
**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 September 30, 2010

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, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" 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 October 22, 2010 was 29,904,347.

POZEN Inc.
FORM 10-Q

For the Nine Months Ended September 30, 2010

INDEX

	<u>Page</u>
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements (unaudited)	
Balance Sheets as of September 30, 2010 and December 31, 2009	1
Statements of Operations for the Three and Nine Months Ended September 30, 2010 and 2009	2
Statements of Cash Flows for the Three and Nine Months Ended September 30, 2010 and 2009	3
Notes to Financial Statements	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3. Quantitative and Qualitative Disclosures About Market Risk	29
Item 4. Controls and Procedures	29
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	30
Item 1A. Risk Factors	30
Item 6. Exhibits	46
Signature and Certifications	
Exhibit Page	

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc. BALANCE SHEETS (Unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,787,947	\$ 23,278,353
Short-term investments	34,785,899	23,432,100
Accounts receivable	4,452,381	1,146,072
Prepaid expenses and other current assets	1,121,041	1,259,255
Total current assets	50,147,268	49,115,780
Property and equipment, net of accumulated depreciation	73,018	43,830
Total assets	<u>\$ 50,220,286</u>	<u>\$ 49,159,610</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,416,775	\$ 2,412,335
Accrued compensation	1,578,125	2,287,200
Accrued expenses and contract costs	3,763,625	3,501,262
Deferred revenue	—	7,201,080
Total current liabilities	7,758,525	15,401,877
Long-term liabilities:		
Accrued contract costs	913,050	—
Total liabilities	8,671,575	15,401,877
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; 29,897,602 and 29,825,365 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	29,898	29,825
Additional paid-in capital	176,822,251	173,715,127
Accumulated other comprehensive income	48,076	11,918
Accumulated deficit	(135,351,514)	(139,999,137)
Total stockholders' equity	41,548,711	33,757,733
Total liabilities and stockholders' equity	<u>\$ 50,220,286</u>	<u>\$ 49,159,610</u>

See accompanying Notes to Financial Statements.

POZEN Inc.
STATEMENTS OF OPERATIONS
(Unaudited)

	<u>Three Months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2010</u>	<u>2009</u>	<u>2010</u>	<u>2009</u>
Revenue:				
Licensing revenue	\$ 4,345,725	\$ 14,290,273	\$ 39,412,764	\$ 22,428,582
Development revenue	<u>3,990</u>	<u>-</u>	<u>97,179</u>	<u>5,536,053</u>
Total revenue	4,349,715	14,290,273	39,509,943	27,964,635
Operating expenses:				
General and administrative	7,019,534	3,442,926	17,901,386	12,654,088
Research and development	<u>5,982,171</u>	<u>4,274,151</u>	<u>17,088,901</u>	<u>16,858,763</u>
Total operating expenses	13,001,705	7,717,077	34,990,287	29,512,851
Interest and other income	<u>65,697</u>	<u>84,390</u>	<u>127,967</u>	<u>472,122</u>
Income (loss) before income tax expense	(8,586,293)	6,657,586	4,647,623	(1,076,094)
Income tax expense	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Net income (loss) attributable to common stockholders	\$ <u>(8,586,293)</u>	\$ <u>6,657,586</u>	\$ <u>4,647,623</u>	\$ <u>(1,076,094)</u>
Basic net income (loss) per common share	\$ <u>(0.29)</u>	\$ <u>0.22</u>	\$ <u>0.16</u>	\$ <u>(0.04)</u>
Shares used in computing basic net income (loss) per common share	<u>29,897,602</u>	<u>29,825,365</u>	<u>29,871,407</u>	<u>29,809,799</u>
Diluted net income (loss) per common share	\$ <u>(0.29)</u>	\$ <u>0.22</u>	\$ <u>0.15</u>	\$ <u>(0.04)</u>
Shares used in computing diluted net income (loss) per common share	<u>29,897,602</u>	<u>30,023,987</u>	<u>30,229,225</u>	<u>29,809,799</u>

See accompanying Notes to Financial Statements.

POZEN Inc.
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended September 30,	
	2010	2009
Operating activities		
Net income (loss)	\$ 4,647,623	\$ (1,076,094)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	21,482	1,335
Loss on sale of fixed assets	—	27,798
Bond accretion/(amortization)	370,602	(313,393)
Noncash compensation expense	2,807,672	3,881,735
Changes in operating assets and liabilities:		
Accounts receivable	(3,306,309)	6,915,339
Prepaid expenses and other current assets	138,214	289,412
Accounts payable and other accrued expenses	470,778	(11,017,317)
Deferred revenue	(7,201,080)	(9,258,531)
Net cash used in operating activities	(2,051,018)	(10,549,716)
Investment activities		
Purchase of equipment	(50,670)	—
Purchase of investments	(42,429,681)	(22,570,431)
Maturities of investments	30,741,438	28,587,181
Net cash (used in) provided by investing activities	(11,738,913)	6,016,750
Financing activities		
Proceeds from issuance of common stock	299,525	32,701
Net cash provided by financing activities	299,525	32,701
Net decrease in cash and cash equivalents	(13,490,406)	(4,500,265)
Cash and cash equivalents at beginning of period	23,278,353	26,119,249
Cash and cash equivalents at end of period	<u>\$ 9,787,947</u>	<u>\$ 21,618,984</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. Historically, the Company has entered into collaboration agreements to commercialize its product candidates 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. The Company has decided to retain control of certain of its product candidates and is evaluating how best to commercialize such product candidates. If the Company elects to commercialize future products ourselves, it would record sales of such products as revenue.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial reporting and the instructions to Form 10-Q and do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of the Company’s management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results for the interim periods have been included. Operating results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results for the year ending December 31, 2010 or future periods. The accompanying financial statements should be read in conjunction with the Company’s audited financial statements and related notes included in the Company’s Annual Report on Form 10-K filed on March 9, 2010 and available on the website of the United States Securities and Exchange Commission (www.sec.gov). The accompanying balance sheet as of December 31, 2009 has been derived from the audited balance sheet as of that date included in the Form 10-K.

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.

Accrued expenses, including contracted costs—Significant management judgments and estimates must be made and used in connection with accrued expenses, including those related to contract costs, such as costs associated with clinical trials. Specifically, the Company must make estimates of costs incurred to date but not yet paid for or not yet invoiced in relation to contracted, external costs. The Company analyzes the progress of product development, clinical trial and related activities, invoices received, amounts paid, and budgeted costs when evaluating the adequacy of the accrued liability for these related costs. Certain accrued contract costs, estimated to be payable after more than twelve months, are classified as long term liabilities rather than as accrued expenses.

The Company believes that its current assumptions and other considerations used to estimate accrued expenses for the period are appropriate. However, determining the date on which certain contract services commence, the extent of services performed on or before a given date and the cost of such, paid and unpaid, involves subjective judgments and estimates and often must be based upon information provided by third parties. In the event that management does not identify certain contract costs which have begun to be incurred or under- or over-estimates the extent of services performed or the costs of such services, management adjusts costs during the period in which the information becomes available.

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. 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 three months. The September 2007 amendment included a \$10.0 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 \$7.2 and \$9.3 million of licensing revenue from the amortization of the AstraZeneca licensing fee and September 2007 amendment for the nine months ended September 30, 2010 and 2009, respectively, and recognized \$3.1 million for the three months ended September 30, 2009. The revenue was fully amortized as of June 30, 2010.

In reviewing the terms of the executed agreement and considering the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 605-25, Multiple Element Arrangements, we concluded that our involvement in the Global Product Team and the Joint Steering Committee during the development phase of the collaboration represents a substantive performance obligation or deliverable as defined in FASB ASC 605-25. Following U.S. Food and Drug Administration, or FDA, approval of the new drug application, or NDA, we believe that participation on the Global Product Team and the Joint Steering Committee represents a right and a governance role only, rather than a substantive performance obligation. Given that the participation on the Global Product Team and Joint Steering Committee during the development phase do not meet criteria in FASB ASC 605-25 for separation (e.g., no separate identifiable fair value), we concluded that this deliverable would be combined with the upfront payments received and treated as a single unit-of-accounting for purposes of revenue recognition. We recognize the combined unit of accounting over the estimated period of obligation, involvement and responsibility – through the estimated NDA approval / transfer date, which coincides with our substantive obligation to serve on the Global Product Team and the Joint Steering Committee. Our substantive obligations were completed in June 2010 when the NDA was transferred to AstraZeneca.

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. During the second quarter of 2010, we received a \$20.0 million milestone payment from AstraZeneca and during the third quarter of 2009, we received a \$10.0 million milestone payment from AstraZeneca. These payments were recorded as licensing revenue in the accompanying statements of operations.

Treximet and VIMOVO royalty revenue is recognized when earned, as will any other future royalty revenues with respect to the manufacture, sale or use of the Company's products or technology. For Treximet and VIMOVO 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 nine months ended September 30, 2010, the Company recognized \$3.9 million and \$11.8 million for Treximet, respectively, and \$0.5 million and \$0.5 million for VIMOVO, respectively, of royalty revenue which is included within licensing revenue in the accompanying statements of operations. During the three and nine months ended September 30, 2009, the Company recognized \$1.2 million and \$3.2 million, respectively, of royalty revenue for Treximet which is included within the licensing revenue in the accompanying statements of operations. During the three and nine months ended September 30, 2009, the Company recognized no royalty revenue for VIMOVO.

With regard to development revenue, 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 payments as revenue in accordance with the agreements because we act as principal in the transaction. 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. 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 nine months ended September 30, 2010 and 2009 were the following:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Development Revenue	\$ 3,990	\$ -	\$ 97,179	\$ 5,536,053
Direct Costs	\$ 7,092	\$ -	\$ 55,031	\$ 3,903,408

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. 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. The Company recorded income on cash investments of \$65,700 and \$84,400 for the three months ended September 30, 2010 and 2009, respectively, including bond amortization and accretion for bonds purchased at a premium or discount. For the nine months ended September 30, 2010 and 2009, the Company recorded \$128,000 and \$472,100 in income on investments, respectively. As of September 30, 2010 and 2009, there were no investments in a significant unrealized loss position.

Short-term investments consisted of the following as of September 30, 2010:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Short-term investments:				
U.S. treasury and agency securities	\$ 11,916,190	\$ 9,726	\$ (88)	\$ 11,925,828
Corporate notes	22,821,633	38,718	(280)	22,860,071
Total short-term investments	<u>\$ 34,737,823</u>	<u>\$ 48,444</u>	<u>\$ (368)</u>	<u>\$ 34,785,899</u>

Short-term investments consisted of the following as of December 31, 2009:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Short-term investments:				
U.S. treasury and agency securities	\$ 20,679,695	\$ 13,065	\$ -	\$ 20,692,760
Corporate notes	2,740,487	1,623	(2,770)	2,739,340
Total short-term investments	<u>\$ 23,420,182</u>	<u>\$ 14,688</u>	<u>\$ (2,770)</u>	<u>\$ 23,432,100</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 \$42,000 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

Under FASB ASC 820, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e. "the exit price") in an orderly transaction between market participants at the measurement date. In determining fair value, we use various valuation approaches, including quoted market prices and discounted cash flows. FASB ASC 820 also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from independent sources. Unobservable inputs are inputs that reflect a company's judgment concerning the assumptions that market participants would use in pricing the asset or liability developed based on the best information available under the circumstances. The fair value hierarchy is broken down into three levels based on the reliability of inputs as follows:

- Level 1 - Valuations based on quoted prices in active markets for *identical* instruments that the Company is able to access. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.
- Level 2 - Valuations based on quoted prices in active markets for instruments that are *similar*, or quoted prices in markets that are not active for identical or similar instruments, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
- Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The financial assets for which we perform recurring remeasurements are cash equivalents and short-term investments. As of September 30, 2010, financial assets utilizing Level 1 inputs included cash equivalents and short-term investments. Financial assets utilizing Level 2 inputs included short-term investments in government agency obligations and corporate fixed income securities.

Fair value is a market-based measure considered from the perspective of a market participant who holds the asset or owes the liability rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. We use prices and inputs that are current as of the measurement date, including during periods of market dislocation, such as the recent illiquidity in the auction rate securities market. In periods of market dislocation, the observability of prices and inputs may be reduced for many instruments. This condition has caused, and in the future may cause, our financial instruments to be reclassified from Level 1 to Level 2 or from Level 2 to Level 3.

FASB ASC 820 requires that the valuation techniques used by us are consistent with at least one of the three possible approaches: the market approach, the income approach, and/or the cost approach. Our Level 1 valuations are based on the market approach and consist primarily of quoted prices for identical items on active securities exchanges. Our Level 2 valuations also use the market approach and are based on significant other observable inputs such as quoted prices for financial instruments not traded on a daily basis. We did not rely on Level 3 input for valuation of our securities at September 30, 2010.

The following table sets forth our financial instruments carried at fair value as of September 30, 2010 and December 31, 2009:

	Financial Instruments Carried at Fair Value	
	September 30, 2010	December 31, 2009
Assets:		
Cash and cash equivalents	\$ 9,787,947	\$ 23,278,353
Short-term investments	34,785,899	23,432,100
Total cash and investments	<u>\$ 44,573,846</u>	<u>\$ 46,710,453</u>

The following table sets forth our financial instruments carried at fair value within the FASB ASC 820 hierarchy and using the lowest level of input as of September 30, 2010:

	Financial Instruments Carried at Fair Value			
	Quoted prices in active Markets for identical items (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Cash and cash equivalents	\$ 9,787,947	\$ —	\$ —	\$ 9,787,947
Short-term investments	—	34,785,899	—	34,785,899
Total cash and investments	<u>\$ 9,787,947</u>	<u>\$ 34,785,899</u>	<u>\$ —</u>	<u>\$ 44,573,846</u>

Realized gains and losses from sales of our investments are included in “Interest and other income” 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— Accumulated other comprehensive income is comprised of unrealized gains and losses on marketable securities and is disclosed as a component of stockholders’ equity. The Company had \$48,076 of unrealized gains on its investments at September 30, 2010 and \$11,918 of unrealized gains at December 31, 2009.

Comprehensive income (loss) consists of the following components for the three and nine months ended September 30, 2010 and 2009:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Net income (loss)	\$ (8,586,293)	\$ 6,657,586	\$ 4,647,623	\$ (1,076,094)
Change in unrealized gain/(loss) on marketable securities	58,472	(23,187)	36,158	(172,487)
Total comprehensive income (loss)	<u>\$ (8,527,821)</u>	<u>\$ 6,634,399</u>	<u>\$ 4,683,781</u>	<u>\$ (1,248,581)</u>

Stock-based Compensation—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.

A summary of all stock awards as of September 30, 2010, and changes during the nine months ended September 30, 2010, is as follows:

Stock Awards (000s)	Time-Based Stock Awards	Performance- Based Awards	Restricted Stock and Restricted Stock Units	Total Stock Awards
Awards outstanding at 12/31/2009	3,836	257	114	4,207
2010 grants	532	—	98	630
2010 exercises	(61)	—	(11)	(72)
2010 forfeitures	(166)	(32)	—	(197)
Awards outstanding at 9/30/2010	4,141	225	201	4,568

Our statements of operations for the three and nine months ended September 30, 2010 and September 30, 2009 includes the following stock-based compensation expense:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Research and development	\$ 213,676	\$ 488,338	\$ 815,436	\$ 1,337,967
General and administrative	693,605	717,192	1,992,236	2,543,768
Operating expense	907,281	1,205,530	2,807,672	3,881,735
Tax benefit	-	-	-	-
Net expense	\$ 907,281	\$ 1,205,530	\$ 2,807,672	\$ 3,881,735

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 1.8 years was \$4.5 million at September 30, 2010 and over an estimated weighted-average amortization period of 1.7 years was \$5.2 million at September 30, 2009.

Stock Plans

On November 20, 1996, the Company established a Stock Option Plan (the “Option Plan”) and authorized the issuance of options for up to 1,605,310 shares of common stock to attract and retain quality employees and to allow such employees to participate in the growth of the Company. In June 2000, the stockholders approved the POZEN Inc. 2000 Equity Compensation Plan (the “2000 Plan”). The 2000 Plan became effective upon the completion of the Company’s initial public offering in October 2000, after which time no further grants were made under the Option Plan. At adoption, the 2000 Plan authorized up to 3,000,000 shares of common stock for issuance under the terms of the 2000 Plan. In May 2004, the stockholders approved an amendment to and restatement of the 2000 Plan. The amendment to the 2000 Plan provided for an increase in the number of shares of common stock authorized for issuance under the 2000 Plan, from 3,000,000 to 5,500,000, or an increase of 2,500,000 shares. In addition, the amendment to the 2000 Plan limited the number of shares that may be issued pursuant to grants other than options under the 2000 Plan to 2,000,000 shares and made certain other clarifying changes. In June 2007, the stockholders approved the amendment and restatement of the 2000 Plan to, among other things, increase the number of shares authorized for issuance under the 2000 Plan from 5,500,000 to 6,500,000 shares and continue the various performance criteria for use in establishing specific vesting targets for certain awards under the 2000 Plan so as to qualify the compensation attributable to any such awards as performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended and the promulgated thereunder, the Code.

In June 2010, our stockholders approved the POZEN Inc. 2010 Equity Compensation Plan, or the 2010 Plan. The 2010 Plan is a successor incentive compensation plan to the 2000 Plan and provides the Company with an omnibus plan to design and structure grants of stock options, stock units, stock awards, stock appreciation rights and other stock-based awards for selected individuals in our employ or service. The 2000 Plan was merged with and into the 2010 Plan and all grants outstanding under the 2000 Plan were issued or transferred under the 2010 Plan. No further grants will be made under the 2000 Plan.

The 2010 Plan provides for grants of incentive stock options, nonqualified stock options, stock awards, and other stock-based awards, such as restricted stock units and stock appreciation rights (“SARs”), to employees, non-employee directors, and consultants and advisors who perform services for us and our subsidiaries. The 2010 Plan authorizes up to 7,452,327 shares of common stock for issuance, which includes 2,000,000 shares of our common stock which are in excess of the number of shares previously reserved under the 2000 Plan. The maximum number of shares for which any individual may receive grants in any calendar year is 1,000,000 shares. The Compensation Committee of the Board of Directors, which administers the 2010 Plan, will determine the terms and conditions of options, including when they become exercisable. Neither our Board nor the Committee can amend the 2010 Plan or options previously granted under the Plan to permit a repricing of options or SARs, without prior stockholder approval. If options granted under the 2010 Plan expire or are terminated for any reason without being exercised, or if stock awards, performance units, or other stock-based awards are forfeited or otherwise terminate, the shares of common stock underlying the grants will again be available for awards granted under the 2010 Plan.

Time-Based Stock 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 nine months ended September 30, 2010 and 2009 are shown in the following table:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Expected volatility	72.2 %	72.5 %	70.9 – 74.3 %	72.5 – 77.8 %
Expected dividends	0 %	0 %	0 %	0 %
Expected terms	6.0 Years	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	1.71 %	2.7 %	1.71 – 2.7 %	2.2 – 2.95 %

For the three and nine months ended September 30, 2010 and 2009, 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 nine months ended September 30, 2010 and 2009, 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 nine months ended September 30, 2010 and 2009 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 September 30, 2010, and changes during the nine months ended September 30, 2010, 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, 2010	3,836	\$ 9.29	5.0	\$ 662
Granted	472	6.50		
Exercised	(41)	4.16		
Forfeited or expired	(24)	8.34		
Outstanding at March 31, 2010	4,243	\$ 9.07	5.2	\$ 6,271
Exercisable at March 31, 2010	2,978	\$ 9.33	4.4	\$ 4,608
Granted	56	7.51		
Exercised	(21)	6.32		
Forfeited or expired	(60)	9.36		
Outstanding at June 30, 2010	4,218	\$ 9.06	5.1	\$ 1,700
Exercisable at June 30, 2010	2,953	\$ 9.40	4.2	\$ 1,232
Granted	4	6.91		
Exercised	-	-		
Forfeited or expired	(81)	10.31		
Outstanding at September 30, 2010	4,141	\$ 9.03	4.9	\$ 1,796
Exercisable at September 30, 2010	2,923	\$ 9.39	4.0	\$ 1,309

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

Time-Based Stock Awards	Underlying Shares (000s)	Weighted- Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
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	<u>4,096</u>	<u>\$ 9.49</u>	<u>5.5</u>	<u>\$ 816</u>
Exercisable at March 31, 2009	<u>2,839</u>	<u>\$ 8.93</u>	<u>4.9</u>	<u>\$ 607</u>
Granted	48	7.75		
Exercised	(1)	2.02		
Forfeited or expired	(188)	9.46		
Outstanding at June 30, 2009	<u>3,955</u>	<u>\$ 9.39</u>	<u>5.4</u>	<u>\$ 2,926</u>
Exercisable at June 30, 2009	<u>2,742</u>	<u>\$ 9.03</u>	<u>4.8</u>	<u>\$ 2,018</u>
Granted	100	6.65		
Exercised	-	-		
Forfeited or expired	(34)	13.36		
Outstanding at September 30, 2009	<u>4,021</u>	<u>\$ 9.29</u>	<u>5.3</u>	<u>\$ 2,362</u>
Exercisable at September 30, 2009	<u>2,773</u>	<u>\$ 9.08</u>	<u>4.5</u>	<u>\$ 1,562</u>

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 September 30, 2010 and 2009 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 nine month period ended September 30, 2010 was \$0.2 million. The total intrinsic value of stock options exercised during the nine month period ended September 30, 2009 was \$0.2 million. No options were exercised during the three months ended September 30, 2010 and September 30, 2009.

Restricted Stock and Restricted Stock Units

For the three and nine months ended September 30, 2010, the Company recognized \$60,000 and \$151,000, respectively, in compensation expense related to restricted stock units. For the three and nine months ended September 30, 2009, the Company recognized \$26,000 and \$104,000, respectively, in compensation expense related to restricted stock units. As of September 30, 2010, there was an aggregate \$0.6 million of unrecognized compensation expense related to unvested restricted stock units. Of the aggregate amount, \$11,000 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 \$490,000 unrecognized compensation expense related to unvested restricted stock units under the March 15, 2010 award of 87,180 restricted stock units with a grant-date per-share fair value of \$6.50 and \$56,000 unrecognized compensation expense related to unvested restricted stock units under the 2010 award of 11,000 restricted stock units with a grant-date per-share fair value of \$7.29. During the third quarter of 2010, no restricted stock units were forfeited. As of September 30, 2010, there was no unrecognized compensation expense related to the May 2004 award of 98,135 restricted stock units. There were 101,667 unvested restricted stock units outstanding at September 30, 2010.

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 vested during September 2009, upon the acceptance by the FDA of the NDA for VIMOVO™ (enteric-coated naproxen / immediate release esomeprazole magnesium, formerly referred to as PN 400). The remaining seventy-five percent (75%) of the options granted vested on April 30, 2010 upon the Company’s receipt of an action letter from the FDA indicating approval of the NDA for VIMOVO. The options have a ten-year term. The May 6, 2008 and September 10, 2008 option grants have exercise prices of \$14.45 per share and \$10.82 per share, respectively, which was equal to the NASDAQ reported market closing price of the Company’s common stock on the date of grant. The weighted average grant-date fair value of these performance-based options was \$9.66 per share and \$7.08 per share for the May 6, 2008 and September 10, 2008 option grants, respectively. The fair value of the performance-based options granted under the PN incentive program was estimated as of the grant date using the Black-Scholes option valuation model without consideration of the performance measures. 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 vested during September 2009, upon acceptance by the FDA of the NDA for VIMOVO. The Company recognized compensation costs for these awards over the expected service period. Total expense related to these awards for the nine months ended September 30, 2010 was \$0.5 million, while total expense for the three and nine months ended September 30, 2009 was \$0.3 million and \$0.9 million, respectively. There was no expense related to these awards for the three months ended September 30, 2010.

As of September 30, 2010, there was no unrecognized compensation expense related to performance-based awards granted under the PN incentive program. There were 31,650 awards forfeited during the nine months ended September 30, 2010. No performance-based awards were exercised during the nine months ended September 30, 2010. At September 30, 2010, the performance-based options had no intrinsic value and a remaining contractual life of 7.6 years.

Net Income (Loss) Per Share—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 three and nine months ended September 30, 2010 and 2009. During the three and nine months ended September 30, 2010 and 2009, 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, if the effect would have been antidilutive. 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 September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Basic weighted average shares outstanding	29,897,602	29,825,365	29,871,407	29,809,799
Effect of dilutive employee and director awards	-	198,622	357,818	-
Diluted weighted-average shares outstanding and assumed conversions	<u>29,897,602</u>	<u>30,023,987</u>	<u>30,229,225</u>	<u>29,809,799</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 modified 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, the lease term was extended for an additional 5 years and 7 months, terminating on September 30, 2015. The modification 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, the Company’s noncancellable future minimum lease payments for operating leases increased by approximately \$2.7 million over the lease term. The Company is recognizing rent expense on a straight-line basis over the term of the lease which resulted in a deferred rent balance of \$272,100 at September 30, 2010.

New Accounting Pronouncements— The Accounting Standards Codification (“ASC”) includes guidance in ASC 605-25 related to the allocation of arrangement consideration to these multiple elements for purposes of revenue recognition when delivery of separate units of account occurs in different reporting periods. This guidance recently was modified by the final consensus reached on EITF 08-1 that was codified by ASU 2009-13. This change increases the likelihood that deliverables within an arrangement will be treated as separate units of accounting, ultimately leading to less revenue deferral for many arrangements. The change also modifies the manner in which transaction consideration is allocated to separately identified deliverables. This guidance is effective prospectively for fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The Company does not believe ASU 2009-13 will have a material impact on its financial statements.

At the March 2010 meeting, the FASB ratified Emerging Issues Task Force, or EITF, Issue No. 08-9, “Milestone Method of Revenue Recognition” (Issue 08-9). The Accounting Standards Update resulting from Issue 08-9 amends ASC 605-28. The Task Force concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. This guidance is effective prospectively for fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The Company does not believe ASC 605-28 will have a material impact on the Company’s financial statements.

Contingencies—The Company and GSK have received Paragraph IV Notice Letters from Par Pharmaceuticals Inc., or Par, Alphapharm Pty Ltd., or Alphapharm, Teva Pharmaceuticals USA, or Teva, and Dr. Reddy's Laboratories, Inc., or Dr. Reddy's, informing us that each company (or in the case of Alphapharm, its designated agent in the United States, Mylan Pharmaceuticals, or Mylan) had filed an Abbreviated New Drug Application, or ANDA, with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm, Teva, and Dr. Reddy's 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, Teva, and Dr. Reddy's. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009, Teva, on April 14, 2009, and Dr. Reddy's on August 21, 2009, all in the United States District Court for the Eastern District of Texas. All four actions were 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, Teva, and Dr. Reddy's resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's, Teva's, and Dr. Reddy'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.

On April 14, 2010, we announced that we had entered into a Settlement Agreement with Teva. Under the terms of the Settlement Agreement, Teva was dismissed without prejudice from the consolidated litigation currently pending, but agreed to be bound by the outcome of such litigation or any resulting settlements with third parties. In compliance with U.S. law, the Settlement Agreement was submitted to the U.S. Federal Trade Commission and the Department of Justice for review. The settlement did not end the ongoing litigation against the other three defendants. The case was tried before Judge Leonard Davis in the Eastern District of Texas on October 12-15, 2010. A decision is expected by the end of the year.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the class action lawsuit described above if appealed or a patent infringement lawsuit against Par, Alphapharm, and Dr. Reddy's. We have incurred \$12.6 million, cumulatively, in legal fees through the end of third quarter 2010. Furthermore, we will have to incur additional 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.

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, 2009, as filed on March 9, 2010.

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,” “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 transforming medicine that can transform lives. We operate a business model that focuses on the following:

- developing innovative products that address unmet medical needs in the marketplace;
- obtaining patents for those innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas by working with strategic outsource partners;
- developing a regulatory pathway with the appropriate agency; and
- determining how best to commercialize our products.

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. We have decided to retain ownership of our PA product candidates which contain a combination of a proton pump inhibitor and enteric coated aspirin in a single tablet and have hired a chief commercial officer who is responsible for developing the commercialization strategy for these products and conducting all the required pre-commercialization activities. In the United States, we intend to lead all commercialization efforts, which may or may not include co-promotion partners. Outside the United States, we intend to secure relationships with one or more strong commercial partners with relevant expertise to commercialize our future products globally. As we commercialize in the United States, we intend to continue utilizing our outsource model to develop a 21st century commercial organization, which would include hiring an internal commercial team to develop strategy and to direct strategic outsource partners in the implementation of such strategy.

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 assist us to successfully commercialize the products ourselves.

We have developed Treximet[®] 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 U.S. Food and Drug Administration, or 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 new drug application, or 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 have developed VIMOVO™ with AstraZeneca AB, or AstraZeneca. VIMOVO™ (formerly referred to as PN 400) is the brand name for a proprietary fixed dose combination of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. On April 30, 2010, the FDA approved VIMOVO™ for the relief of the signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS) and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca to co-develop and commercialize VIMOVO™, 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 of VIMOVO 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 FDA has decided to reconsider this issue and has announced that a meeting of its Gastrointestinal Advisory Board (Advisory Board) will be held on November 4, 2010, which will discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. If the Advisory Board recommends and the FDA accepts a recommendation that endoscopic gastric ulcers are no longer an acceptable endpoint, the impact on marketed products like VIMOVO, which were approved based on the results of pivotal trials using these endpoints, is unclear.

Based upon the FDA's earlier confirmation that endoscopic gastric ulcers were an acceptable primary endpoint, the two pivotal trials were completed and met their primary endpoints. In both trials, patients taking VIMOVO experienced significantly ($p < 0.001$) fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period with gastric ulcer incidence rates of 4.1 and 7.1% for VIMOVO and 23.1 and 24.3% for enteric-coated naproxen in studies 301 and 302, respectively. Data combined from both studies showed that in patients taking low dose aspirin ($n = 201$), the incidence of gastric ulcers in the VIMOVO arm was 3.0% compared to 28.4% for those taking EC naproxen ($p < 0.001$) and patients taking VIMOVO who were not taking low dose aspirin ($n = 653$) experienced a 6.4% incidence of gastric ulcers compared to 22.2% among those taking EC naproxen ($p < 0.001$). Additional analyses examined the incidence of endoscopically confirmed duodenal ulcers among patients taking VIMOVO. In study 301, patients taking VIMOVO experienced a 0.5% incidence of duodenal ulcers compared to 5.1% taking EC naproxen ($p = 0.003$), and in study 302, patients taking VIMOVO experienced a 1.0% incidence of duodenal ulcers, compared to 5.7% incidence among patients taking EC naproxen ($p = 0.007$). The most frequently reported adverse events among patients taking both VIMOVO and enteric coated naproxen in the pivotal trials were GI disorders, including dyspepsia, erosive esophagitis and erosive duodenitis. In addition to the Phase 3 pivotal trials, we have completed a long-term, open label safety study. In 2008 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 VIMOVO was submitted on June 30, 2009 and was accepted for filing by FDA in August 2009. POZEN received a \$10.0 million milestone payment from AstraZeneca in September 2009 for the achievement of such milestone. In October 2009, AstraZeneca submitted a Marketing Authorization Application, or MAA, for VIMOVO in the European Union, or EU, via the Decentralized Procedure, or DCP, and has filed or plans to file for approval in a number of other countries which are not covered by the DCP. On October 11 2010, we announced with AstraZeneca that VIMOVO had received positive agreement for approval in 23 countries across the EU following all 22 Concerned Member States agreeing with the assessment of the Netherlands Health Authority (MEB), acting as the Reference Member State for the DCP. The Member States are now pursuing pricing and reimbursement and national approvals.

Our PA product candidates, containing a combination of a PPI and aspirin, are 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 for PA32540 for the secondary prevention of cardiovascular disease in patients at risk for gastric ulcers. 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. The FDA has decided to reconsider this issue and has announced that a meeting of its Advisory Board will be held on November 4, 2010, which will discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. If the Advisory Board recommends and the FDA accepts a recommendation that endoscopic gastric ulcers are no longer an acceptable endpoint, it is possible that the FDA may not continue to accept the principles set forth in the SPA for PA32540, and we may be required to redesign our pivotal Phase 3 trials for PA32540 and conduct additional clinical trials using other endpoints, which will require additional expense and delay NDA approval, or we may be required to commit to conduct additional post-approval studies if the product candidate is approved. Based upon the FDA's earlier confirmation that endoscopic gastric ulcers were an acceptable primary endpoint, in October 2009, we began two pivotal Phase 3 and one long-term safety study for PA32540 for the cardiovascular indication. The primary endpoint of the pivotal studies, which will include approximately 500 subjects per study, is the cumulative incidence of gastric ulcers over the six-month treatment period. The duration of the long-term safety study will be one year and will include approximately 400 subjects. Enrollment of subjects into the long-term safety study has been completed and, based upon the current rate of enrollment in the two pivotal Phase 3 studies, we anticipate filing an NDA in 2012.

We are aware of publications that contain data regarding a possible drug-drug interaction between clopidogrel (Plavix[®]), a widely prescribed anti-platelet agent, and certain enteric-coated proton pump inhibitors when platelet aggregation is assessed in ex-vivo tests. On November 11, 2009, the FDA issued new drug safety information to healthcare professionals through a publication entitled "Information for Healthcare Professionals: Update to the labeling of Clopidogrel Bisulfate (marketed as Plavix) to alert healthcare professions about a drug interaction with enteric-coated omeprazole (marketed as Prilosec[®] and Prilosec[®] OTC)." The publication stated that the effect of clopidogrel on platelets was reduced by as much as 47% in people receiving clopidogrel and omeprazole together. The FDA's action was based, in part, on two crossover clinical studies of 72 healthy subjects administered Plavix alone and with 80 mg EC omeprazole, either together or administered 12 hours apart.

To assess whether a similar interaction occurs between clopidogrel and PA32540, which contains immediate release omeprazole, we have completed a Phase 1 drug-drug interaction study to evaluate the ex-vivo platelet aggregation effects of PA32540 plus clopidogrel dosed at the same time or dosed 10 hours apart compared to aspirin 325mg plus clopidogrel dosed together. When PA32540 and clopidogrel were dosed together, data from the study showed a mean 36.7% platelet inhibition compared to a mean 44.0% platelet inhibition when aspirin and clopidogrel were dosed together suggesting a drug-drug interaction based on the study's pre-specified primary analysis. When PA32540 and clopidogrel were dosed 10 hours apart, data from the study indicate no ex-vivo drug-drug interaction based on the study's pre-specified primary analysis. The relevance of these ex vivo platelet data on cardiovascular events is not known. Published data on a clinical interaction between PPIs and Plavix from several randomized controlled trials in cardiovascular patients have reported no clinical impact on cardiovascular outcomes [Bhatt et al (COGENT 1 2009) and O'Donoghue et al (TIMI 38 2009)]. FDA assessment of these data and the implication to a future PA32540 label are not known at this time.

We are also continuing to evaluate how best to commercialize the PA product candidates and programs and have hired a chief commercial officer to evaluate the commercial opportunities for these product candidates. We are also conducting both formulation development and early stage clinical studies with other PA product candidates for indications in addition to secondary prevention of cardiovascular events. We are evaluating the regulatory requirements to obtain an indication for PA for the secondary prevention of colorectal neoplasia. In January 2010, we received input from FDA to discuss with respect to the development requirements for a possible indication in colorectal neoplasia. Further discussions are planned. We are also evaluating the possibility of developing another dosage strength of PA for the treatment of osteoarthritis (OA) and similar conditions and have scheduled a meeting with the FDA in December 2010 to obtain input with respect to the regulatory requirements to obtain such an indication. In addition, we continue to evaluate the commercial potential of such a product. We intend to conduct further studies for these and other PA indications when adequate funds are available.

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 September 30, 2010, our accumulated deficit was approximately \$135.4 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 70% of our total operating expenses. For the nine months ended September 30, 2010, our research and development expenses represented approximately 49% 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, conduct pre-commercialization activities, and acquire and/or develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of our 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. and for AstraZeneca to successfully commercialize VIMOVO™ globally. 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;
- Our ability to successfully defend our regulatory market exclusivity and patent rights against generic challenges and to succeed in obtaining extensions of such exclusivity for which we may be eligible;
- Our ability to commercialize our products either by ourselves or with commercial partners in a highly regulated and extremely competitive marketplace; and
- The acquisition and/or in-licensing, and development of our therapeutic product candidates.

We do not currently have internal commercialization or manufacturing capabilities. We have entered into collaborations and may continue to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. We have decided to retain control of our PA product candidates. To that end, we have hired a chief commercial officer to evaluate the commercial opportunities for these product candidates and to develop a worldwide commercial strategy, which will include developing internal commercialization capabilities to enable us to commercialize our products ourselves. Our ability to generate revenue in the near term 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, 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 Approved Products and Product Candidates

There follows a brief discussion of the status of the development of our approved products and our product candidates, as well as the costs relating to our development activities. Our direct research and development expenses were \$11.8 million for the nine months ended September 30, 2009, and \$13.2 million for the nine months ended September 30, 2010. 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 \$4.9 million for the nine months ended September 30, 2009, and \$3.6 million for the nine months ended September 30, 2010. Total compensation for 2009 included a \$1.3 million charge for non-cash compensation for stock option expense and a \$0.8 million charge for non-cash compensation for stock option expense for 2010. Other research and development department costs were \$0.2 million for the nine months ended September 30, 2009, and \$0.3 million for the nine months ended September 30, 2010.

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 Treximet 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, including evaluations in a pediatric population. 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 and Treximet programs of \$111,300 for the nine months ended September 30, 2010. We incurred total direct development costs of \$26.1 million associated with the development of our MT 400 and Treximet programs. We recorded in the nine months ended September 30, 2010, \$11.8 million of Treximet royalty revenue, of which \$3.9 million is in accounts receivable at September 30, 2010. 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 Paragraph IV Notice Letters from Par, Alphapharm, Teva, and Dr. Reddy's informing us that each company (or in the case of Alphapharm, its designated agent in the United States, Mylan Pharmaceuticals, or Mylan) had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm, Teva and Dr. Reddy's 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, Teva, and Dr. Reddy's. Accordingly, we filed suit against Par on November 14, 2008; Alphapharm and Mylan on January 2, 2009, Teva on April 14, 2009, and Dr. Reddy's on August 21, 2009, all in the United States District Court for the Eastern District of Texas. All four actions were 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, Teva and Dr. Reddy's resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's, Teva's and Dr. Reddy'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.

On April 14, 2010, we announced that we had entered into a Settlement Agreement with Teva. Under the terms of the Settlement Agreement, Teva was dismissed without prejudice from the consolidated litigation currently pending, but will agree to be bound by the outcome of such litigation or any resulting settlements with third parties. In compliance with U.S. law, the Settlement Agreement was submitted to the U.S. Federal Trade Commission and the Department of Justice for review. The settlement did not end the ongoing litigation against the other three defendants. The case was tried before Judge Leonard Davis in the Eastern District of Texas on October 12-15, 2010. A decision is expected by the end of the year.

PN/VIMOVO Program

Under our PN program, we 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 developed under the agreement, VIMOVO[®] (formerly PN 400), was approved by the FDA on April 30, 2010 for the relief of the signs and symptoms of osteoarthritis (“OA”), rheumatoid arthritis (“RA”) and ankylosing spondylitis (“AS”) and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

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 an 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 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 VIMOVO 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. On March 2, 2007, we filed an IND with the FDA for VIMOVO and in April 2007, the first Phase 1 study was initiated. We conducted two Phase 3 pivotal trials of VIMOVO 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 FDA has decided to reconsider this issue and has announced that an Advisory Board meeting will be held on November 4, 2010, which will discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. If the Advisory Board recommends and the FDA accepts a recommendation that endoscopic gastric ulcers are no longer an acceptable endpoint the impact on marketed products like VIMOVO, which were approved based on the results of pivotal trials using these endpoints, is unclear.

Based upon the FDA's earlier confirmation that gastric ulcer incidence was an acceptable primary endpoint, the two pivotal trials were completed and met their primary endpoints. In both trials, patients taking VIMOVO experienced significantly ($p<0.001$) fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric-coated naproxen during the six-month treatment period, with gastric ulcer incidence rates of 4.1 and 7.1% for VIMOVO and 23.1 and 24.3% for enteric-coated naproxen in studies 301 and 302, respectively. Data combined from both studies showed that in patients taking low dose aspirin ($n=201$), the incidence of gastric ulcers in the VIMOVO arm was 3.0% compared to 28.4% for those taking EC naproxen ($p<0.001$) and patients taking VIMOVO who were not taking low dose aspirin ($n=653$) experienced a 6.4% incidence of gastric ulcers compared to 22.2% among those taking EC naproxen ($p<0.001$). Additional analyses examined the incidence of endoscopically confirmed duodenal ulcers among patients taking VIMOVO. In study 301, patients taking VIMOVO experienced a 0.5% incidence of duodenal ulcers compared to 5.1% taking EC naproxen ($p=0.003$), and in study 302, patients taking VIMOVO experienced a 1.0% incidence of duodenal ulcers, compared to 5.7% incidence among patients taking EC naproxen ($p=0.007$). The most frequently reported adverse events among patients taking both VIMOVO and enteric coated naproxen in the pivotal trials were GI disorders, including dyspepsia, erosive esophagitis and erosive duodenitis. In addition, we conducted a long-term, open label safety study for VIMOVO. We also conducted additional studies at AstraZeneca's expense. The NDA for VIMOVO was submitted on June 30, 2009 and was accepted for filing in August 2009. We received a \$10.0 million milestone payment from AstraZeneca in September 2009 for the achievement of such milestone. On April 30, 2010, VIMOVO was approved by FDA for the relief of the signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS) and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. We received a \$20.0 million milestone payment from AstraZeneca in May 2010 in connection with such approval. As required by the terms of our agreement with AstraZeneca, we transferred ownership of the NDA and other regulatory filings for VIMOVO to AstraZeneca on June 1, 2010, and AstraZeneca now has responsibility for all ongoing regulatory obligations for the product in the U.S., including post marketing clinical trial requirements, in addition to responsibility for all regulatory obligations outside the U.S.

Additionally, we 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 products outside the U.S., including interactions with regulatory agencies. In October 2009, AstraZeneca submitted a MAA for VIMOVO in the EU via the DCP and has filed and plans to file for approval in a number of other countries which are not covered by the DCP. On October 11, 2010, we announced with AstraZeneca that VIMOVO had received positive agreement for approval in 23 countries across the EU following all 22 Concerned Member States agreeing with the assessment of the Netherlands Health Authority, acting as the Reference Member State for the DCP. The Member States are now pursuing pricing and reimbursement and national approvals. We will receive a \$25.0 million milestone if VIMOVO receives approval (including pricing and reimbursement approval) in a major ex-U.S market.

We incurred direct development costs associated with the development of our PN program of \$123,000 for the nine months ended September 30, 2010, of which, \$97,000 was funded by development revenue from AstraZeneca. We incurred total direct development cost of \$95.8 million associated with the development of our PN program of which \$57.0 million 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 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). Additionally, 75% of subjects treated with the PA32540 tablet showed no gastrointestinal damage at all, where as $< 50\%$ of subjects treated showed no gastrointestinal damage at all 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. 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. The FDA has decided to reconsider this issue and has announced that an Advisory Board meeting will be held on November 4, 2010, which will discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. If the Advisory Board recommends and the FDA accepts a recommendation that endoscopic gastric ulcers are no longer an acceptable endpoint, we may be required to redesign our pivotal Phase 3 trials for PA32540 described below and conduct additional clinical trials using other endpoints, which will require additional expense and delay NDA approval, or we may be required to commit to conduct additional post-approval studies if the product candidate is approved.

Based upon the FDA's earlier confirmation that gastric ulcer incidence was an acceptable primary endpoint, in October 2009, we began two pivotal Phase 3 and one long-term safety study for PA32540 for the cardiovascular indication. The primary endpoint of the pivotal studies, which will include approximately 500 subjects per study, is the cumulative incidence of gastric ulcers over the six-month treatment period. The duration of the long-term safety study will be one year and will include approximately 400 subjects. Enrollment of subjects into the long-term safety study has been completed and, based upon the current rate of enrollment in the two pivotal Phase 3 studies, we anticipate filing an NDA in 2012.

We are aware of publications that contain data regarding a possible drug-drug interaction between clopidogrel (Plavix[®]), a widely prescribed anti-platelet agent, and certain enteric-coated proton pump inhibitors when platelet aggregation is assessed in ex-vivo tests. On November 11, 2009, the FDA issued new drug safety information to healthcare professionals through a publication entitled "Information for Healthcare Professionals: Update to the labeling of Clopidogrel Bisulfate (marketed as Plavix) to alert healthcare professions about a drug interaction with enteric-coated omeprazole (marketed as Prilosec[®] and Prilosec[®] OTC)." The publication stated that the effect of clopidogrel on platelets was reduced by as much as 47% in people receiving clopidogrel and omeprazole together. The FDA's action was based, in part, on two crossover clinical studies of 72 healthy subjects administered Plavix alone and with 80 mg EC omeprazole, either together or administered 12 hours apart.

To assess whether a similar interaction occurs between clopidogrel and PA32540, which contains immediate release omeprazole, we have completed a Phase 1 drug-drug interaction study to evaluate the ex-vivo platelet aggregation effects of PA32540 plus clopidogrel dosed at the same time or dosed 10 hours apart compared to aspirin 325mg plus clopidogrel dosed together. When PA32540 and clopidogrel were dosed together, data from the study showed a mean 36.7% platelet inhibition compared to a mean 44.0% platelet inhibition when aspirin and clopidogrel were dosed together suggesting a drug-drug interaction based on the study's pre-specified primary analysis. When PA32540 and clopidogrel were dosed 10 hours apart, data from the study indicate no ex-vivo drug-drug interaction based on the study's pre-specified primary analysis. The relevance of these ex-vivo platelet data on cardiovascular events is not known. Published data on a clinical interaction between PPIs and Plavix from several randomized controlled trials in cardiovascular patients have reported no clinical impact on cardiovascular outcomes [Bhatt et al (COGENT 1 2009) and O'Donoghue et al (TIMI 38 2009)]. The FDA assessment of these data and the implication to a future PA32540 label are not known at this time.

We are also continuing to evaluate how best to commercialize the PA product candidates and programs and have hired a chief commercial officer to evaluate the commercial opportunities for these product candidates. We are also conducting both formulation development and early stage clinical studies with other PA product candidates for indications in addition to secondary prevention of cardiovascular events. We are evaluating the regulatory requirements to obtain an indication for PA for the secondary prevention of colorectal neoplasia. In January 2010, we received input from FDA to discuss with respect to the development requirements for a possible indication in colorectal neoplasia. Further discussions are planned. We are also evaluating the possibility of developing another dosage strength of PA for the treatment of osteoarthritis (OA) and similar conditions and have scheduled a meeting with the FDA in December 2010 to obtain input with respect to the regulatory requirements to obtain such an indication. In addition, we continue to evaluate the commercial potential of such a product. We intend to conduct further studies for these and other PA indications when adequate funds are available.

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 have decided to retain control of our PA product candidates and currently do not intend to out-license the PA program in the United States. To that end, we have hired a chief commercial officer to evaluate the commercial opportunities for these product candidates. We believe value can be added to the PA product candidates as progress is made through clinical development and, if we ultimately chose to partner the products later in the development program or after approval, either outside the United States or on a global basis, we believe it would be under economic terms more favorable to us.

We are conducting market research on the PA product candidates, 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 \$12.6 million during the nine months ended September 30, 2010. We incurred total direct development cost of \$32.8 million associated with the development of our PA program. 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, we 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 September 30, 2010, we accrued \$3.9 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 (October 2, 2025) 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 Paragraph IV Notice Letters from Par, Alphapharm, Teva and Dr. Reddy's informing us that each company (or in the case of Alphapharm, its designated agent in the United States, Mylan Pharmaceuticals, or Mylan) had filed an ANDA with the FDA seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm, Teva and Dr. Reddy's 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 elected not to exercise its first right to bring infringement suits against Par, Alphapharm, Teva, and Dr. Reddy's. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009, Teva on April 14, 2009, and Dr. Reddy's on August 21, 2009, all in the United States District Court for the Eastern District of Texas. All four actions were 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 Teva, and Dr. Reddy's resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's Teva's, and Dr. Reddy'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.

On April 14, 2010, we announced that we had entered into a Settlement Agreement with Teva. Under the terms of the Settlement Agreement, Teva was dismissed without prejudice from the consolidated litigation currently pending, but will agree to be bound by the outcome of such litigation or any resulting settlements with third parties. In compliance with U.S. law, the Settlement Agreement was submitted to the U.S. Federal Trade Commission and the Department of Justice for review. The settlement did not end the ongoing litigation against the other three defendants. The case was tried before Judge Leonard Davis in the Eastern District of Texas on October 12-15, 2010. A decision is expected by the end of the year.

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). 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 VIMOVO (formerly 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. In May 2010, we received a \$20 million payment for the NDA approval of VIMOVO. We will receive an additional \$25.0 million milestone if VIMOVO receives approval (including pricing and reimbursement approval) in a major ex-U.S. market and up to \$260.0 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved.

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 VIMOVO.

We retained 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.

On September 30, 2010, we accrued \$0.5 million of VIMOVO royalty revenue. 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 September 30, 2010 compared to the three months ended September 30, 2009

Net income (loss) per share: Net loss attributable to common stockholders for the three months ended September 30, 2010 was \$(8.6) million or \$(0.29) per share, on a diluted basis, as compared to a net income of \$6.7 million, or \$0.22 per share, on a basic and diluted basis, for the three months ended September 30, 2009. The net income (loss) for the three months ended September 30, 2010 included a \$(0.9) million or \$(0.03) per share charge for non-cash stock-based compensation expense as compared to \$1.2 million or \$0.04 per share for the same period of 2009.

Revenue: We recognized total revenue of \$4.3 million for the three months ended September 30, 2010 as compared to total revenue of \$14.3 million for the three months ended September 30, 2009. The decrease in revenue was primarily due to the September 2009 receipt of a \$10.0 million milestone payment received from AstraZeneca for the FDA's acceptance of the NDA for VIMOVO. Licensing revenue for the three months ended September 30, 2010 was \$4.3 million compared to \$14.3 million for 2009. Development revenue was \$4,000 for the three months ended September 30, 2010 and there was no development revenue for the three months ended September 30, 2009. 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. As of September 30, 2010, all deferred revenue has been recognized. 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 \$7,100 for the three months ended September 30, 2010. There were no costs associated with the billed direct costs for the three months ended September 30, 2009. All costs associated with our development revenues are included in research and development expenses in our Statements of Operations. Our 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 increased by \$1.7 million to \$6.0 million for the three months ended September 30, 2010, as compared to the same period of 2009. The increase was due primarily to an increase in direct development costs for our PA program. Direct development costs for our PA program increased by \$2.2 million to \$4.7 million, primarily due to clinical trial activities and other product development activities during the three months ended September 30, 2010, as compared to the same period of 2009. Direct development costs for the exploratory programs and other departmental expenses decreased by \$0.5 million to \$1.3 million, primarily due to decreased personnel costs, as compared to the same period of 2009. 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 \$3.6 million to \$7.0 million for the three months ended September 30, 2010, as compared to the same period of 2009. The increase was due primarily to increased legal costs for patent defense and marketing research expenses, as compared to 2009. 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 on cash investments was \$65,700 and \$84,400 for the three months ended September 30, 2010 and 2009, respectively.

Nine months ended September 30, 2010 compared to the nine months ended September 30, 2009

Net income (loss) per share: Net income attributable to common stockholders for the nine months ended September 30, 2010 was \$4.6 million or \$0.15 per share, on a diluted basis, as compared to a net loss of \$(1.1) million, or \$(0.04) per share, on a basic and diluted basis, for the nine months ended September 30, 2009. The net income (loss) for the nine months ended September 30, 2010 included a \$2.8 million or \$0.09 per share charge for non-cash stock-based compensation expense as compared to \$(3.9) million or \$(0.13) per share for the same period of 2009.

Revenue: We recognized total revenue of \$39.5 million for the nine months ended September 30, 2010 as compared to total revenue of \$28.0 million for the nine months ended September 30, 2009. The increase in revenue was primarily due to the receipt of a \$20.0 million milestone payment from AstraZeneca for the FDA approval of VIMOVO in the second quarter of 2010 as compared to a \$10.0 million milestone payment for the FDA acceptance of the NDA in the third quarter of 2009. For the nine months ended September 30, 2010, there was a \$9.0 million increase in Treximet royalty revenue along with first time VIMOVO royalty revenue, partially offset by a decrease of \$5.4 million in development revenue, compared to 2009. Licensing revenue for the nine months ended September 30, 2010 was \$39.4 million compared to \$22.4 million for 2009. Development revenue was \$97,000 for the nine months ended September 30, 2010 compared to \$5.5 million for 2009. 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. All deferred revenue has been recognized as of September 30, 2010. 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 \$55,000 and \$3.9 million for the nine months ended September 30, 2010 and 2009, respectively. All costs associated with our development revenues are included in research and development expenses in our Statements of Operations. Our 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 increased by \$230,000 to \$17.1 million for the nine months ended September 30, 2010, as compared to the same period of 2009. The increase was due primarily to an increase in direct development costs for our PA program. Direct development costs for our PA program increased by \$9.0 million to \$12.6 million, while the PN program decreased by \$7.2 million to \$0.1 million, primarily due to increases or decreases in the clinical trial activities and other product development activities during the nine months ended September 30, 2010, as compared to the same period of 2009. Direct development costs for the exploratory programs decreased by \$0.4 million to \$0.6 million, as compared to the same period of 2009. Other direct development costs and departmental expenses decreased by \$1.2 million to \$3.8 million primarily due to decreased personnel costs, as compared to the same period of 2009. 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 \$5.2 million to \$17.9 million for the nine months ended September 30, 2010, as compared to the same period of 2009. The increase was due primarily to increased legal costs for patent defense, as compared to the same period of 2009. 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 on cash investments was \$0.1 million and \$0.5 million for the nine months ended September 30, 2010 and 2009, respectively.

Income Taxes

We estimate an annual effective tax rate of 0% for the year ended December 31, 2010. Our effective tax rate was 0% for the nine month period ended September 30, 2010. 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 FASB ASC 740. 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 2007. However, the loss carryforwards generated prior to 2007 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 nine months ended September 30, 2010 and 2009, there were no such interest and penalties.

Liquidity and Capital Resources

At September 30, 2010, cash and cash equivalents, along with short-term investments, totaled \$44.6 million, a decrease of \$2.1 million compared to December 31, 2009. The decrease in cash was primarily due to the operating expenses for the period offset in part by a \$20.0 million milestone payment received from AstraZeneca in the second quarter along with cash receipts for 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 \$29.0 million in operating cash during the nine months ended September 30, 2010 pursuant to the terms of our collaboration agreements with AstraZeneca and GSK. In addition, our balance sheet included a \$4.5 million accounts receivable for royalties under the GSK agreement and development work performed under the AstraZeneca agreement. Cash received from financing activities during the period totaled \$0.3 million reflecting net proceeds from the exercise of stock options.

Based upon the indirect method of presenting cash flow, cash used in operating activities totaled \$2.1 million and \$10.5 million for the nine months ended September 30, 2010 and September 30, 2009, respectively. Net cash used in investing activities during the nine months ended September 30, 2010 totaled \$11.7 million, and net cash provided by investing activities for the nine months ended September 30, 2009 totaled \$6.0 million reflecting investing activities associated with the purchase and sale of short-term securities. Cash required for our operating activities during 2010 is projected to increase from our 2009 requirements as a result of increased development activities. During the nine months ended September 30, 2010 and September 30, 2009 we recorded non-cash stock-based compensation expense of \$2.8 million and \$3.9 million, respectively, associated with the grant of stock options and restricted stock.

As of September 30, 2010, we had \$9.8 million in cash and cash equivalents and \$34.8 million in short-term investments. Our operating expenses for 2010 and 2011 may exceed the net level of our operating expenses in 2009, should we decide to conduct pre-commercialization activities as a result of our decision to retain control of our PA product candidate. We believe that we will have sufficient cash reserves and cash flow to maintain our planned level of business activities through 2011. However, our anticipated cash flow includes continued receipt of royalty revenue from GSK's sale of Treximet, an assumption of new royalty revenue from AstraZeneca's sale of VIMOVO and an assumption that we will receive a \$25 million milestone if VIMOVO receives approval (including pricing and reimbursement approval) in a major ex-U.S. market. In addition, 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. If our projected expenses increase for our product candidates currently in development, or if we expand our studies for additional indications for our PA product candidate, then, as a result of these or other factors, we may need to raise additional capital.

POZEN submitted three applications for grants under the Qualifying Therapeutic Discovery Project Program with the Internal Revenue Service, or IRS. The Patient Protection and Affordable Care Act (enacted on March 23, 2010) created a program providing \$1 billion of federal subsidy for 50% of certain expenses incurred in 2009 and 2010 for projects of companies with < 250 employees with a reasonable potential to: result in new therapies to treat areas of unmet medical need; prevent, detect, or treat chronic diseases; reduce long-term healthcare costs in the US or significantly advance the goal of curing cancer within a 30-year period. The grants will be competitively awarded with priority given to projects with the greatest potential to create and sustain high-quality, high-paying jobs in the US and to advance US competitiveness in the fields of life, biological and medical sciences. The most any one company can receive is \$5.0 million but depending on the number of eligible projects, the allocation per project may significantly smaller. There is no certainty that submitted applications will receive any grant proceeds; we expect to be notified at the end of October whether the IRS has approved or denied the applications.

Therefore, 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 have registered 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 in pre-commercialization activities for our products for which we retain control and 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; 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.

No change in our internal control over financial reporting occurred during the third 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

The Company and GSK have received Paragraph IV Notice Letters from Par, Alphapharm, Teva and Dr. Reddy's, informing us that each company (or in the case of Alphapharm, its designated agent in the United States, Mylan Pharmaceuticals, or Mylan) had filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or FDA, seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm, Teva and Dr. Reddy's 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, Teva and Dr. Reddy's. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009, Teva on April 14, 2009, and Dr. Reddy's on August 21, 2009, all in the United States District Court for the Eastern District of Texas. All four actions were 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, Teva and Dr. Reddy's resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's, Teva's and Dr. Reddy'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.

On April 14, 2010, we announced that we had entered into a Settlement Agreement with Teva. Under the terms of the Settlement Agreement, Teva was dismissed without prejudice from the consolidated litigation currently pending, but will agree to be bound by the outcome of such litigation or any resulting settlements with third parties. In compliance with U.S. law, the Settlement Agreement was submitted to the U.S. Federal Trade Commission and the Department of Justice for review. . The settlement did not end the ongoing litigation against the other three defendants. The case was tried before Judge Leonard Davis in the Eastern District of Texas on October 12-15, 2010. A decision is expected by the end of the year.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the class action lawsuit described above if appealed or the patent infringement lawsuits against Par, Alphapharm, and Dr. Reddy's. Furthermore, we will continue to incur expenses in connection with these lawsuits if either we or the defendants chose to appeal the outcome of the District Court case, which expenses 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 for products which we license out is dependent upon the commercialization efforts of our partners, including the sales and marketing efforts of GSK relating to Treximet and of AstraZeneca related to VIMOVO.

We have incurred significant losses since our inception. As of September 30, 2010, we had an accumulated deficit of approximately \$135.4 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, sales of VIMOVO by AstraZeneca, or future sales of other product candidates by 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 and VIMOVO, along with the successful development, approval and commercialization of our current product candidates. If we fail to gain timely approval to commercialize our products from the FDA and other foreign regulatory bodies, we will be unable to generate the revenue we will need to build our business. These approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all of the indications for which we seek approval. 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 VIMOVO and the primary endpoint in the ongoing 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. The FDA has decided to reconsider this issue and has announced that an Advisory Board meeting will be held on November 4, 2010, which will discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. If the Advisory Board recommends and the FDA accepts a recommendation that endoscopic gastric ulcers are no longer an acceptable endpoint, we may be required to redesign our pivotal Phase 3 trials for PA32540 described below and conduct additional clinical trials using other endpoints, which will require additional expense and delay NDA approval, or we may be required to commit to conduct additional post-approval studies if the product candidate is approved. The impact on marketed products like VIMOVO, which were approved based on the results of pivotal trials using these endpoints, is unclear. There can be no assurance that the FDA will reach a timely decision with respect to an acceptable endpoint and, if so, the impact of such decision on our products and product candidates.

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, the FDA 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 VIMOVO (formerly referred to as PN 400) and the primary endpoint in our on-going Phase 3 trials for PA32540. 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 FDA has since decided to reconsider this issue and has announced that an Advisory Board meeting will be held on November 4, 2010, which will discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. If the Advisory Board recommends and the FDA accepts a recommendation that endoscopic gastric ulcers are no longer an acceptable endpoint, we may be required to redesign our pivotal Phase 3 trials for PA32540 described below and conduct additional clinical trials using other endpoints, which will require additional expense and delay NDA approval, or we may be required to commit to conduct additional post-approval studies if the product candidate is approved. AstraZeneca may also be required to conduct additional post-approval studies of VIMOVO. 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. Long-term cardiovascular safety studies were not required at for FDA approval of our VIMOVO. However, we cannot guarantee that such studies will not be required in the future if new information about naproxen safety concerns becomes available. 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 and 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, and VIMOVO, which was approved for commercial sale in the U.S. on April 30, 2010, none of our other product candidates are 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 the 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 VIMOVO. 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. Manufacturing facilities may also be subject to state regulations. We, or our third-party manufacturers, may not be able to comply with cGMP regulations or other FDA regulatory requirements, or applicable state regulations, 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 certifications 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.

We and GSK have received Paragraph IV Notice Letters from Par, Alphapharm, Teva and Dr. Reddy's informing us that each company (or in the case of Alphapharm, its designated agent in the United States, Mylan Pharmaceuticals, or Mylan) had filed an Abbreviated New Drug Application, or ANDA, with the FDA, seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm, Teva and Dr. Reddy's 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, Teva and Dr. Reddy's. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009, Teva on April 14, 2009 and Dr. Reddy's on August 21, 2009, all in the United States District Court for the Eastern District of Texas. All four actions were 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, Teva and Dr. Reddy's resulted in the FDA automatically instituting a stay, or bar, of approval of Par's, Alphapharm's, Teva's and Dr. Reddy'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.

On April 14, 2010, we announced that we had entered into a Settlement Agreement with Teva. Under the terms of the Settlement Agreement, Teva was dismissed without prejudice from the consolidated litigation currently pending, but will agree to be bound by the outcome of such litigation or any resulting settlements with third parties. In compliance with U.S. law, the Settlement Agreement was submitted to the U.S. Federal Trade Commission and the Department of Justice for review. The settlement did not end the ongoing litigation against the other three defendants. Discovery in the litigation is in process and the case is currently scheduled for trial in the fourth quarter of 2010. The case was tried before Judge Leonard Davis in the Eastern District of Texas on October 12-15, 2010. A decision is expected by the end of the year.

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, our business and our results of operations.

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.

With respect to the products we have licensed, we depend upon collaborations with third parties to develop these product candidates and we depend substantially upon third parties to commercialize these products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and possibly future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. For those future products we commercialize ourselves, we will continue to depend substantially upon third parties to implement our commercial strategy. 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 in January 2009, 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 VIMOVO. 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 VIMOVO which could have occurred if the FDA determined in January 2009 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 elected not to exercise its first right to bring infringement suits against Par, Alphapharm, Teva, and Dr. Reddy's which have submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets and we filed suit against the four companies in the federal court of the United State District Court for the Eastern District of Texas. The case was tried before Judge Leonard Davis in the Eastern District of Texas on October 12-15, 2010. A decision is expected by the end of the year.

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 may 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 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 may need to enter into a new development and commercialization agreement and may 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, or if we decide to commercialize the products previously partnered by ourselves, 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 sales and distribution capabilities, either internally or through the use of third parties, 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 or our agreement with AstraZeneca to sell VIMOVO globally, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. We have decided to retain control of our PA product candidates. We have hired a chief commercial officer to evaluate the commercial opportunities for our product candidates and develop a worldwide commercial strategy, which will include developing internal commercialization capabilities to enable us to commercialize future products ourselves. We cannot guarantee that, should we elect to develop our own internal 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, including our pivotal trials for PA32540, 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 a possible genotoxicity signal 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 the potential market and 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 proton pump inhibitor products, and its impact on cardiovascular outcomes. If the clinical relevance of the possible interaction is unresolved by the time PA 32540 enters the marketplace, even if the interaction is later proven definitively to have no clinical impact on cardiovascular outcomes, the market potential of the product may be reduced.

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 a genotoxicity signal 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 metacloprimide, one of the components of MT 100, we made the decision to discontinue further development of MT 100 and we 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 VIMOVO and any other PN products that may be developed and 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[®]. The competition for our PA product candidates for which we are conducting studies for secondary prevention of cardiovascular events will come from aspirin itself as well as other products used for secondary prevention. AstraZeneca, with whom we are collaborating in the development of VIMOVO, has publicly announced that it has filed a NDA for a combination product containing aspirin and esomeprazole which, if approved, may enter the market before and compete with our PA32540 product candidates.

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 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.

We and GSK have received Paragraph IV Notice Letters from Par, Alphapharm, Teva and Dr. Reddy's informing us that each company (or in the case of Alphapharm, its designated agent in the United States, Mylan Pharmaceuticals, or Mylan) had filed an Abbreviated New Drug Application, or ANDA, with the FDA, seeking approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets. Par, Alphapharm, Teva and Dr. Reddy's 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, Teva, and Dr. Reddy's. Accordingly, we filed suit against Par on November 14, 2008, Alphapharm and Mylan on January 2, 2009, Teva on April 14, 2009, and Dr. Reddy's on August 21, 2009, all in the United States District Court for the Eastern District of Texas. All four actions were 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, Teva's, and Dr. Reddy'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 in progress.

On April 14, 2010, we announced that we had entered into a Settlement Agreement with Teva. Under the terms of the Settlement Agreement, Teva was dismissed without prejudice from the consolidated litigation currently pending, but will agree to be bound by the outcome of such litigation or any resulting settlements with third parties. In compliance with U.S. law, the Settlement Agreement was submitted to the U.S. Federal Trade Commission and the Department of Justice for review. The settlement did not end the ongoing litigation against the other three defendants. The case was tried before Judge Leonard Davis in the Eastern District of Texas on October 12-15, 2010. A decision is expected by the end of the year.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the patent infringement lawsuits against Par, Alphapharm, and Dr. Reddy's. 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, and Dr. Reddy's, 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, Teva, and Dr. Reddy's 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, Teva, and Dr. Reddy's, 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 develop, acquire 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 and VIMOVO as an alternative to 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.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. Effective January 1, 2010, the new law increases the minimum Medicaid drug rebates for pharmaceutical companies, expands the 340B drug discount program, and makes changes to affect the Medicare Part D coverage gap, or “donut hole.” The law also revises the definition of “average manufacturer price” for reporting purposes (effective October 1, 2010), which could increase the amount of the Company’s Medicaid drug rebates to states, once the provision is effective. The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2011). Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products, and we could be adversely affected by current and future health care reforms.

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 nine months ended September 30, 2010 totaled \$35.0 million, including non-cash compensation expense of \$2.8 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 2007 through 2009, our average annual operating expenses (including average non-cash deferred compensation of \$5.2 million) were \$55.3 million (\$37.9 million net of development revenue received from AstraZeneca for development activities performed under the agreement). As of September 30, 2010, we had an aggregate of \$44.6 million in cash, cash equivalents and short-term investments. Our operating expenses for 2010 and 2011 may exceed the net level of our operating expenses in 2009, should we decide to conduct pre-commercialization activities as a result of our decision to retain control of our PA product candidate. We believe that we will have sufficient cash reserves and cash flow to maintain our planned level of business activities through 2011. However, our anticipated cash flow includes continued receipt of royalty revenue from GSK's sale of Treximet, an assumption of new royalty revenue from AstraZeneca's sale of VIMOVO and an assumption that we will receive a \$25 million milestone if VIMOVO receives approval (including pricing and reimbursement approval) in a major ex-U.S. country. In addition, 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. If our projected revenues decrease, we may need to raise additional capital. If our projected expenses increase for our product candidates currently in development, or if we expand our studies for additional indications for our PA product candidate, then, as a result of these or other factors, we may need to raise additional capital.

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, William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer, or Elizabeth A. Cermak, Executive Vice President and Chief Commercial 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.

Risks Related to Potential Commercialization of our Product Candidates

We are currently evaluating the commercial opportunities for our current product candidates in connection with our development of a worldwide commercialization strategy. If we decide to pursue the commercial opportunities for our future products ourselves and we are unable to develop sales and marketing capabilities on our own, or through contract sales forces or acquisition, we will not be able to fully exploit the commercial potential of our future products and the costs of pursuing such a strategy may have a material adverse impact on our results of operations.

Although we do not have sales and marketing experience, we are currently evaluating the commercial opportunities for our product candidates in connection with our development of a worldwide commercialization strategy. If we decide to pursue commercialization opportunities for our future products ourselves, we anticipate making significant expenditures to grow a sales force to sell such products and expand our marketing capabilities to support such growth. In order to successfully exploit our future products, we must successfully market and sell our products and establish or develop the needed third party contracts to market and distribute these products. Any failure or extended delay in the expansion of our sales and marketing capabilities or inability to effectively operate in the marketplace could adversely impact our business. There can be no assurance that if we decide to pursue commercialization opportunities ourselves that our sales and marketing efforts will generate significant revenues and costs of pursuing such a strategy may have a material adverse impact on our results of operations. Events or factors that may inhibit or hinder our commercialization efforts include:

- developing our own commercial team will be expensive and time-consuming and could result in high cash burn or reduced profitability;
- failure to acquire sufficient or suitable personnel to establish, oversee, or implement our commercialization strategy;
- failure to recruit, train, oversee and retain adequate numbers of effective sales and marketing personnel;
- failure to acquire sales personnel that can effectively obtain access to or persuade adequate numbers of physicians to prescribe our products;
- unforeseen costs and expenses associated with creating or acquiring and sustaining an independent sales and marketing organization;
- incurrence of costs in advance of anticipated revenues and subsequent failure to generate sufficient revenue to offset additional costs; and
- our ability to fund our commercialization efforts on terms acceptable to us, if at all.

If we decide to pursue commercialization opportunities for our future products ourselves, failure to comply with the laws governing the marketing and sale of such future products may result in regulatory agencies taking action against us, which could significantly harm our business.

If we decide to pursue commercial opportunities for our future products ourselves, we will be subject to a large body of legal and regulatory requirements. In particular, there are many federal, state and local laws that we will need to comply with if we become engaged in the marketing, promoting, distribution and sale of pharmaceutical products. The FDA extensively regulates, among other things, promotions and advertising of prescription drugs. In addition, the marketing and sale of prescription drugs must comply with the Federal fraud and abuse laws, which are enforced by the Office of the Inspector General of the Division, or OIG, of the Department of Health and Human Services. These laws make it illegal for anyone to give or receive anything of value in exchange for a referral for a product or service that is paid for, in whole or in part, by any federal health program. The federal government can pursue fines and penalties under the Federal False Claims Act which makes it illegal to file, or induce or assist another person in filing, a fraudulent claim for payment to any governmental agency. Because, as part of our commercialization efforts, we may provide physicians with samples we will be required to comply with the Prescription Drug Marketing Act, or PDMA, which governs the distribution of prescription drug samples to healthcare practitioners. Among other things, the PDMA prohibits the sale, purchase or trade of prescription drug samples. It also sets out record keeping and other requirements for distributing samples to licensed healthcare providers.

In addition, we will need to comply with the body of laws comprised of the Medicaid Rebate Program, the Veterans' Health Care Act of 1992 and the Deficit Reduction Act of 2005. This body of law governs product pricing for government reimbursement and sets forth detailed formulas for how we must calculate and report the pricing of our products so as to ensure that the federally funded programs will get the best price. Moreover, many states have enacted laws dealing with fraud and abuse, false claims, the distribution of prescription drug samples and gifts and the calculation of best price. These laws typically mirror the federal laws but in some cases, the state laws are more stringent than the federal laws and often differ from state to state, making compliance more difficult. We expect more states to enact similar laws, thus increasing the number and complexity of requirements with which we would need to comply.

Compliance with this body of laws is complicated, time consuming and expensive. Because we do not have experience in developing, managing and training our employees regarding, a comprehensive healthcare compliance program, we cannot assure you that we will be in compliance with all potentially applicable laws and regulations. Even minor, inadvertent irregularities can potentially give rise to claims that the law has been violated. Failure to comply with all potentially applicable laws and regulations could lead to penalties such as the imposition of significant fines, debarment from participating in drug development and marketing and the exclusion from government-funded healthcare programs. The imposition of one or more of these penalties could adversely affect our revenues and our ability to conduct our business as planned.

In addition, the Federal False Claims Act, which allows any person to bring suit alleging the false or fraudulent submission of claims for payment under federal programs and other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that companies like us may have to defend a false claim action. We could also become subject to similar false claims litigation under state statutes. If we are unsuccessful in defending any such action, such action may have a material adverse effect on our business, financial condition and results of operations.

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 October 22, 2010, 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 by us or our largest stockholders 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. Approximately 14% of our outstanding shares are beneficially held by John Plachetka, our President and Chief Executive Officer. Additionally, we believe, based upon our review of public filings by certain stockholders and other publicly available information, an aggregate of approximately 25% of our outstanding share are held by four other stockholders, with no one stockholder beneficially owning greater than 8% 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 or distributions 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 executive officers may sell shares pursuant to a Rule 10b5-1 trading plans. 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. Purchasers of our common stock in any future offerings by us will incur immediate dilution to the extent of the difference between our net tangible book value per share after the offering and the price paid per share by new investors.

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 6. Exhibits

<u>Exhibit Number</u>	<u>Description</u>
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)

October 29, 2010

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

October 29, 2010

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

October 29, 2010

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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.

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: October 29, 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: October 29, 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: October 29, 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: October 29, 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.

