generate revenue is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, and to successfully develop product candidates, to obtain regulatory approvals and to successfully manufacture and commercialize our future products. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included elsewhere in this Quarterly Report on Form 10-Q. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

Status and Expenses Related to Our Product Candidates

There follows a brief discussion of the status of the development of our product candidates, as well as the costs relating to our development activities. Our direct research and development expenses were \$9.2 million for the six months ended June 30, 2009, and \$26.6 million for the six months ended June 30, 2008. Our research and development expenses that are not direct development costs consist of personnel and other research and development departmental costs and are not allocated by product candidate. We generally do not maintain records that allocate our employees' time by the projects on which they work and, therefore, are unable to identify costs related to the time that employees spend on research and development by product candidate. Total compensation and benefit costs for our personnel involved in research and development were \$3.3 million for the six months ended June 30, 2009, and \$3.5 million for the six months ended June 30, 2008. Total compensation for the six months ended June 30, 2009 including a \$0.8 million charge for non-cash compensation for stock option expense and a \$0.9 million charge for non-cash compensation for stock option expense for the six months ended June 30, 2008. Other research and development department costs were \$0.1 million for the six months ended June 30, 2009, and \$0.1 million for the six months ended June 30, 2008.

MT 400/Treximet

On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks with or without aura in adults. GSK notified us of its intention to launch the product and was available in pharmacies in May 2008. As part of our NDA program for Treximet, we conducted five Phase 1 trials, two Phase 3 pivotal trials, and one 12-month open label safety trial using a formulation of Treximet developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate Treximet, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of Treximet (the "combination drug rule" that the FDA requires of all combination products). The efficacy endpoint for the combination was sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine. Further, GSK continues to conduct market support studies for Treximet. As required by the terms of our agreement with GSK, we transferred ownership of the NDA and other regulatory filings for Treximet to GSK on May 14, 2008, and GSK now has responsibility for all ongoing regulatory obligations for the product, including post marketing clinical trial requirements.

We incurred direct development costs associated with the development of MT 400 of \$0.2 million for the six months ended June 30, 2009. We recorded in the six months ended June 30, 2009, \$2.0 million of Treximet royalty revenue, of which, \$0.9 million is in accounts receivable at June 30, 2009. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

We, along with GSK, have received notices of Paragraph IV Notice Letters from Par, Alphapharm, and Alphapharm's designated agent, Mylan, and Teva, informing us that each company had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm and Teva have each indicated in their respective Notice Letters that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it has elected not to exercise its first right to bring infringement suits against Par, Alphapharm and Teva. Accordingly, we filed suit against Par on November 14, 2008; Alphapharm and Mylan on January 2, 2009 and Teva on April 14, 2009, all in the United States District Court for the Eastern District of Texas. All three actions have since been consolidated into one suit. Our filing of these patent infringement lawsuits within forty-five days of our receipt of the respective Notice Letters from Par, Alphapharm and Teva resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's and Teva's respective ANDAs for up to 30 months or until a final court decision is entered in the infringement suit in favor of the ANDA applicant, whichever occurs first. Treximet currently has regulatory exclusivity through April 15, 2011. Treximet may be eligible for

an additional six months of exclusivity upon the completion of certain pediatric studies. Written and document discovery are at an early stage. The cases are set for trial in the fourth quarter of 2010.

PN Program

Under our PN program, we have completed formulation development and clinical studies for several combinations of a PPI and a NSAID in a single tablet intended to provide effective management of pain and inflammation associated with chronic conditions such as osteoarthritis, and intended to have fewer gastrointestinal complications compared to a NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. We initially conducted studies with two PN product formulations in this program - PN 100, a combination of the PPI lansoprazole and the NSAID naproxen, and PN 200, a combination of the PPI omeprazole and naproxen, prior to entering into our collaboration with AstraZeneca. Our present development and commercialization efforts under the PN program are covered under our exclusive collaboration agreement with AstraZeneca, which we entered into on August 1, 2006 and which was amended in September 2007 and October 2008. Under our agreement with AstraZeneca, we are co-developing with AstraZeneca, and AstraZeneca will commercialize, proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. The initial product to be developed under the agreement, PN 400, is being studied for the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing NSAID-associated gastric ulcers. On March 2, 2007, we filed an IND with the FDA for PN 400 and in April 2007, the first Phase 1 study was initiated.

In discussions with the FDA during 2005 regarding our development plans for studies to pursue FDA approval of PN 100 and PN 200, the FDA agreed that by including naproxen as the NSAID within the PN formulation, we could expect that all indications for chronic use of naproxen in adults would accrue to the PN product, if clinical trials successfully demonstrated improved safety (lower incidence of gastric ulcers) of the PN product compared with naproxen alone and the PN formulation was shown to be bioequivalent to marketed formulations of enteric-coated, or EC, naproxen. Prior to entering into our collaboration agreement with AstraZeneca, we completed a study designed to demonstrate the bioequivalence of the naproxen component of our PN 200 product candidate development formulation to EC naproxen. This study demonstrated that the PN 200 product was bioequivalent to the reference drug, EC Naprosyn®, with respect to the naproxen component.

In early 2006, we submitted a SPA to the FDA for our pivotal Phase 3 clinical trials for PN 200. The SPA is a process in which the FDA provides evaluations and guidance on clinical trial protocols for pivotal Phase 3 clinical trials. In April 2006, we announced that we had reached an agreement with the FDA on the Phase 3 pivotal clinical trials for PN 200 for the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing NSAID-associated gastric ulcers. We also reached agreement with the FDA that the development program and study design proposed for PN 200 would be applicable to a product that contained an isomer of omeprazole combined with naproxen. In light of our collaboration agreement with AstraZeneca, we, along with AstraZeneca have met with the FDA and confirmed the core development program and the principles in the SPA already agreed upon do apply to the new product consisting of proprietary fixed dose combinations of esomeprazole magnesium with naproxen.

In the third quarter of 2006, we began recruiting subjects for a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy. The primary endpoint for the trial was the cumulative incidence of gastric ulcers over six months of treatment. Because we did not have final results until the fourth quarter of 2007, we, together with AstraZeneca reviewed the interim results of this trial prior to commencing Phase 3 studies of PN 400 in September 2007. This study has now been completed and the results which have been presented publicly, indicated significantly fewer endoscopically confirmed gastric ulcers during the six month treatment period in subjects on PN 200 compared to subjects receiving enteric-coated naproxen alone. We conducted two PN 400 Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which is the reduction in endoscopic gastric ulcers. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. The two pivotal trials have been completed and met their primary endpoints. In both trials, patients taking PN 400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period. In addition, we are conducting a long-term, open label safety study for PN 400. We have terminated a non-pivotal smaller study in patients at high risk (i.e., previous bleeding from a gastric ulcer) of gastrointestinal related events from NSAIDs which is not required for approval. We have conducted additional studies at AstraZeneca's expense. The NDA for PN 400 was submitted on June 30, 2009. Pending regulatory approval, the proposed trade name of PN 400 is VIMOVO™.

In 2005, we also had discussions with the FDA concerning the implications of the FDA's guidance issued in June 2005 concerning labeling of NSAID-containing products, which resulted from an FDA advisory committee meeting held in February 2005. The advisory committee addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs. Based on our discussions with the FDA reviewing division for PN products, we believe that, unless new information about naproxen

safety concerns becomes available, long-term cardiovascular safety studies will not be required at this time for FDA approval of our PN product candidates containing naproxen. However, we cannot guarantee that such studies will not be required. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements and study design necessary to support approval of NDAs for our PN product candidates.

Additionally, we have met with four national European regulatory agencies to discuss the proposed development program for PN. Under our agreement with AstraZeneca, AstraZeneca has responsibility for the development program for PN outside the U.S., including interactions with regulatory agencies. It is our understanding that AstraZeneca intends to file marketing applications for PN 400 in certain ex-U.S. countries based upon clinical data being generated for the NDA after the NDA is filed.

We cannot reasonably estimate or know the amount or timing of the costs necessary to obtain regulatory approval of PN 400. Nor can we reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any PN product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PN products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our PN program of \$7.3 million for the six months ended June 30, 2009, \$5.5 million of which was funded by development revenue from AstraZeneca. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PA Program

As part of our PA program, we are exploring the development of a combination of a PPI and aspirin in a single tablet. Similar to the PN program, our PA product candidate is intended to induce fewer gastrointestinal complications compared to an aspirin taken alone in patients at risk for developing aspirin associated gastric ulcers. Our PA product candidates are covered under the same patent as PN, but we have retained all rights to this program.

Our initial PA product candidate, PA32540, is currently in early-stage clinical development. We completed a Phase 1 proof of concept study in Canada of an earlier formulation of PA containing 325 mg of aspirin and 20 mg of omeprazole (PA32520) in the first quarter of 2007. The primary endpoint was gastrointestinal damage as measured by the Lanza scoring system used in our previous PN studies. The results were highly significant ($p < 0.001$) with 10% of the PA group having Lanza 3 or 4 gastrointestinal damage, whereas 57.5% of the EC aspirin group had this level of gastrointestinal damage during the 28 day study. We also completed a second proof of concept study with PA32520 as compared to 81 mg of EC aspirin. These results confirmed the earlier levels of gastric damage as measured by Lanza scoring at about 10% for PA32520. While these results in the second study were numerically different between treatment groups, they did not achieve statistical significance from the results obtained with 81mg EC aspirin (21%). After reviewing these data, we decided to increase the dose of omeprazole to 40 mg per tablet and conduct an additional 28 day Phase 1 study using the formulation containing 40 mg of immediate release of omeprazole and 325 mg of aspirin (PA32540) compared to 325 mg EC aspirin. Topline results from this study indicate a highly significant ($P = 0.003$) reduction in gastrointestinal damage with the higher strength PA32540 tablet as compared with 325 mg EC aspirin (2.5% vs. 27.5% grade 3 or 4 Lanza scores, respectively). In this last study, 75% of subjects treated with the PA32540 tablet showed no gastrointestinal damage at all as compared to < 50% with the PA32520 tablet. An IND for the product was filed in the fourth quarter of 2007 and we met with the FDA in July 2007 to discuss the overall development program requirements. We completed a study which demonstrated that the salicylic acid component of PA32540 was bioequivalent to the reference drug, EC aspirin, with respect to the aspirin component, and which we believe will allow our PA product to receive all the cardio- and cerebrovascular secondary prevention claims of aspirin. In June 2008, we filed an SPA with the FDA for our pivotal Phase 3 trials for PA32540, the primary endpoint for which is the reduction in endoscopic gastric ulcers. The SPA is a process by which the FDA and a company reach agreement on the Phase 3 pivotal trial protocol design, clinical endpoints and statistical analyses that are acceptable to support regulatory approval. In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs and in February 2009, we received written confirmation from the FDA that endoscopic gastric ulcer incidence was an acceptable endpoint for the Phase 3 clinical studies we proposed in our SPA for PA32540. We are aware of publications that contain conflicting data regarding a possible interaction between clopidogrel (Plavix[®]) and certain enteric-coated proton pump inhibitor products. To determine whether an interaction occurs between clopidogrel and PA32540, we intend to undertake a Phase 1 drug-drug interaction study to evaluate the platelet aggregation effects of PA32540 plus clopidogrel compared to aspirin plus clopidogrel. We plan to begin Phase 3 studies for PA32540 in the second half of 2009. We are also continuing to evaluate how best to commercialize the PA product candidates and programs. We are also conducting both formulation development and early stage clinical studies with other PA product candidates for indications in addition to cardiovascular protection.

Additionally, we have met with three national European regulatory agencies to discuss the proposed development program for PA. Each of these regulatory agencies has indicated that reduction in gastric ulcers is an appropriate endpoint for the pivotal trials, along with demonstrating bioequivalence to the reference drug, EC aspirin, with respect to the aspirin component. Dose ranging studies may also be required.

We cannot reasonably estimate or know the amount or timing of the costs necessary to continue exploratory development and/or complete the development of any PA product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PA products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals. We currently do not intend to partner the PA program prior to starting the Phase 3 program. We believe value can be added to the PA product candidates as progress is made through Phase 3 and, if we chose to partner the products as we have in the past, we believe it would be under economic terms more favorable to us.

We intend to conduct extensive market research on the PA product concepts, to support our evaluation of how best to commercialize the PA product candidates and programs, which may include commercializing the products ourselves in certain territories. Changing from a commercialization strategy in which the PA product candidates are out-licensed, in exchange for milestone and royalty payments, will depend on our available financial resources, the associated risks of such a change and its overall impact on the PA product candidates' value.

We incurred direct development costs associated with the development of our PA program of \$1.0 million during the six months ended June 30, 2009. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Collaborative Arrangements

We have entered into and may continue to enter into collaborations with established pharmaceutical or pharmaceutical services companies to develop, commercialize and/or manufacture our product candidates. Our existing collaborations are described below.

GlaxoSmithKline (GSK)

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-HT_{1B/1D} agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex[®] (sumatriptan succinate) or Amerge[®] (naratriptan hydrochloride), with a long-acting NSAID. We were responsible for development of the first combination product, while GSK provided formulation development and manufacturing. Pursuant to the terms of the agreement, we received \$25.0 million in initial payments from GSK following termination of the waiting period under the Hart-Scott-Rodino notification program and the issuance of a specified patent. In May 2004, we received a \$15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. In October 2005, we received a \$20.0 million milestone payment upon the FDA's acceptance for review of the NDA for Treximet, the trade name for the product. On April 26, 2008 the Company received, from GSK, \$20.0 million in milestone payments which were associated with the approval of, and GSK's intent to commercialize, Treximet. In addition, GSK will pay us two sales performance milestones totaling \$80.0 million if certain sales thresholds are achieved. Up to an additional \$10.0 million per product is payable upon achievement of milestones relating to other products. On June 30, 2009, the Company accrued \$0.9 million of Treximet royalty revenue and GSK will also pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (August 14, 2017) based upon the scheduled expiration of currently issued patents). GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre-determined share of the market for the combination product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop or to launch the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

We, along with GSK, have received notices of Paragraph IV Notice Letters from Par, Alphapharm, Alphapharm's designated agent, Mylan, and Teva, informing us that each company had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm and Teva have each indicated in their respective Notice Letters that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it has elected not to exercise its first right to bring infringement suits against Par, Alphapharm and Teva. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009 and Teva on April 14, 2009, all in the United States District Court for the Eastern District of Texas. All three actions have since been consolidated into one suit. Our filing of these patent infringement lawsuits within forty-five days of our receipt of the respective Notice Letters from Par, Alphapharm and Teva resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's and Teva's respective ANDAs for up to 30 months or until a final court decision is entered in the infringement suit in favor of the ANDA applicant, whichever occurs first. Treximet currently has regulatory exclusivity through April 15, 2011. Treximet may be eligible for an additional six months of exclusivity upon the completion of certain pediatric studies. Written and document discovery are at an early stage. The cases are set for trial in the fourth quarter of 2010.

AstraZeneca AB (AstraZeneca)

In August 2006, we entered into a collaboration and license agreement dated as of August 1, 2006 and effective September 7, 2006 with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers. Under the terms of the agreement, we granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under our patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). AstraZeneca had the right, which has now expired, to elect to include Japan in the licensed territory within two years after the effective date of the agreement. Pursuant to the terms of the agreement, we received an upfront license fee of \$40.0 million from AstraZeneca following termination of the waiting period under the Hart-Scott-Rodino notification program.

In September 2007, we agreed with AstraZeneca to amend our collaboration and license agreement effective as of September 6, 2007. Under the terms of the amendment, AstraZeneca has agreed to pay us up to \$345.0 million, in the aggregate, in milestone payments upon the achievement of certain development, regulatory and sales events. In September 2007 we received a \$10.0 million payment upon execution of the amendment and a \$20.0 million payment in recognition of the achievement of the primary endpoints for the PN400-104 study, a study which compared acid suppression of different doses of PN 400, and achievement of the interim results of the PN200-301 study, a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy, meeting mutually agreed success criteria. An additional \$55.0 million will be paid upon achievement of certain development and regulatory milestones, and \$260.0 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved. Under the original agreement, we were to have received development and regulatory milestones totaling \$160.0 million, of which \$20.0 million was to be paid upon the successful completion of the proof of concept studies, and sales performance milestones totaling \$175.0 million.

In addition, the amendment revised the royalty rates we were to have received under the original agreement. Under the original agreement, we were to receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees during the royalty term. The royalty rate varied based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, ranging from the mid-single digits to the mid-teens. Under the amendment, we will now receive a flat, low double digit royalty rate during the royalty term on annual net sales of products made by AstraZeneca, its affiliates and sublicensees, in the U.S. and royalties ranging from the mid-single digits to the high-teens on annual net sales of products made by AstraZeneca, its affiliates and sublicensees outside of the U.S. The amendment also revises the rate of reduction to the royalty rate based upon loss of market share due to generic competition inside and outside of the U.S. to account for the new royalty structure.

Our right to receive royalties from AstraZeneca for the sale of such products under the collaboration and license agreement, as amended, expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights relating to such products in that country, and (b) ten years after the first commercial sale of such products in such country.

We further amended the collaboration and license agreement effective October 1, 2008 to shorten the timing of AstraZeneca's reimbursement obligation for certain development expenses incurred by us under the agreement and to update the description of the target product profile studies (as defined in the agreement) for PN 400.

We retain responsibility for the development and filing of the NDA for the product in the U.S. AstraZeneca is responsible for all development activities outside the U.S., as well as for all manufacturing, marketing, sales and distribution activities worldwide. We have agreed to bear all expenses related to certain specified U.S. development activities. All other development expenses, including all manufacturing-related expenses, will be paid by AstraZeneca. The agreement established joint committees with representation of both

us and AstraZeneca to manage the development and commercialization of the product. The committees operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

The agreement, unless earlier terminated, will expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement, at any time, at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us.

Results of Operations

Three months ended June 30, 2009 compared to the three months ended June 30, 2008

Net income (loss) per share: Net loss attributable to common stockholders for the three months ended June 30, 2009 was \$(4.3) million or \$(0.14) per share, on a basic and diluted basis, as compared to a net income of \$13.3 million, or \$0.43 per share, on a diluted basis, for the three months ended June 30, 2008. The net income (loss) for the three month period ended June 30, 2009 included a \$(1.5) million or \$(0.05) per share charge for non-cash stock-based compensation expense as compared to \$(1.7) million, or \$(0.06) per share for the same period of 2008.

Revenue: We recognized \$4.9 million of revenue for the three months ended June 30, 2009 as compared to \$33.1 million for the three months ended June 30, 2008. Licensing revenue for the three months ended June 30, 2009 was \$4.0 million compared to \$24.5 million for 2008. The decrease in revenue was primarily due to the \$20.0 million in milestone payments received from GSK for the approval of, and GSK's intent to commercialize, Treximet in 2008. Development revenue was \$0.9 million for the three months ended June 30, 2009 compared to \$8.6 million for 2008. The decrease was due to the decrease in development services accompanying the completion of PN clinical activities. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non-refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately \$13.4 million remains in deferred revenue at June 30, 2009. Substantive milestone payments are recognized as revenue upon completion of the contractual events. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our costs associated with the billed direct costs totaled \$0.2 million and \$8.0 million for the three months ended June 30, 2009 and 2008, respectively. All costs associated with our development revenues are included in research and development expenses in our Statements of Operations. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Research and development: Research and development expenses decreased by \$12.6 million to \$4.6 million for the three months ended June 30, 2009, as compared to the same period of 2008. The decrease was due primarily to a decrease in direct development costs for PN and PA program activities, as compared to the same period of 2008. Direct development costs for the PN program decreased by \$10.4 million to \$2.6 million, primarily due to the decrease in development services accompanying the completion of PN clinical activities, as compared to the same period of 2008. Direct development costs for the PA program decreased by \$0.9 million to \$0.3 million, while exploratory programs decreased by \$0.9 million to \$0.2 million during the second quarter of 2009, as compared to the same period of 2008. Other departmental expenses decreased by \$0.4 million primarily due to decreased personnel costs, as compared to the same period of 2008. We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, and regulatory matters.

General and administrative: General and administrative expenses increased by \$1.6 million to \$4.8 million for the three months ended June 30, 2009, as compared to the same period of 2008. The increase was due primarily to increased legal costs for patent defense and marketing research expenses which were \$1.5 million and \$0.6 million, respectively, as compared to the same period of 2008. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was \$0.1 million for the three months ended June 30, 2009 and \$0.2 million for the three months ended June 30, 2008. Investment income from bond amortization for the three month period ended June 30, 2009 totaled \$0.1

million as compared to \$0.3 million during the same period of 2008. Investment income decreased primarily due to declining short-term interest rates.

Six months ended June 30, 2009 compared to the six months ended June 30, 2008

Net income (loss) per share: Net loss attributable to common stockholders for the six months ended June 30, 2009 was \$(7.7) million or \$(0.26) per share, on a basic and diluted basis, as compared to a net income of \$6.0 million, or \$0.19 per share, on a diluted basis, for the six months ended June 30, 2008. The net income (loss) for the six months ended June 30, 2009 included a \$(2.7) million or \$(0.09) per share charge for non-cash stock-based compensation expense as compared to \$(2.7) million or \$(0.09) per share for the same period of 2008.

Revenue: We recognized total revenue of \$13.7 million for the six months ended June 30, 2009 as compared to total revenue of \$41.0 million for the six months ended June 30, 2008. The decrease in revenue was primarily due to the \$20.0 million of milestone payments received in 2008 from GSK for the approval of, and GSK's intent to commercialize Treximet. Licensing revenue for the six months ended June 30, 2009 was \$8.1 million compared to \$28.4 million for 2008. Development revenue was \$5.5 million for the six months ended June 30, 2009 compared to \$12.6 million for 2008. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non-refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately \$13.4 million remains in deferred revenue at June 30, 2009. Substantive milestone payments are recognized as revenue upon completion of the contractual events. Additionally, our development revenues include the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described under our collaboration agreements. Our costs associated with the billed direct costs totaled \$4.0 million and \$11.0 million for the six months ended June 30, 2009 and 2008, respectively. All costs associated with our development revenues are included in research and development expenses in our Statements of Operations. The collaboration agreements establish the rates for billing personnel-related time incurred and consequently, the associated costs incurred to perform the additional development activities are not separately captured from ongoing personnel costs.

Research and development: Research and development expenses decreased by \$17.7 million to \$12.6 million for the six months ended June 30, 2009, as compared to the same period of 2008. The decrease was due primarily to a decrease in direct development costs for our PN program and exploratory programs. Direct development costs for the PN program decreased by \$16.1 million to \$7.3 million, primarily due to clinical trial activities and other product development activities during the six months ended June 30, 2009, as compared to the same period of 2008. Direct development costs for the PA program decreased by \$0.8 million to \$1.0 million. Direct development costs for the exploratory programs decreased by \$1.0 million to \$0.3 million, offset by an increase of \$0.5 million in the early stage gastroenterology program, ORD2020, as compared to the same period of 2008. Other departmental expenses decreased by \$0.2 million primarily due to decreased personnel costs, as compared to the same period of 2008. We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities and regulatory matters.

General and administrative: General and administrative expenses increased by \$3.2 million to \$9.2 million for the six months ended June 30, 2009, as compared to the same period of 2008. The increase was due primarily to increased legal costs for patent defense and marketing research expenses, which were \$2.5 million and \$0.9 million, respectively, as compared to the same period of 2008. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, legal expenses, market research, and public company activities.

Other income: Interest income was \$0.1 million and \$0.7 million for the six months ended June 30, 2009 and 2008, respectively. Investment income from bond amortization for the six months ended June 30, 2009 totaled \$0.2 million as compared to \$0.6 million during the same period of 2008. Investment income decreased primarily due to declining short term interest rates.

Income Taxes

We estimate an annual effective tax rate of 0% for the year ended December 31, 2009. Our effective tax rate was 0% for the six month period ended June 30, 2009. However, the actual effective rate may vary depending upon actual licensing fees and milestone payments received, specifically the pre-tax book income for the year, and other factors. Income taxes have been accounted for using the liability method in accordance with SFAS 109, "Accounting for Income Taxes." Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Tax Reform Act of 1986, or the Act, provides for a limitation on the annual use of net operating loss and research and development tax credit carry-forwards (following certain ownership changes, as defined by the Act) that could limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Act, as a result of, among other reasons, past financings. Accordingly, our ability to utilize the

aforementioned carry-forwards may be limited. Additionally, because tax laws limit the time during which these carry-forwards may be applied against future taxes, we may not be able to take full advantage of these carry-forwards for federal and state income tax purposes.

We currently file income tax returns in the U.S. federal jurisdiction, and the state of North Carolina. We are no longer subject to federal or North Carolina income tax examinations by tax authorities for years before 2005. However, the loss carryforwards generated prior to 2005 may still be subject to change, if we subsequently begin utilizing these losses in a year that is open under statute and subject to federal or North Carolina income tax examinations by tax authorities.

We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the six months ended June 30, 2009 and 2008, there were no such interest and penalties.

Liquidity and Capital Resources

At June 30, 2009, cash and cash equivalents, along with short-term investments, totaled \$48.0 million, a decrease of \$13.7 million compared to December 31, 2008. The decrease in cash was primarily due to the operating loss for the period and the reduction of accounts payable and accrued expenses offset in part by cash receipts for development activities and royalty payments received pursuant to the terms of our agreements with AstraZeneca and GSK. Our cash is invested in money market funds that invest primarily in short-term, highly rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short-term corporate fixed income obligations and U.S. Government agency obligations.

Short-term investments are held in a managed investment account designed to increase the return on our cash. This account, which is invested as described above, is managed within our Board approved investment policy, which restricts investments to maturities of less than twelve months, limits concentration to 5% or less and requires minimum credit ratings of A1/P1, among other requirements. We have considered the impact of the current economic environment in evaluating the fair value of our investments. We believe we are adhering to a conservative investment policy. Nonetheless, given the current credit crisis and other market risks, a downgrade in any of our A1/P1 investments could result in required action under our investment policy, and may result in an investment loss.

Because certain holdings in the managed account have maturities longer than three months, we have classified these holdings as short-term investments in our balance sheet and accounting principles require reporting such investments at market value. Any difference between market value and cost is reported in the stockholders' equity section of our financial statements as comprehensive income or loss.

We received \$15.0 million in operating cash during the six months ended June 30, 2009 pursuant to the terms of our collaboration agreements with AstraZeneca and GSK. In addition, our balance sheet included a \$0.9 million accounts receivable for royalties under the terms of the GSK agreement. Cash received from financing activities during the period totaled \$32,702 reflecting net proceeds from the exercise of stock options.

Based upon the indirect method of presenting cash flow, cash used in operating activities totaled \$13.8 million for the six months ended June 30, 2009. Cash used in operating activities was \$2.4 million for the six months ended June 30, 2008. Net cash provided by investing activities during the six months ended June 30, 2009 totaled \$4.5 million, and net cash used in investing activities for the six months ended June 30, 2008 totaled \$4.2 million reflecting investing activities associated with the purchase and sale of short-term securities. Cash required for our operating activities during 2009 is projected to increase from our 2008 requirements as a result of decreased milestone payments. We currently expect to end the year with greater than \$45.0 million in cash, cash equivalents and short term investments, assuming the receipt of \$10 million in milestones. During the six months ended June 30, 2009 and June 30, 2008 we recorded non-cash stock-based compensation expense of \$2.7 million and \$2.7 million, respectively, associated with the grant of stock options and restricted stock.

As of June 30, 2009, we had \$16.9 million in cash and cash equivalents and \$31.1 million in short-term investments. Our cash operating expenses for 2009 and 2010 are expected to be in the \$35 million to \$45 million range. We believe that we will have sufficient cash reserves and cash flow to maintain our planned level of business activities through 2010.

As part of our ongoing assessment of our business and liquidity needs, we regularly assess available funding options and will consider available funding opportunities as they arise. We may sell shares of common stock in the future to fund additional development activities and increase our working capital. We have filed with the Securities and Exchange Commission, or SEC, and the SEC has declared effective, a shelf registration statement on Form S-3 under which we may register up to 8,540,000 shares of our common stock for sale in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to an aggregate of 540,000 of such shares, and we will not receive any of the proceeds from the sales of shares

made by the selling stockholders. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

Our forecast of the period of time through which we expect that our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary as a result of a number of factors. Our future capital requirements will depend on many factors, including:

- the number and progress of our clinical trials and other trials and studies;
- our success, or any delays, in obtaining, regulatory approval of our product candidates and success in, and manner of, commercializing our products;
- the success of our existing collaborations and our ability to establish additional collaborations;
- costs incurred to commercialize our products ourselves should we decide not to enter into additional collaborations;
- the extent to which we acquire or invest in businesses, technologies or products;
- costs incurred to enforce and defend our patent claims and other intellectual rights;
- our ability to negotiate favorable terms with various contractors assisting in our trials and studies;
- costs incurred in the defense of the class action lawsuit that is pending against us and our president and chief executive officer and certain executive officers relating to Treximet; and
- costs incurred in the defense of our Treximet patents against generic companies that have filed ANDAs with the FDA to market the product prior to the expiration of our patents.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The proceeds from revenue from our collaboration agreements have been invested in money market funds that invest primarily in short-term, highly-rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short-term corporate fixed income obligations and U.S. Government and Government agency obligations. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Our management's report on internal control over financial reporting procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) is included with the financial statements reflected in Item 1 of this Quarterly Report on Form 10-Q and is incorporated herein by reference.

No change in our internal control over financial reporting occurred during the second fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of its securities against the Company, its chairman and chief executive officer and one of its directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, the Company received the plaintiffs' amended and consolidated complaint which added two current officers of the Company as additional defendants. The Company and individual defendants filed a motion to dismiss the amended and consolidated complaint with the Court on June 26, 2008. On August 27, 2008, the plaintiffs voluntarily dismissed their claims against one of the Company's directors. On February 19, 2009, Magistrate Judge Dixon, to whom the Court had referred the motion to dismiss, issued a Recommendation that the Court grant the Company and individual defendants' motion to dismiss without leave for plaintiffs to file another amended complaint. Plaintiffs filed objections to the recommendation on March 23, 2009 and a corrected version of the objections on March 26, 2009. Defendants' response to these objections was filed on April 20, 2009. The matter is now awaiting decision by the Court. The Company and the individual defendants intend to continue to defend these claims vigorously but there can be no assurance that the Court will accept the Recommendation of the Magistrate Judge.

The Company and GSK have received notices of Paragraph IV Notice Letters from Par, Alphapharm, Alphapharm's designated agent, Mylan, and Teva, informing us that each company had filed an Abbreviated New Drug Application, or ANDA, with the Food and Drug Administration, or FDA, seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm and Teva have each indicated in their respective Notice Letters that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it has elected not to exercise its first right to bring infringement suits against Par, Alphapharm and Teva. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009 and Teva on April 14, 2009, all in the United States District Court for the Eastern District of Texas. All three actions have since been consolidated into one suit. The Company's filing of these patent infringement lawsuits within forty-five days of our receipt of the respective Notice Letters from Par, Alphapharm and Teva resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's and Teva's respective ANDAs for up to 30 months or until a final court decision is entered in the infringement suit in favor of the ANDA applicant, whichever occurs first. Treximet currently has regulatory exclusivity through April 15, 2011. Treximet may be eligible for an additional six months of exclusivity upon the completion of certain pediatric studies. Written and document discovery are at an early stage. The cases are set for trial in the fourth quarter of 2010.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above or the patent infringement lawsuits against Par, Alphapharm and Teva. Furthermore, we will have to incur expenses in connection with these lawsuits, which may be substantial. In the event of an adverse outcome or outcomes, our business could be materially harmed. Moreover, responding to and defending pending litigation will result in a significant diversion of management's attention and resources and an increase in professional fees.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Business

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. Product revenue is dependent upon the commercialization efforts of our partners, including the sales and marketing efforts of GSK relating to Treximet.

We have incurred significant losses since our inception. As of June 30, 2009, we had an accumulated deficit of approximately \$140.9 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing and amount of payments that we may receive from others. We expect to continue to incur

significant operating losses associated with our research and development efforts and do not know the amount or timing of product revenue we will receive as a result of sales of Treximet by GlaxoSmithKline, or GSK, or future sales of our other product candidates by our commercial partners. For example, GSK's inability to launch Treximet with approved promotional and professional materials, including direct to consumer advertising, may have had an adverse impact on uptake of the product, thus affecting our royalty revenue.

Our only current potential sources of revenue are the payments that we may receive pursuant to our collaboration agreements with GSK and AstraZeneca. We received the remaining regulatory milestone payments under our collaboration agreement with GSK related to Treximet payable upon approval by the U.S. Food and Drug Administration, or FDA, and notification of GSK's intent to commercialize Treximet, receipt of which were delayed as a result of our receipt of a second approvable letter for the product on August 1, 2007.

We depend heavily on the success of our product candidates, which may never be approved for commercial use. If we are unable to develop, gain approval of or commercialize those product candidates, we will never receive revenues from the sale of our product candidates.

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful commercialization of Treximet, along with the successful development, approval and commercialization of our current product candidates. Many factors could negatively affect our ability to obtain regulatory approval for our product candidates. For example, approval of Treximet for commercial use was significantly delayed by our receipt of two approvable letters, the first of which we received in June 2006 in which the FDA requested additional safety information on Treximet, some of which required new studies. On August 1, 2007, we received a second approvable letter from the FDA for Treximet in which the FDA requested that we further address the FDA's concern about the product's potential for genotoxicity.

In October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. Reduction of endoscopic gastric ulcers was the primary endpoint in our Phase 3 trials for PN 400 and the proposed primary endpoint in the current study design of the Phase 3 trials for our PA32540 product. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. If the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint in clinical trials, we might have been required to conduct additional trials and provide additional data which would have required additional expenses and delayed new drug application, or NDA, approval of PN 400.

In addition to the inability to obtain regulatory approval, many other factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including those discussed in the risk factors that follow as well as negative, inconclusive or otherwise unfavorable results from any studies or clinical trials, such as those that we obtained with respect to MT 500, which led to our decision to discontinue development of that product candidate in 2002.

Changes in regulatory approval policy or statutory or regulatory requirements, or in the regulatory environment, during the development period of any of our product candidates may result in delays in the approval, or rejection, of the application for approval of one or more of our product candidates. If we fail to obtain approval, or are delayed in obtaining approval, of our product candidates, our ability to generate revenue will be severely impaired.

The process of drug development and regulatory approval for product candidates takes many years, during which time the FDA's interpretations of the standards against which drugs are judged for approval may evolve or change. The FDA can also change its approval policies based upon changes in laws and regulations. In addition, it can decide, based on its then current approval policies, any changes in those policies and its broad discretion in the approval process, to weigh the benefits and the risks of every drug candidate. As a result of any of the foregoing, the FDA may decide that the data we submit in support of an application for approval of a drug candidate are insufficient for approval. For example, in October 2008, the FDA has informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. Reduction of endoscopic gastric ulcers was the primary endpoint in our Phase 3 trials for PN 400. In late January 2009, FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. In the event the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint, we might have been required to conduct additional trials and provide additional data which would have required additional expenses and delayed NDA approval of PN 400. Further, changes in policy or interpretation may not be the subject of published guidelines and may therefore be difficult to evaluate. For example, the FDA has not recently published guidelines for the approval of new migraine therapies, and we have had to rely on periodic guidance from the FDA obtained (in conversations) informally and in other meetings, the content of which may be subject to significant modification over the period of a drug's development program. There is also the risk that we and the FDA may interpret such guidance differently.

Further, additional information about the potential risks of marketed drugs may affect the regulatory approval environment, or the FDA's approval policies, for new product candidates. For example, in February 2005 an advisory committee convened by the FDA met to address the potential cardiovascular risks of COX-2 selective NSAIDs and related drugs in response to disclosures made about possible adverse effects from the use of some of these drugs. On April 7, 2005, the FDA issued a Public Health Advisory, or the Advisory, based, in part, upon the recommendations of the advisory committee. The Advisory stated that it would require that manufacturers of all prescription products containing NSAIDs provide warnings regarding the potential for adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to the FDA advisory committee meeting in February 2005, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required for approval of new NSAID products that may be used on an intermittent or chronic basis. We do not know to what extent the FDA's actions may otherwise adversely affect or delay the approvability of our PN or other product candidates that contain NSAIDs.

If we, or our current or future collaborators, do not obtain and maintain required regulatory approvals for one or more of our product candidates, we will be unable to commercialize those product candidates. Further, if we are delayed in obtaining or unable to obtain, any required approvals, our collaborators may terminate, or be entitled to terminate, their agreements with us or reduce or eliminate their payments to us under these agreements or we may be required to pay termination payments under these agreements.

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the U.S. In order to market our products abroad, we must comply with extensive regulation by foreign governments. If we are unable to obtain and maintain FDA and foreign government approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing that product candidate. Except for Treximet, which was approved for commercial sale in the U.S. on April 15, 2008, none of our other product candidates have been approved for sale in the U.S. or any foreign market and they may never be approved. For example, we received two approvable letters relating to our NDA for Treximet which communicated FDA's concerns that delayed marketing approval. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In June 2006, we received the first approvable letter in which the FDA requested additional safety information on Treximet, and in August 2007, we received a second approvable letter in which the FDA requested that we address their concern about the potential implications from one preclinical in vitro chromosomal aberration study in which a signal for genotoxicity was seen for the combination of naproxen sodium and sumatriptan. We have also previously received not-approvable letters from the FDA relating to our NDAs for MT 100 and MT 300.

In the U.S., a separate NDA or supplement must be filed with respect to each indication for which marketing approval of a product is sought. Each NDA, in turn, requires the successful completion of preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials demonstrating the safety and efficacy of the product for that particular indication. We may not receive regulatory approval of any of the NDAs that we file with the FDA or of any approval applications we may seek in the future outside the U.S.

Further, our current or future collaboration agreements may terminate, or require us to make certain payments to our collaborators, or our collaborators may have the right to terminate their agreements with us or reduce or eliminate their payments to us under these agreements, based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates. For example, under our PN collaboration agreement with AstraZeneca, AstraZeneca has the right to terminate the agreement if certain delays occur or specified development and regulatory objectives are not met. For example, this termination right could have been triggered by AstraZeneca if the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint and we had been required to conduct additional trials which would have delayed NDA approval for PN 400. Both AstraZeneca and GSK have the right to terminate their respective agreement with us upon 90 days notice for any reason. If we or our contract manufacturers do not maintain required regulatory approvals, we may not be able to commercialize our products. Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and is subject to continuous review. The FDA may also require us to conduct additional post-approval studies. These post-approval studies may include carcinogenicity studies in animals or further human clinical trials. The later discovery of previously unknown problems with the product, manufacturer or manufacturing facility may result in criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and therefore would not receive any revenues from that product.

We and our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product candidates, and are subject to additional FDA inspection. We, or our third-party manufacturers, may not be

able to comply with cGMP regulations or other FDA regulatory requirements, which could result in a delay or an inability to manufacture the products. If we or our partners wish or need to identify an alternative manufacturer, delays in obtaining FDA approval of the alternative manufacturing facility could cause an interruption in the supply of our products.

Labeling and promotional activities are subject to scrutiny by the FDA and state regulatory agencies and, in some circumstances, the Federal Trade Commission. FDA enforcement policy prohibits the marketing of unapproved products as well as the marketing of approved products for unapproved, or off-label, uses. These regulations and the FDA's interpretation of them may limit our or our partners' ability to market products for which we gain approval. Failure to comply with these requirements can result in federal and state regulatory enforcement action. Further, we may not obtain the labeling claims we or our partners believe are necessary or desirable for the promotion of our product candidates.

If third parties challenge the validity of the patents or proprietary rights of our marketed products or assert that we have infringed their patents or proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly and time consuming and could negatively impact the commercialization of Treximet and/or any of our products that we develop or acquire. We have received notice of paragraph IV certifications notifying us of the filing of ANDAs with the FDA for approval to market a generic version of Treximet. We filed patent infringement lawsuits in response to these ANDAs that could lead to costly and time consuming patent litigation.

The intellectual property rights of pharmaceutical companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. Our success in developing and commercializing pharmaceutical products may depend, in part, on our ability to operate without infringing on the intellectual property rights of others and to prevent others from infringing on our intellectual property rights. There has been substantial litigation regarding patents and other intellectual property rights in the pharmaceutical industry. For example, third parties seeking to market generic versions of branded pharmaceutical products often file ANDAs with the FDA, containing a certification stating that the ANDA applicant believes that the patents protecting the branded pharmaceutical product are invalid, unenforceable and/or not infringed. Such certifications are commonly referred to as paragraph IV certifications.

The Company and GSK have received notices of Paragraph IV Notice Letters from Par, Alphapharm, Alphapharm's designated agent, Mylan, and Teva, informing us that each company had filed an Abbreviated New Drug Application, or ANDA, with the Food and Drug Administration, or FDA, seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm and Teva have each indicated in their respective Notice Letters that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it has elected not to exercise its first right to bring infringement suits against Par, Alphapharm and Teva. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009 and Teva on April 14, 2009, all in the United States District Court for the Eastern District of Texas. All three actions have since been consolidated into one suit. The Company's filing of these patent infringement lawsuits within forty-five days of our receipt of the respective Notice Letters from Par, Alphapharm and Teva resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's and Teva's respective ANDAs for up to 30 months or until a final court decision is entered in the infringement suit in favor of the ANDA applicant, whichever occurs first. Treximet currently has regulatory exclusivity through April 15, 2011. Treximet may be eligible for an additional six months of exclusivity upon the completion of certain pediatric studies. Written and document discovery are at an early stage. The cases are set for trial in the fourth quarter of 2010.

Litigation can be time consuming and costly and we cannot predict with certainty the outcome. If we are unsuccessful in such a proceeding and the FDA approved a generic version of our product, such an outcome would have a material adverse effect on sales of Treximet and our business.

Our reliance on collaborations with third parties to develop and commercialize our products is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize our products and adversely affecting our profitability.

Under our current strategy, we expect to depend upon collaborations with third parties to develop our product candidates and we expect to depend substantially upon third parties to commercialize our products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and any future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and intend in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, although not a primary component of our current strategy, the identification of new compounds or product candidates for development has led us, and may continue to require us, to enter into license or other collaborative agreements with others, including pharmaceutical companies and research institutions. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties.

Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their agreements with us or reduce their payments to us under those agreements on limited or no notice and for no reason or reasons outside of our control. We currently have a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology, including Treximet, in the U.S., a global collaboration with AstraZeneca for the development and commercialization of proprietary combinations of gastroprotective agents and naproxen, and a collaboration with Valeant NA in the U.S. for the development and commercialization of MT 300. In these collaboration agreements, our collaborators have the right to terminate the agreement upon a default by us. In addition, GSK and AstraZeneca are entitled to terminate their respective agreements with us upon 90 days' notice for any reason. Additionally, both GSK and AstraZeneca have the right to reduce the royalties on net sales of products payable to us under their respective agreements if generic competitors attain a pre-determined share of the market for products marketed under the agreements, or if either GSK or AstraZeneca must pay a royalty to one or more third parties for rights it licenses from those third parties to commercialize products marketed under the agreements. AstraZeneca is also entitled to terminate its agreement with us if certain delays occur or specified development or regulatory objectives are not met. This termination could have been triggered by AstraZeneca if the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint and we had been required to conduct additional trials which would have delayed NDA approval for PN 400. Valeant NA is entitled to terminate its agreement with us and a \$1.0 million withdrawal fee would be payable by us in the event we choose to withdraw the NDA if we determine that additional studies or data that are required by the FDA for approval of the NDA would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300. Due to our belief that the FDA will not approve the NDA for MT 300 and there are no additional required studies, we began discussions with Valeant NA regarding termination of our agreement. Valeant NA has demanded payment of the \$1.0 million withdrawal fee, which we are disputing.

If our current or future licensees exercise termination rights they may have, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us.

A further risk we face with our collaborations is that business combinations and changes in the collaborator or their business strategy may adversely affect their willingness or ability to complete their obligations to us.

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various regulatory, commercialization and other activities or with respect to the timing of the development, such as our agreement with GSK under which GSK determined, among other things, the exact formulation and composition of the product candidates using our MT 400 technology for use in the Treximet clinical trials. Similarly, under our agreement with AstraZeneca, AstraZeneca has the right to manufacture clinical trial material itself or through a third party. If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated. Any delay or termination of clinical development or commercialization, such as the delay in FDA approval we experienced as a result of approvable letters we received from the FDA in June 2006 and August 2007 related to our Treximet NDA, or a delay in FDA approval of PN 400 which could have occurred if the FDA determined that endoscopic gastric ulcers were no longer an acceptable primary endpoint in clinical trials and we were required to conduct additional clinical trials for the product, would delay or possibly eliminate our potential product revenues. Further, our collaborators may be able to exercise control, under certain circumstances, over our ability to protect our patent rights under patents covered by the applicable collaboration agreement. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements and would have exclusive control over such enforcement litigation. GSK advised us that it has elected not to exercise its first right to bring infringement suits against Par, Alphapharm and Teva which have submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets and we have filed suit against the three companies in the federal court of the United State District Court for the Eastern District of Texas.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day-to-day control over the activities of our contractors or collaborators;
- our collaborators may fail to defend or enforce patents they own on compounds or technologies that are incorporated into the products we develop with them;
- third parties may not fulfill their regulatory or other obligations;
- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and
- disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates and/or the commercialization of our products or reduction in the milestone payments we receive from our collaborators, or could result in our not being able to commercialize our products. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time-consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development of our product candidates and/or the commercialization of our products will be delayed or may never be realized.

A collaborator may withdraw support or cease to perform work on our product candidates if the collaborator determines to develop its own competing product candidate or other product candidates instead.

We have entered into collaboration and license agreements, and expect to continue to enter into such agreements, with companies that have products and are developing new product candidates that compete or may compete with our product candidates or which have greater commercial potential. If one of our collaborators should decide that the product or a product candidate that the collaborator is developing would be more profitable for the collaborator than our product candidate covered by the collaboration or license agreement, the collaborator may withdraw support for our product candidate or may cease to perform under our agreement. In the event of a termination of the collaborator's agreement upon such cessation of performance, we would need to negotiate an agreement with another collaborator in order to continue the development and commercialization efforts for the product candidate. If we were unsuccessful in negotiating another agreement, we might have to cease development activities of the particular product candidate. For example, our development and commercialization agreements with GSK and AstraZeneca are subject to this risk. GSK has publicly disclosed that it is exploring the development of several compounds for the treatment of migraine. If GSK decides to focus its development and commercialization efforts on its own products rather than continuing to commercialize Treximet or work with us on any other product candidates that may be developed under the agreement, it has the ability to terminate our agreement upon 90 days' written notice. And under the terms of our agreement with AstraZeneca, either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement, at any time, at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us. However, under the circumstance above, or similar circumstance, we would need to enter into a new development and commercialization agreement and would need to start the development process all over again. If we were able to negotiate a new development and commercialization agreement to develop our technology, which is not certain, we would face delays and redundant expenses in that development.

We need to maintain current agreements and enter into additional agreements with third parties that possess sales, marketing and distribution capabilities, or establish internally the capability to perform these functions, in order to successfully market and sell our future drug products.

We have no sales or distribution personnel or capabilities at the present time. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to provide those capabilities, or, alternatively, we are unable to develop internally sales and distribution capabilities, we will not be able to successfully commercialize our products. To the extent that we enter into marketing and sales agreements with third parties, such as our agreement with GSK which gives GSK responsibility for marketing and selling Treximet in the United States, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. Further, we cannot guarantee that, should we elect to develop our own sales and distribution capabilities, we would have sufficient resources to do so, or would be able to hire the qualified sales and marketing personnel we would need.

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, and clinical trials for our product candidates. Any negative or unanticipated results, unforeseen costs or delays in the conduct of these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could cause us to discontinue development of a product candidate or reduce, delay or eliminate our receipt of potential revenues for one or more of our product candidates and adversely affect our ability to achieve profitability.

Generally, we must demonstrate the efficacy and safety of our product candidates before approval to market can be obtained from the FDA or the regulatory authorities in other countries. Our existing and future product candidates are and will be in various stages of clinical development. Depending upon the type of product candidate and the stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, as well as clinical trials, on these product candidates before we submit marketing applications in the United States and abroad. These studies and trials can be very costly and time-consuming. For example, long-term cardiovascular safety studies, such as those the FDA has indicated will be required for approval of certain product candidates containing NSAIDs, typically take approximately three years. In

addition, we rely on third parties to perform significant aspects of our studies and clinical trials, introducing additional sources of risk into our development programs.

It should be noted that the results of any of our preclinical and clinical trial testing are not necessarily predictive of results we will obtain in subsequent or more extensive clinical trials or testing. This may occur for many reasons, including, among others, differences in study design, including inclusion/exclusion criteria, the variability of patient characteristics, including patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, our results from the first of our two Phase 3 pivotal clinical trials of Treximet differed from the results of our second Phase 3 clinical trial and from the Phase 2 proof-of-concept trial of MT 400 that we conducted prior to entering into our collaboration with GSK. Whereas in the Phase 2 trial statistical significance was reached at two hours over placebo in the relief of all associated symptoms of migraine (nausea, photophobia and phonophobia), in the first Phase 3 study Treximet failed to achieve statistical significance at two hours compared to placebo in the relief of nausea. In the second Phase 3 pivotal clinical trial, Treximet demonstrated superiority over the individual components measured by sustained pain-free response ($p < 0.001$ vs. naproxen; $p = 0.009$ vs. sumatriptan) and met all other regulatory endpoints versus placebo.

The successful completion of any of our clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that are unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Further, even though we may have completed all clinical trials for a product candidate that were planned for submission in support of a marketing application, we may be required to conduct additional clinical trials, studies or investigations or to submit additional data to support our marketing applications. In addition, we and/or our marketing or development partners may determine that pre-approval marketing support studies should be conducted. Unanticipated adverse outcomes of such studies, including recognition of certain risks to human subjects, could have a material impact on the approval of filed or planned market applications or could result in limits placed on the marketing of the product. We may also determine from time to time that it would be necessary to seek to provide justification to the FDA or other regulatory agency that would result in evaluation of the results of a study or clinical trial in a manner that differs from the way the regulatory agency initially or customarily evaluated the results. In addition, we may have unexpected results in our preclinical or clinical trials or other studies that require us to reconsider the need for certain studies or trials or cause us to discontinue development of a product candidate. For example, in reviewing our NDA for Treximet, the FDA expressed concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan. Further, additional information about potential drug-drug interactions may restrict the patient population for our products, thus limiting our potential revenue. For example, recent scientific publications contain conflicting data regarding a possible interaction between clopidogrel (Plavix[®]), a widely prescribed anti-platelet agent, and certain enteric-coated proton pump inhibitor products. If an interaction is proven to exist, it may impact the number of patients for whom our PA product candidates, which contain the proton pump inhibitor, omeprazole in an immediate release form, could be prescribed for cardiovascular protection.

Once submitted, an NDA requires FDA approval before the product described in the application can be distributed or commercialized. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, the FDA requested additional safety information on Treximet in the approvable letter we received in June 2006 relating to our NDA for Treximet, which required conduct of additional studies, and in August 2007, we received a second approvable letter in which the FDA raised an additional concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan.

Further, although we believed that we provided the necessary data to support approval of the NDAs for MT 100, our proprietary combination of metoclopramide hydrochloride and naproxen sodium, and MT 300, the FDA issued not-approvable letters for the MT 100 and MT 300 NDAs in May 2004 and October 2003, respectively, and based upon our understandings from our most recent communication with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the NDA for MT 300. In addition, based upon our receipt of the not approvable letter for MT 100 and the outcome of an August 2005 FDA Advisory Committee meeting relating to the potential risk of tardive dyskinesia associated with the use of one of the components of MT 100, we made the decision to discontinue further development of MT 100 and have withdrawn the MAA for the product in the U.K.

The FDA may also require data in certain subpopulations, such as pediatric use, or, if such studies were not previously completed, may require long-term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver of such a requirement. We face similar regulatory hurdles in other countries to those that we face in the U.S.

Our costs associated with our human clinical trials vary based on a number of factors, including:

- the order and timing of clinical indications pursued;
- the extent of development and financial support from collaborative parties, if any;
- the need to conduct additional clinical trials or studies;
- the number of patients required for enrollment;
- the difficulty of obtaining sufficient patient populations and clinicians;
- the difficulty of obtaining clinical supplies of our product candidates; and
- governmental and regulatory delays.

We currently depend and will in the future depend on third parties to manufacture our product candidates. If these manufacturers fail to meet our requirements or any regulatory requirements, the product development and commercialization of our product candidates will be delayed.

We do not have, and have no plans to develop, the internal capability to manufacture either clinical trial or commercial quantities of products that we may develop or have under development. We rely upon third-party manufacturers and our partners to supply us with our product candidates. We also need supply contracts to sell our products commercially. There is no guarantee that manufacturers that enter into commercial supply contracts with us will be financially viable entities going forward, or will not otherwise breach or terminate their agreements with us. If we do not have the necessary commercial supply contracts, or if our current manufacturer is, or any of our future manufacturers are, unable to satisfy our requirements or meet any regulatory requirements, and we are required to find alternative sources of supply, there may be additional costs and delays in product development and commercialization of our product candidates or we may be required to comply with additional regulatory requirements.

If our competitors develop and commercialize products faster than we do or if their products are superior to ours, our commercial opportunities will be reduced or eliminated.

Our product candidates will have to compete with existing and any newly developed migraine therapies or therapies for any newly developed product candidates for the treatment of other diseases. There are also likely to be numerous competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non-competitive. For example, our primary competitors will likely include large pharmaceutical companies (including, based upon their current migraine portfolios, GSK, Merck & Co., AstraZeneca, Johnson & Johnson, Pfizer, Inc. and Endo Pharmaceuticals), biotechnology companies, universities and public and private research institutions. The competition for our PN products that receive regulatory approval will come from the oral NSAID market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC™), combinations of NSAIDs and PPIs taken as separate pills and the only remaining COX-2 inhibitor, Celebrex®, and new agents such as prasugrel, which has been approved in several countries and is currently under review by FDA.

Based upon their drug product and pipeline portfolios and the overall competitiveness of our industry, we believe that we face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. Our competitors, either alone or with collaborative parties, may also succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do.

Many of these competitors, either alone or together with their collaborative parties, also have significantly greater experience than we do in:

- developing product candidates;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates; and
- manufacturing and marketing products.

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA or other regulatory approval or commercializing products where we cannot or before we do. Any delays we encounter in obtaining regulatory approvals for our product candidates, such as we experienced as a result of the approvable letters we received from the FDA in June 2006 and August 2007 relating to the Treximet NDA, and as a result of the not-approvable letters we received from the FDA on MT 100 and MT 300 increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

If there is an adverse outcome in the securities class action lawsuit that has been filed against us or our current directors and officers, or we are unable to defend our patents in patent infringement lawsuits against generic companies filing ANDAs for our products, our business may be materially harmed. Further, defending against these lawsuits may be expensive and will divert the attention of our management.

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of our securities against us, our chairman and chief executive officer and one of our directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by us concerning our migraine drug candidate, Treximet, during the purported class period, July 31, 2006 through August 1, 2007. By order dated February 15, 2008, the Court appointed joint co-lead plaintiffs. On April 25, 2008, we received the plaintiffs' amended and consolidated complaint which added two of our current officers as additional defendants. We and the individual defendants filed a motion to dismiss the amended and consolidated complaint with the Court on June 26, 2008. On August 27, 2008, the plaintiffs voluntarily dismissed their claims against one of our directors. On February 19, 2009, Magistrate Judge Dixon, to whom the Court had referred the motion to dismiss, issued a Recommendation that the Court grant the Company and individual defendants' motion to dismiss without leave for plaintiffs to file another amended complaint. Plaintiffs filed objections to the recommendation on March 23, 2009 and a corrected version of the objections on March 26, 2009. Defendants' response to these objections was filed on April 20, 2009. The matter is now awaiting a decision by the Court. The Company and the individual defendants intend to continue to defend these claims vigorously but there can be no assurance that the Court will accept the Recommendation of the Magistrate Judge.

The Company and GSK have received notices of Paragraph IV Notice Letters from Par, Alphapharm, and Alphapharm's designated agent, Mylan, and Teva, informing us that each company had filed an Abbreviated New Drug Application, or ANDA, with the Food and Drug Administration, or FDA, seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm and Teva have each indicated in their respective Notice Letters that they intend to market a generic version of Treximet tablets before the expiration of U.S. Patent Nos. 6,060,499, 6,586,458 and 7,332,183. GSK advised us that it has elected not to exercise its first right to bring infringement suits against Par, Alphapharm and Teva. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009 and Teva on April 14, 2009, all in the United States District Court for the Eastern District of Texas. All three actions have since been consolidated into one suit. The Company's filing of these patent infringement lawsuits within forty-five days of our receipt of the respective Notice Letters from Par, Alphapharm and Teva resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's and Teva's respective ANDAs for up to 30 months or until a final court decision is entered in the infringement suit in favor of the ANDA applicant, whichever occurs first. Treximet currently has regulatory exclusivity through April 15, 2011. Treximet may be eligible for an additional six months of exclusivity upon the completion of certain pediatric studies. Written and document discovery are at an early stage. The cases are set for trial in the fourth quarter of 2010.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above or the patent infringement lawsuits against Par, Alphapharm and Teva. Furthermore, we will have to continue to incur expenses in connection with these lawsuits, which may likely be substantial. In the event of an adverse outcome or outcomes, our business could be materially harmed. Moreover, responding to and defending pending litigation will result in a significant diversion of management's attention and resources and an increase in professional fees.

If we are unable to protect our patents or proprietary rights, or if we are unable to operate our business without infringing the patents and proprietary rights of others, we may be unable to develop our product candidates or compete effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability, and the ability of our licensors, to obtain and to keep protection for our products and technologies under the patent laws of the United States and other countries, so that we can stop others from using our inventions. Our success also will depend on our ability to prevent others from using our trade secrets. In addition, we must operate in a way that does not infringe, or violate, the patent, trade secret and other intellectual property rights of other parties.

We cannot know how much protection, if any, our patents will provide or whether our patent applications will issue as patents. The breadth of claims that will be allowed in patent applications cannot be predicted and neither the validity nor enforceability of claims in issued patents can be assured. If, for any reason, we are unable to obtain and enforce valid claims covering our products and technology, we may be unable to prevent competitors from using the same or similar technology or to prevent competitors from marketing identical products. For example, if we are unsuccessful in litigation against Par, Alphapharm, Teva and other companies who may file ANDAs for Treximet, such companies could market a generic version of the product after marketing exclusivity expires. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our products, any patents that protect our product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us.

In certain territories outside the U.S., our issued patents may be subject to opposition by competitors within a certain time after the patent is issued. Such opposition proceedings and related appeals may not be resolved for several years, and may result in the partial or total revocation of the issued patent. For example, in October 2005 oppositions were filed against our issued European patent for MT 400 by Merck & Co., Inc. and Almirall Prodesfarma asserting that the European patent should not have been granted. As a result of these oppositions and subsequent proceedings, the European Patent Office found that claims relating to combinations of sumatriptan and naproxen for the treatment of migraine were valid. However, broader claims relating to certain other 5-HT 1B/1D agonists and long-acting NSAIDs were held to be insufficiently supported by the presently available technical evidence.

We may need to submit our issued patents for amendment or reissue if we determine that any claims within our patents should not have been issued. While such a submission may be based on our view that only specified claims should not have been granted to us, there can be no assurance that a patent examiner will not determine that additional claims should not have been granted to us. Such was the case with one of our patents covering MT 100, which we submitted for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. In April 2006, we received an office action on the reissue application and, consistent with our decision not to devote further resources to the development of this product in the U.S., the reissue application was abandoned in January 2007.

We may need to license rights to third party patents and intellectual property to continue the development and marketing of our product candidates. If we are unable to acquire such rights on acceptable terms, our development activities may be blocked and we may be unable to bring our product candidates to market.

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know-how, or determine the scope and validity of others' patent or proprietary rights. For example, we filed patent infringement lawsuits against Par, Alphapharm and Teva in the federal court in the Eastern District of Texas in connection with their respective ANDA submissions to the FDA containing paragraph IV certifications for approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets, a generic version of Treximet tablets, before the expiration of our patents. With respect to some of our product candidates, under certain circumstances, our development or commercialization collaborators have the first right to enforce our patents and would have exclusive control over such enforcement litigation. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements. GSK advised us that it has elected not to exercise its first right to bring an infringement suit against Par, Alphapharm and Teva, each of which have submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets.

If we are found to infringe the patent rights of others, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and marketing activities. Additionally, if we or our development or commercialization collaborator seek to enforce our patents and are unsuccessful, we may be subject to claims for bringing a failed enforcement action, including claims alleging various forms of antitrust violations (both state and federal) and unfair competition. If we are found to be liable for such claims, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and commercialization activities. Even if we are successful in defending any such claims of infringement or in asserting claims against third parties, such litigation is expensive, may have a material effect on our operations, and may distract management from our business operations. Regardless of its eventual outcome, any lawsuit that we enter into may consume time and resources that would impair our ability to develop and market our product candidates.

We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and, as a result, we may not be able to protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how. Also, many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

If we fail to acquire, develop and commercialize additional products or product candidates, or fail to successfully promote or market approved products, we may never achieve profitability.

As part of our business strategy, we plan to identify, self-invent and/or acquire product candidates or approved products in areas in which we possess particular knowledge. Because we do not directly engage in basic research or drug discovery, we may rely upon third parties to sell or license product opportunities to us. Other companies, including some with substantially greater financial, marketing and sales resources, are competing with us to acquire such products and product candidates. We may not be able to acquire rights to additional products or product candidates on acceptable terms, if at all. In addition, if we acquire new products or product candidates with different marketing strategies, distribution channels and bases of competition than those of our current product candidates, we may not be able to compete favorably in those product categories.

None of our products may be accepted by the market.

The commercial success of our product candidates depends upon the acceptance of these products in the marketplace. Even if a product displays a favorable efficacy and safety profile in clinical trials, market acceptance of a product will not be known until after it is launched and a product may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

- the acceptance by physicians and third-party payors of Treximet as an alternative to Imitrex, generic sumatriptan, and other therapies;
- the receipt and timing of regulatory approvals;
- the availability of third-party reimbursement;
- the indications for which the product is approved;
- the rate of adoption by healthcare providers;
- the rate of product acceptance by target patient populations;
- the price of the product relative to alternative therapies;
- the availability of alternative therapies;
- the extent and effectiveness of marketing efforts by our collaborators, and third-party distributors and agents;
- the existence of adverse publicity regarding our products or similar products; and
- the extent and severity of side effects as compared to alternative therapies.

If we do not receive adequate third-party reimbursements for our future products, our revenues and profitability will be reduced.

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the U.S., private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of a newly approved healthcare product. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our products, our products may fail to achieve market acceptance.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to contain or reduce the costs of healthcare through various means. We expect that a number of federal, state and foreign proposals will seek to control the cost of drugs through governmental regulation. We are unsure of the form that any healthcare reform legislation may take or what actions federal, state, foreign and private payors may take in response to any proposed reforms. Therefore, we cannot predict the effect of any implemented reform on our business.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

The testing and marketing of pharmaceutical products entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have product liability insurance that covers our commercialized product and human clinical trials in an amount equal to up to \$10 million annual aggregate limit with a \$0.1 million deductible per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We will explore, on an on-going basis, expanding our insurance coverage related to the sale of Treximet and for the inclusion of future marketed products when we obtain marketing approval for such

products and commercial sales of such products begin. However, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

We may need additional funding and may not have access to capital. If we are unable to raise capital when needed, we may need to delay, reduce or eliminate our product development or commercialization efforts.

In the future, we may need to raise additional funds to execute our business strategy. We have incurred losses from operations since inception and we may continue to incur additional operating losses. Our actual capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the progress of preclinical studies, clinical and other testing or the need conduct additional trials, studies or other testing;
- the time and cost involved in obtaining any regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the timing of our receipt, if any, of milestone payments and royalties under collaborative agreements;
- the effect of changes and developments in, or termination of, our collaborative, license and other relationships;
- the terms and timing of any additional collaborative, license and other arrangements that we may establish; and
- our ability to commercialize or arrange for the commercialization of our product candidates.

Our operating expenses for the six months ended June 30, 2009 totaled \$21.8 million, (\$16.3 million net of development revenue received from AstraZeneca for development activities performed under the agreement) including non-cash compensation expense of \$2.7 million related to stock options and other stock-based awards, primarily associated with our adoption of SFAS No. 123(R) on January 1, 2006. For fiscal years 2006 through 2008, our average annual operating expenses (including average non-cash deferred compensation of \$5.3 million) were \$53.6 million (\$36.5 million net of development revenue received from AstraZeneca for development activities performed under the agreement). As of June 30, 2009, we had an aggregate of \$48.0 million in cash, cash equivalents and short-term investments. If our operating expenses for 2009 and 2010 approximate the net level of our operating expenses in 2008, we believe that we will have sufficient cash reserves and cash flow to maintain that level of business activities through 2010 provided certain increased development expenses are paid by our collaborative partner. However, our expenses might increase during that period beyond currently expected levels if we decide to, or any regulatory agency requires us to, conduct additional clinical trials, studies or investigations for any of our product candidates, including in connection with the agency's consideration, or reconsideration, of our regulatory filings for our product candidates. In addition, we may be required to pay Valeant NA a withdrawal fee of \$1.0 million if we do not prevail in our current dispute with them as to whether a withdrawal fee is payable under our MT 300 collaboration agreement.

We may be unable to raise additional equity funds when we desire to do so due to unfavorable market conditions in our industry or generally, or other unforeseen developments in our business. Further, we may not be able to find sufficient debt or equity funding, if at all, on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs and therefore may not be able to execute our business strategy. Further, to the extent that we obtain additional funding through collaboration and licensing arrangements, it may be necessary for us to give up valuable rights to our development programs or technologies or grant licenses on terms that may not be favorable to us.

The sale by us of additional equity securities or the expectation that we will sell additional equity securities may have an adverse effect on the price of our common stock.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our research and development efforts.

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an amended and restated employment agreement with us on March 14, 2006, which was amended on September 28, 2007, for a three-year term with automatic one-year renewal terms. We have also entered into employment agreements with certain of our other key management personnel, which provide for one or two-year terms with automatic one-year renewal terms which were amended on September 28, 2007. If we should lose the services of Dr. Plachetka, or are unable to replace the services of our other key personnel who may leave the Company, such as Dr. Everardus Orlemans, Ph.D., Senior Vice President, Product Development, John G. Fort, M.D., Chief Medical Officer, or William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer or if we fail to recruit other key scientific personnel, we may be unable to achieve our business objectives. There is intense competition for qualified scientific personnel. Since our business is very science-oriented, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on

the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

Factors That May Affect Our Stockholders

Our stock price is volatile, which may result in significant losses to stockholders.

There has been significant volatility in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include:

- fluctuations in our operating results;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- commercial success of Treximet and our other products in the marketplace once approved;
- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- announcements by our collaborative partners regarding our products or product candidates;
- developments in new or pending litigation;
- public concern as to the safety and efficacy of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors, including the sale or attempted sale of a large amount of our common stock into the market. From October 16, 2000, when our common stock began trading on The NASDAQ National Market (now known as The NASDAQ Global Market), through July 24, 2009, the high and low sales prices of our common stock ranged from \$2.25 to \$21.75. Broad market fluctuations may also adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock in the public market could depress our stock price.

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market and two of our stockholders and their affiliates beneficially hold approximately 21% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, our chief executive officer may sell up to an aggregate of 725,000 shares pursuant to a Rule 10b5-1 trading plan. Sales under this or a similar plan began in October 2006. Further, stockholders' ownership will be diluted if we raise additional capital by issuing equity securities. We filed with the Securities and Exchange Commission a shelf registration statement on Form S-3, which became effective January 15, 2009, for an offering under which we may register up to 8,540,000 shares of our common stock for sale to the public in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to 540,000 of such shares, and we would not receive any of the proceeds from sales of those shares.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.

Provisions of our charter and bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change the direction or management of POZEN. For example, these provisions:

- authorize the issuance of "blank check" preferred stock without any need for action by stockholders;
- provide for a classified board of directors with staggered three-year terms;
- require supermajority stockholder approval to effect various amendments to our charter and bylaws;
- eliminate the ability of stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Further, in January 2005 our board of directors adopted a stockholder rights plan, similar to plans adopted by many other publicly-traded companies. The stockholder rights plan is intended to deter an attempt to acquire us in a manner or on terms not approved by our board of directors.

Item 4. Submission of Matters to a Vote of Security Holders

Our annual meeting of stockholders was held on June 3, 2009. There were present at the annual meeting of stockholders in person or by proxy stockholders holding an aggregate of 26,986,790 shares of our common stock out of a total number of 29,812,035 shares of common stock issued and outstanding and entitled to vote at the meeting. Our stockholders voted on two matters, as follows:

1. The stockholders elected three Class III directors to each serve for a three year term (until our 2012 annual meeting of stockholders and until their successors have been duly elected and qualified) by the following votes (there were no abstentions or broker non-votes in connection with the election of the Class III directors):

	Number of Shares of Common Stock	
	For:	Withheld:
John R. Plachetka, Pharm.D.	26,760,237	228,658
James J. Mauzey	26,768,237	220,658
Angela M. Larson	26,654,322	334,573

The other directors whose terms of office as director continued after the meeting are as follows: Arthur S. Kirsch, Kenneth B. Lee, Jr., Jacques F. Rejeange, and Paul J. Rizzo.

2. The stockholders ratified the appointment of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2009 by the following votes (there were no broker non-votes in connection with the ratification of our independent auditor):

Number of Shares of Common Stock		
For:	Against:	Abstain:
26,683,320	285,146	20,429

Item 6. Exhibits

Exhibit Number	Description
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

POZEN Inc.
(Registrant)

July 31, 2009

By: /s/ JOHN R. PLACHETKA
John R. Plachetka
President and Chief Executive Officer

July 31, 2009

By: /s/ WILLIAM L. HODGES
William L. Hodges
Chief Financial Officer

July 31, 2009

By: /s/ JOHN E. BARNHARDT
John E. Barnhardt
Principal Accounting Officer

EXHIBIT INDEX

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32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Section 302 Certification

I, John R. Plachetka, certify that:

1. I have reviewed this Form 10-Q of POZEN Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 31, 2009

/s/ John R. Plachetka
 John R. Plachetka, Pharm.D.
 President and Chief Executive Officer
 (principal executive officer)

Section 302 Certification

I, William L. Hodges, certify that:

1. I have reviewed this Form 10-Q of POZEN Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 31, 2009

/s/ William L. Hodges

William L. Hodges

Senior Vice President, Finance and Administration and
Chief Financial Officer

**CEO CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

In connection with Form 10-Q of POZEN Inc. (the “Company”), as filed with the Securities and Exchange Commission (the “Report”), I, John R. Plachetka, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 31, 2009

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
Chief Executive Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**CFO CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

(18 U.S.C. SECTION 1350)

In connection with Form 10-Q of POZEN Inc. (the “Company”), as filed with the Securities and Exchange Commission (the “Report”), I, William L. Hodges, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 31, 2009

/s/ William L. Hodges

William L. Hodges
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.