FORM 10−Q

POZEN INC /NC − POZN

Filed: November 03, 2006 (period: September 30, 2006)

Quarterly report which provides a continuing view of a company's financial position

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

FORM 10−Q

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

For the quarterly period ended September 30, 2006

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	**62−1657552**
(State or other jurisdiction of incorporation or organization)	**(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. x 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 x Accelerated Filer ¨ Non−Accelerated Filer

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

The number of shares outstanding of the registrant's common stock as of October 27, 2006 was 29,353,082.

POZEN Inc.
(A Development Stage Company)
FORM 10−Q

For the Nine Months Ended September 30, 2006

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

POZEN Inc.
(A Development Stage Company)
BALANCE SHEETS
(Unaudited)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,163,589	$ 27,467,789
Short−term investments	33,451,348	18,370,701
Accounts receivable	1,567,819	––
Prepaid expenses and other current assets	118,227	613,682
Total current assets	68,300,983	46,452,172
Property and equipment, net of accumulated depreciation	205,738	234,839
Total assets	$ 68,506,721	$ 46,687,011
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 510,438	$ 1,443,676
Accrued compensation	1,125,847	2,591,633
Accrued expenses	1,196,140	1,201,023
Deferred revenue	14,571,200	6,552,000
Total current liabilities	17,403,625	11,788,332
Long−term liabilities:		
Deferred revenue	28,000,000	1,000,000
Total liabilities	45,403,625	12,788,332
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; 29,330,721 and 29,002,306 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	29,323	29,002
Additional paid−in capital	154,526,122	146,399,373
Accumulated other comprehensive income (loss)	566	(8,551)
Deficit accumulated during the development stage	(131,452,915)	(112,521,145)
Total stockholders' equity	23,103,096	33,898,679
Total liabilities and stockholders' equity	$ 68,506,721	$ 46,687,011

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period From Inception (September 26, 1996) Through September 30,
	2006	2005	2006	2005	2006
Revenue	$ 3,424,819	$ 2,399,000	$ 6,548,619	$ 6,410,374	$ 62,000,901
Operating expenses:					
General and administrative	3,662,984	2,473,439	10,393,998	7,198,656	60,466,949
Research and development	4,275,168	4,900,642	16,422,811	14,231,894	142,432,011
Total operating expenses	7,938,152	7,374,081	26,816,809	21,430,550	202,898,960
Other income:					
Interest and other income	447,127	289,303	1,336,420	846,507	10,379,622
Net loss	(4,066,206)	(4,685,778)	(18,931,770)	(14,173,669)	(130,518,437)
Non−cash preferred stock charge	−−	−−	−−	−−	27,617,105
Preferred stock dividends	−−	−−	−−	−−	934,478
Net loss attributable to common stockholders	$ (4,066,206)	$ (4,685,778)	$ (18,931,770)	$ (14,173,669)	$ (159,070,020)
Basic net loss per common share	$ (0.14)	$ (0.16)	$ (0.65)	$ (0.49)	
Shares used in computing basic net loss per common share	29,240,696	28,929,503	29,173,200	28,919,245	
Diluted net loss per common share	$ (0.14)	$ (0.16)	$ (0.65)	$ (0.49)	
Shares used in computing diluted net loss per common share	29,240,696	28,929,503	29,173,200	28,919,245	

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,		Period from Inception (September 26, 1996) Through September 30, 2006
	2006	2005	
Operating activities:			
Net loss	$ (18,931,770)	$ (14,173,669)	$ (130,518,437)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	70,282	121,304	911,700
Write−down of impaired asset	−−	69,272	155,576
Gain on sale of investments	−−	224,058	−−
Bond premium amortization	(636,165)	(386,047)	(1,207,845)
Noncash compensation expense	4,742,155	1,046,974	16,979,132
Noncash financing charge	−−	−−	450,000
Changes in operating assets and liabilities:			
Accounts receivable	(1,567,819)	−−	(1,567,819)
Prepaid expenses, and other current assets	495,455	989,259	(118,227)
Accounts payable and accrued expenses	(1,042,211)	(1,914,737)	2,832,425
Deferred revenue	35,019,200	(6,656,070)	42,571,200
Net cash provided by (used in) operating activities	18,149,127	(20,679,656)	(69,512,295)
Investment activities:			
Purchase of equipment	(41,181)	(37,626)	(1,273,014)
Purchase of investments	(46,735,365)	(38,201,508)	(93,742,938)
Sale of investments	32,300,000	18,575,942	61,500,000
Net cash used in investing activities	(14,476,546)	(19,663,192)	(33,515,952)
Financing activities:			
Proceeds from issuance of preferred stock	−−	−−	48,651,850
Proceeds from issuance of common stock	2,023,219	124,447	83,697,971
Proceeds from notes payable	−−	−−	3,000,000
Proceeds from stockholders' receivables	−−	−−	1,004,310
Payment of dividends	−−	−−	(162,295)
Net cash provided by financing activities	2,023,219	124,447	136,191,836
Net (decrease) increase in cash and cash equivalents	5,695,800	(40,218,401)	33,163,589
Cash and cash equivalents at beginning of period	27,467,789	51,764,129	−−
Cash and cash equivalents at end of period	$ 33,163,589	$ 11,545,728	$ 33,163,589
Supplemental schedule of cash flow information:			
Cash paid for interest	$ −−	$ −−	$ 191,348
Supplemental schedule of noncash investing and financing activities:			
Conversion of notes payable to preferred stock	$ −−	$ −−	$ 3,000,000
Preferred stock dividend	$ −−	$ −−	$ 772,183
Forfeiture of common stock options and warrants	$ −−	$ −−	$ 314,379
Conversion of common stock warrants to common stock	$ −−	$ −−	$ 1,080,001

See accompanying Notes to Financial Statements.

POZEN Inc.
(A Development Stage Company)
NOTES TO FINANCIAL STATEMENTS
(Unaudited)

1. Development Stage Company

POZEN Inc. (“POZEN” or the “Company”) was incorporated in the State of Delaware on September 25, 1996. The Company is a pharmaceutical company focused primarily on products for the treatment of acute and chronic pain and other pain−related conditions. The Company's product development emphasis is on diseases with unmet medical needs where the Company can improve efficacy, safety and/or patient convenience. Since inception, the Company has focused its efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine. The Company is also exploring the development of product candidates in other pain−related therapeutic areas. The Company intends to enter into collaboration agreements to commercialize its product candidates, and has entered into, and expects to continue to enter into such collaborations. The Company has not obtained regulatory approval to market any of its product candidates in the United States (U.S.). The United Kingdom's (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a marketing authorization for the Company's product candidate MT 100 for the acute treatment of migraine in the UK.

Statement of Financial Accounting Standards Board (“SFAS”) No. 7, “Accounting and Reporting by Development Stage Enterprises,” states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. The Company will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of the Company's product candidates. As of September 30, 2006, the Company had $33.2 million in cash and cash equivalents and $33.5 million in short−term investments. If the Company's operating expenses for 2006 and 2007 remain at the level of its operating expenses in 2005, the Company believes it will have sufficient cash reserves to maintain that level of business activities throughout 2007, provided that certain development expenses are paid by AstraZeneca, as outlined in the Agreement. The Company's expenses might increase in 2006 and 2007 if any regulatory agency requires the Company to conduct additional clinical trials, studies or investigations in connection with their consideration, or reconsideration, of the Company's regulatory filings for any of its product candidates. The Company is not currently obligated to make any milestone payments to third parties and does not currently have any other required material payment obligations during that period. However, regulatory delays, such as the Company is currently experiencing related to the approvable letter the Company received from the U.S. Food and Drug Administration (FDA) in June 2006 related to the Company's New Drug Application (NDA) for Trexima, or unforeseen developments in the development of the Company's existing and future product candidates, may increase the Company's cash requirements beyond its currently assumed needs.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements−−The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission (“SEC”) regulations for interim financial information. These financial statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring accruals) necessary to present fairly the balance sheets, statements of operations and statements of cash flows for the periods presented in accordance with accounting principles generally accepted in the United States. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to SEC rules and regulations. It is presumed that users of this interim financial information have read or have access to the audited financial statements and footnote disclosure for the preceding fiscal year contained in the Company's Annual Report on Form 10−K, filed on March 8, 2006. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2006.

Revenue Recognition−−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 future product sales. These agreements are accounted for in accordance with SEC Staff Accounting Bulletin No. 101, “Revenue Recognition”, as amended by SAB 104, “Revenue Recognition” (“SAB 101”), and Emerging Issues Task Force 00−21 (“EITF 00−21”), “Revenue Arrangements with Multiple Deliverables.” The non−refundable portion of upfront payments received under the Company's existing agreements is deferred by the Company upon receipt and recognized on a straightline 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 (AstraZeneca) related to the August 2006 Collaboration and License Agreement with AstraZeneca has been deferred and will be amortized over 40 months. The AstraZeneca licensing fee relates to the Company's proprietary fixed dose combinations of the proton pump inhibitor (PPI) esomeprazole magnesium with the non−steroidal anti−inflammatory drug (NSAID) naproxen, in a single tablet.

- The June 2003 initial licensing and patent−issuance milestone payments totaling $25.0 million for MT 400 received from GSK have been deferred and were originally being amortized over 42 months. During the third quarter of 2005 the amortization period was decreased to 39 months based upon the August 2005 submission to the FDA of the Trexima NDA which was earlier than anticipated. The decrease in the deferred period resulted in a $357,000 increase in amortization in future quarters as compared to the second quarter 2005 amortization. During the second quarter of 2006 the remaining amortization period of 6 months was increased to 15 months based upon the June 2006 receipt of an approvable letter from the FDA related to the Trexima NDA and an estimated extension of 9 months, which represents what the Company believes to be the conclusion of any obligation on its part under the agreement. The increase in the deferred period resulted in a $1.3 million decrease in amortization in future quarters as compared to the first quarter 2006 amortization.

- The September 2003 $1.0 licensing fee for MT 300 ($2.0 million non−refundable upfront licensing fee net of a potential termination fee of $1.0 million) received from Valeant Pharmaceuticals North America (Valeant NA), a subsidiary of Valeant Pharmaceuticals International (formerly Xcel Pharmaceuticals Inc.), has been amortized over 32 months. As the result of the receipt in October 2003 of a not−approvable letter from the FDA relating to the NDA for MT 300, after three months of amortization, this estimated deferral period was increased from an original estimate of 20 months to 32 months ending in April 2006, resulting in a $56,000 decrease in future quarterly amortization from the prior quarterly amortization.

Milestone payments are recognized as 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.

Additionally, the Company's licensing agreements may include payment for services provided by the Company on an hourly rate and direct expense basis. The Company records such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project. In accordance with FASB Emerging Issues Task Force (EITF) pronouncement 99−19, under the AstraZeneca Agreement, the Company will recognize as revenue the direct costs and certain personnel−related expense incurred in performing additional development activities described within the AstraZeneca Agreement.

Royalty revenue will be recognized when earned with respect to the manufacture, sale or use of the Company's products or technology. For those arrangements where royalties are reasonably estimable, the Company will recognize revenue based on estimates of royalties earned during the applicable period and reflect in future revenue any differences between the estimated and actual royalties.

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. Under the Company's investment policy, investments that have a maturity of greater than three months and less than one year are classified as short−term, are considered to be available−for−sale and are carried at fair value with unrealized gains and losses recognized in other comprehensive income (loss). Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis. Generally, investments with maturities beyond twelve months are classified as long−term. Marketable and non−marketable equity investments are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, the investment would be written down to fair value and the write−down would be permanent. For the nine month periods ended September 30, 2005 and 2006, the Company had $0.4 million and $0.6 million of bond amortization and $(9,099) and $566 of unrealized gain (loss) on investments included in accumulated other comprehensive income (loss) for each period, respectively.

Accumulated Other Comprehensive Income (Loss)−−Accumulated other comprehensive income (loss) is comprised of unrealized gains and losses on marketable securities and is disclosed as a component of stockholders' equity. The Company had $(9,099) and $566 of unrealized gain (loss) on its investments that are classified as accumulated other comprehensive income (loss) at September 30, 2005 and 2006, respectively.

Comprehensive loss consists of the following components for the three and nine months ended September 30, 2006 and 2005:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net loss	$ (4,066,206)	$ (4,685,778)	$ (18,931,770)	$ (14,173,669)
Unrealized gain (loss) on marketable securities	10,856	(1,614)	566	(9,099)
Total comprehensive loss	$ (4,055,350)	$ (4,687,392)	$ (18,931,204)	$ (14,182,768)

Stock−based Compensation−−On January 1, 2006, we adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share−Based Payment," which requires us to account for share−based payment transactions using a fair value−based method and recognize the related expense in our results of operations. Prior to our adoption of SFAS No. 123(R), as permitted by SFAS No. 123, we accounted for share−based payments to employees using the Accounting Principles Board Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees," intrinsic value method. Accordingly, prior to January 1, 2006 we generally recognized compensation expense for restricted stock awards and did not recognize compensation cost for employee stock options, as all such options had an exercise price equal to the market value of the underlying common stock on the date of the grant. SFAS No. 123(R) allows companies to choose one of two transition methods: the modified prospective transition method or the modified retrospective transition method. We chose to use the modified prospective transition methodology. Under this transition method, our compensation cost recognized includes compensation costs for all share−based payments granted prior to, but not yet vested as of, January 1, 2006 based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and compensation cost for all share−based payments granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Accordingly, we have not restated our financial results for prior periods.

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

The adoption of SFAS No. 123(R) had a significant impact on our results of operations. Our consolidated statements of operations for the three and nine months ended September 30, 2006 includes the following stock−based compensation expense:

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Research and development	$ 468,700	$ 1,582,400
General and administrative	1,005,300	3,159,800
Operating loss	(1,474,000)	(4,742,200)
Tax benefit	–	–
Net loss	$ (1,474,000)	$ (4,742,200)

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 2.02 years was $10.7 million at September 30, 2006. Unrecognized stock−based compensation expense expected to be recognized over the remaining period ending December 31, 2006 was $1.6 million at September 30, 2006.

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. Awards were permitted to be made under the Option Plan to eligible employees, officers, consultants and non−employee directors in the form of incentive or nonqualified stock options. Eligible participants under the Option Plan include executive and key employees of the Company. The vesting periods for options granted under the Option Plan range from immediate vesting at issuance to four years or immediately upon a significant change in ownership as defined by the plan document. The exercise price for incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (110% with respect to incentive stock options granted to optionees who are holders of 10% or more of the Company's common stock).

In May 2000, the Board of Directors adopted, and in June 2000 the stockholders approved, the POZEN Inc. 2000 Equity Compensation Plan (the "Plan"). The 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. The Plan provides for grants of incentive stock options, nonqualified stock options, stock awards, performance units, and other stock−based awards, such as restricted stock units and stock appreciation rights, to employees, non−employee directors, advisors and consultants. At adoption, the Plan authorized up to 3,000,000 shares of common stock for issuance under the terms of the Plan. The maximum number of shares for which any individual may receive grants in any calendar year is 1,000,000 shares. The vesting periods for awards made under the Plan generally range from immediate vesting at issuance to four years or may fully vest immediately, as described in and in accordance with the Plan, upon a change of control as defined in the Plan. If options granted under the 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 Plan.

In 2004, the Board of Directors adopted and the stockholders approved an amendment to and restatement of the Plan. The amendment to the Plan provided for an increase in the number of shares of common stock authorized for issuance under the Plan, from 3,000,000 to 5,500,000, or an increase of 2,500,000 shares. In addition, the amendment to the Plan limited the number of shares that may be issued pursuant to grants other than options under the Plan to 2,000,000 shares and made certain other clarifying changes. These plans are discussed in more detail in Note 7 to our financial statements for the fiscal year ended December 31, 2005 included in our Annual Report on Form 10−K filed on March 8, 2006.

In May 2004 an award of 98,135 restricted stock units was made to the Company's chief executive officer under the Plan. The restricted stock award vests in equal amounts on January 1, 2005, January 1, 2006 and January 1, 2007 and is payable in shares of common stock upon cessation of employment or the provision of service to the Company or, as provided in and in accordance with the plan, upon a change of control.

On January 3, 2005, pursuant to an incentive program (the “Trexima 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 506,772 shares of common stock. As of September 30, 2006, due to forfeitures resulting from employee terminations, options to purchase an aggregate of 375,251 shares of common stock remain outstanding under the Trexima incentive program. Each performance−based option will vest in full upon the later to occur of (i) January 3, 2007 or (ii) the receipt by the Company of an action letter from the FDA indicating approval of the NDA for the product candidate Trexima, which is being developed pursuant to the Company's collaboration agreement with GSK; provided, however that 25% of each such option will be forfeited if receipt of the FDA approval letter for the Trexima NDA does not occur prior to June 30, 2007, and 100% of each such option will be forfeited if receipt of the FDA approval letter for the Trexima NDA does not occur on or before December 31, 2007. These performance−based options, which were granted under the Plan, as amended and restated, have a ten−year term and an exercise price of $7.06, which was equal to the Nasdaq reported market closing price of the common stock on January 3, 2005, the date of grant.

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 during the nine months ended September 30, 2006 are shown in the following table:

	Three months ended September 30, 2006	Nine months ended September 30, 2006
Expected volatility	83.0%	76.0 − 83.0%
Expected dividends	0%	0%
Expected terms	6.25 Years	6.25 Years
Risk−free interest rate	4.9%	4.3 − 5.1%

The expected volatility rate is currently estimated based on an equal weighting of the historical volatility of POZEN common stock over a six year period. The expected term was estimated based on a simplified method, as allowed under SEC Staff Accounting Bulletin No. 107, averaging the vesting term and original contractual term. 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 month periods ended September 30, 2006 was based on historical rates. As required under SFAS No. 123(R), we adjust the estimated forfeiture rate to our actual experience.

A summary of the time−based stock awards as of September 30, 2006, and changes during the nine months ended September 30, 2006, is as follows:

Stock Awards	Underlying Shares (000s)	Weighted−Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
Outstanding at January 1, 2006	3,317	$ 7.67		
Granted	826	10.91		
Exercised	157	5.34		
Forfeited or expired	49	9.28		
Outstanding at March 31, 2006	3,937	8.42	7.6	$ 32,663
Exercisable at March 31, 2006	1,927	$ 7.38	6.2	$ 17,968
Granted	57	12.81		
Exercised	18	2.10		
Forfeited or expired	288	10.41		
Outstanding at June 30, 2006	3,688	8.36	7.3	$ 2,445
Exercisable at June 30, 2006	1,816	$ 7.31	5.9	$ 2,168
Granted	81	10.31		
Exercised	154	7.46		
Forfeited or expired	69	10.39		
Outstanding at September 30, 2006	3,546	7.19	7.1	$ 16,134
Exercisable at September 30, 2006	1,730	$ 7.38	5.7	$ 9,590

The aggregate intrinsic value 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 three and nine month periods ended September 30, 2006 was equal to the market price of the underlying common stock on the grant date. The total intrinsic value of stock options exercised during the three and nine month periods ended September 30, 2006 was $0.4 million and $1.2 million, respectively.

Restricted Stock

As of September 30, 2006, there was $0.1 million in unrecognized compensation expense related to unvested restricted stock units under the May 2004 award of 98,135 restricted stock units granted to our chief executive officer described above. That cost is expected to be recognized over the period ending December 31, 2006. The grant−date fair value of these restricted stock units was $12.24 per share. There were 32,712 unvested restricted stock units outstanding at September 30, 2006 and no time−based restricted stock was granted nor forfeited during the three and nine month periods ended September 30, 2006.

Performance−Based Awards

The fair value of each performance−based option granted under the Trexima incentive program was estimated as of the grant date using the Black−Scholes option valuation model without consideration of the performance measures. The inputs for expected volatility, expected term, expected dividends, and risk−free interest rate used in estimating fair value of performance−based awards in the nine months ended September 30, 2006, are the same as those noted above under Time−Based Stock Awards.

Determining the appropriate amount to expense based on the achievement of stated goals in a performance−based award requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is ultimately recognized and any previously recognized compensation cost is reversed.

As of September 30, 2006, there was $0.3 million in unrecognized compensation related to performance−based awards granted under the Trexima incentive program. That cost is expected to be recognized over the period ending September 30, 2007. The grant−date fair value of these performance−based options was $3.77 per share. There were 375,251 unvested performance−based options outstanding at September 30, 2006. No performance−based awards were granted nor exercised during the nine months ended September 30, 2006; 13,342 and 65,160 awards were forfeited during the three and nine month periods ended September 30, 2006. At September 30, 2006 the performance−based options had an intrinsic value of $2.2 million and a remaining contractual life of 8.3 years.

2005 Stock−Based Compensation

The following table illustrates the effect on net loss and net loss per share for the three and nine months ended September 30, 2005, if we had accounted for all employee stock−based compensation during that period based on the fair value method as prescribed by SFAS No. 123(R).

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss attributable to common stockholders as reported	$ (4,685,778)	$ (14,173,669)
Add: Stock−based employee compensation expense reflected in reported net loss, net of related tax effects	$ 615,197	$ 955,746
Deduct: Total stock−based employee compensation expense determined under the fair value−based method for all awards, net of related tax effects	(1,305,369)	(4,349,233)
Pro forma net loss attributable to common stockholders	$ (5,375,950)	$ (17,567,156)
Earnings per share		
Basic net loss per common share as reported	$ (0.16)	$ (0.49)
Basic net loss per common share pro forma	$ (0.19)	$ (0.61)
Diluted net loss per common share as reported	$ (0.16)	$ (0.49)
Diluted net loss per common share pro forma	$ (0.19)	$ (0.61)

For the purpose of the above table, the fair value of each option grant was estimated as of the date of grant by using the Black−Scholes option pricing model with the following weighted−average assumptions used for grants in the nine month period ended September 30, 2005: a risk−free interest rate of 3.90% to 4.05%; a dividend yield of 0%; a weighted−average expected life of 7.0 years; and a volatility rate of 97% to 98%. The expected volatility was estimated using the historical volatility over a period of four years preceding the applicable period. The weighted−average fair value of options granted in the nine month period ended September 30, 2005 was $7.10. There were no grants issued during the three month period ended September 30, 2005.

Net Loss Per Share−−Basic and diluted net loss per common share amounts are presented in conformity with SFAS 128, “Earnings per Share,” for all periods presented. In accordance with SFAS 128, basic and diluted net loss per common share amounts have been computed using the weighted−average number of shares of common stock outstanding for the nine months ended September 30, 2005 and 2006. During the nine months ended September 30, 2005 and 2006, the Company had potential common stock equivalents related to its outstanding stock options. These potential common stock equivalents were not included in diluted loss per share for these periods because the effect would have been antidilutive. Accordingly, basic and diluted net loss per share is the same for the three months ended September 30, 2005 and 2006. In accordance with SFAS 128, the Company has excluded the impact of any shares which might be issued under the Rights Plan, detailed below, from the EPS calculation because the Rights are not exercisable since the specified contingent future event has not occurred.

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, 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.

New Accounting Pronouncements−−In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share−Based Payment," which is a revision of SFAS Statement No. 123, *Accounting for Stock−Based Compensation* ("SFAS No. 123"). SFAS No. 123(R) supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share−based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. We adopted SFAS No. 123(R) on January 1, 2006. SFAS No. 123(R) requires us to account for share−based payment transactions using a fair value−based method and recognize the related expense in our results of operations. Prior to our adoption of SFAS No. 123(R), as permitted by SFAS No. 123, we accounted for share−based payments to employees using the APB 25 intrinsic value method and, therefore we generally recognized compensation expense for restricted stock awards and did not recognize compensation cost for employee stock options as such options had an exercise price equal to the market price of the underlying common stock on the date of grant. SFAS No. 123(R) allows companies to choose one of two transition methods: the modified prospective transition method or the modified retrospective transition method. We chose to use the modified prospective transition methodology. We have not restated our financial results from prior periods as a result of our adoption of SFAS No. 123(R).

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

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates, and expected terms. The expected volatility rates are estimated based on historical and implied volatilities of our common stock. The expected term represents the average time that options that vest are expected to be outstanding based on the vesting provisions and our historical exercise, cancellation and expiration patterns. We estimate pre−vesting forfeitures when recognizing compensation expense based on historical rates.

Determining the appropriate amount to expense for performance−based awards based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

The Company continues to assess the impact that FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes − an interpretation of FASB Statement No. 109" ("FIN 48"), will have on its consolidated financial statements. Issued by the FASB in June 2006, FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, and disclosure. FIN 48 is effective for fiscal years beginning after December 15, 2006, and is required to be adopted by the Company in the first quarter of fiscal 2007.

Contingencies−−Five purported class action lawsuits were filed during 2004 by holders of the Company's securities against the Company and certain of its current and former officers, in the U. S. District Court for the Middle District of North Carolina, alleging violations of securities laws. These actions were consolidated for pre−trial purposes. A lead plaintiff has been appointed by the court and a consolidated amended complaint was filed on December 20, 2004. The amended complaint alleges, among other claims, violations of federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b−5 and Section 20(a) of the Exchange Act against the Company and the Company's chairman and chief executive officer, arising out of allegedly false and misleading statements made by the Company concerning its product candidates, MT 100 and MT 300, during the class period. On January 27, 2005, the Company filed a motion to dismiss the amended complaint. The motion to dismiss was denied on August 30, 2005 and the case is now in discovery phase. On March 27, 2006, a motion for class certification was filed. The Company filed its brief in opposition to class certification on June 30, 2006. The Company and the defendant believe that the allegations in this action are without merit and intend to defend this case vigorously.

While the Company cannot predict the outcome or reasonably estimate the range of potential loss, if any, from this litigation, it is the current judgment of management that it is unlikely that this litigation will have a material adverse effect on the Company's results of operations, financial condition or cash flows.

Under its 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 has not been recognized as revenue and will not be recognized as revenue until the conditions in the agreement have been satisfied or resolved.

On July 21, 2005, the Company received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. The Company does not believe the withdrawal fee is payable. 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 indicated its intention to pursue the dispute resolution provisions provided for in the agreement. The Company intends to vigorously defend its position under the agreement. At this time, it is not possible to determine if any withdrawal fee will be required to be paid to Valeant NA when the ultimate resolution of this dispute is reached, however, it is the current judgment of management that no reserve is currently required.

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, 2005, as filed on March 8, 2006.

This report includes “forward−looking statements” within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward−looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as “may,” “will,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue” and similar words, although some forward−looking statements are expressed differently. You should be aware that the forward−looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward−looking statements. The forward−looking statements are subject to a number of risks and uncertainties which are discussed in this Quarterly Report on Form 10−Q, Part II, under the heading “Item 1A. Risk Factors” and elsewhere in this report and in other documents filed by us with the Securities and Exchange Commission. 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 primarily on products for the treatment of acute and chronic pain and other pain−related conditions. Our product development emphasis is on diseases with unmet medical needs where we can improve efficacy, safety and/or patient convenience. Since our inception, we have focused our efforts primarily on the development or regulatory approval of pharmaceutical products for the treatment of migraine. We are also exploring the development of product candidates in other pain−related therapeutic areas. We intend to enter into collaboration agreements to commercialize our product candidates, and have entered into, and expect to continue to enter into such collaborations. We have not obtained regulatory approval to market any of our product candidates in the United States (U.S.). The United Kingdom's (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a marketing authorization for our product candidate MT 100 for the acute treatment of migraine in the UK.

Our business activities to date have included:

- product candidate research and development;
- designing and funding clinical trials for our product candidates;
- regulatory and clinical affairs;
- intellectual property prosecution and expansion; and
- business development, including product acquisition and/or licensing and collaboration activities.

We are currently developing Trexima™ in collaboration with GlaxoSmithKline (GSK). Trexima is GSK's proposed brand name for the combination of sumatriptan succinate, formulated with GSK's RT Technology™, and naproxen sodium in a single tablet designed for the acute treatment of migraine. Trexima 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 (NSAID). Under our MT 400 technology, we seek 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 a New Drug Application (NDA) for Trexima with the U.S. Food and Drug Administration (FDA) in August 2005 and on June 8, 2006, we received an approvable letter related to our NDA for Trexima requiring us to provide certain additional safety information relating to Trexima. 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. We, along with GSK, met with the FDA on July 26, 2006 to discuss the approvable letter and we expect to submit a full response to the FDA's approvable letter in the fourth quarter of the year. We expect the FDA will complete its review within six months of this submission.

We are also developing product candidates that combine a type of acid inhibitor, a proton pump inhibitor (PPI), with an NSAID (our PN program). These product candidates are intended to provide management of pain and inflammation associated with conditions such as osteoarthritis, and are intended to have fewer gastrointestinal complications compared to an NSAID taken alone. In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca AB (AstraZeneca) to co−develop and commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet using our PN formulation technology. Another product candidate under our PN development program, PA 325, a combination of a PPI and aspirin, is currently in formulation development and is not covered under our agreement with AstraZeneca.

In addition, we are exploring the development of product candidates containing lornoxicam, an NSAID that is currently marketed outside the U.S. (including Europe and Japan). These product candidates, which are being developed under an exclusive license agreement with Nycomed Danmark ApS (Nycomed) granting us certain rights to develop and commercialize products containing lornoxicam, are intended to treat pain or other pain−related indications. We have filed Investigational New Drug Applications (INDs) with the FDA for an oral and an injectable lornoxicam formulation.

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of September 30, 2006, our accumulated deficit was approximately $131.5 million. 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 70% of our total operating expenses. For the nine months ended September 30, 2006, our research and development expenses represented approximately 54% of our total operating expenses.

Statement of Financial Accounting Standards Board (“SFAS”) No. 7, “Accounting and Reporting by Development Stage Enterprises,” states that an enterprise shall be considered to be in the development stage if either planned principal operations have not commenced or planned principal operations have commenced, but there has been no significant revenue therefrom. We will remain a development stage company until such time as significant revenues have been generated from the marketing and sale of our product candidates.

We expect that we may continue to incur operating losses over the next several years as we complete the development and seek regulatory approval for our product candidates, develop other product candidates and acquire and develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of Trexima and our other product candidates in the clinical and regulatory process;
- 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;
- The acquisition and/or in−licensing, and development, of other therapeutic product candidates; and
- Costs related to the pending class action lawsuit against us and our president and chief executive officer relating to the approvability of MT 100 and MT 300.

We do not currently have commercialization or manufacturing capabilities. We have entered into collaborations and currently plan to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. Our ability to generate revenue is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, and successfully develop product candidates, obtain regulatory approvals and successfully manufacture and commercialize our future products.

Status of Our Product Candidates

There follows a brief discussion of the status of each of our product candidates, as well as the costs relating to our development activities. 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 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 our research and development activities during the nine month period ended September 30, 2006 were $5.2 million. Other research and development department costs for the nine month period ended September 30, 2006 were $0.4 million.

MT 400/Trexima

On June 8, 2006, we received an approvable letter from the FDA related to the NDA for Trexima. 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. The approvable letter reflected that the FDA has determined that Trexima is effective as an acute treatment for migraine headaches. The FDA has requested additional safety information on Trexima, some of which require new studies. We, along with GSK, met with the FDA on July 26, 2006 to discuss the approvable letter and we expect to submit a full response to the approvable letter providing additional safety information in the fourth quarter of the year. We expect the FDA will complete its review within six months of this submission. There are no guarantees that FDA will find the submission to be satisfactory, that the FDA will approve the NDA, or that additional testing will not be required prior to approval.

As part of our Phase 3 clinical program for Trexima, we conducted two Phase 3 pivotal trials using a formulation of Trexima developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate Trexima, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours; we believe that this is the current FDA standard for establishing efficacy of migraine products. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of Trexima (the “combination drug rule” that the FDA requires of all combination products). The efficacy endpoint for the combination is 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.

In February 2005, we completed the first Phase 3 pivotal trial, in which Trexima demonstrated superiority over the individual components measured by sustained pain−free response ($p<.001$) and, with the exception of the incidence of nausea−free at two hours, all other regulatory endpoints were met ($p <.001$). Trexima did reach statistical significance for the nausea endpoint compared to placebo by three hours and maintained superiority through twenty−four hours. All of the active treatments (Trexima, sumatriptan and naproxen) had a similar incidence of nausea at two hours compared to placebo. In April 2005, we completed the second Phase 3 pivotal trial, in which Trexima 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.

We met with the FDA in April 2005 to discuss the results of our two Phase 3 pivotal trials, along with other information required for the submission of the Trexima NDA. The Trexima NDA submission was made in August 2005 and was accepted for review by the FDA in October 2005. In October 2005, we received a $20.0 million payment from GSK, payable under our collaboration agreement with GSK upon the FDA's acceptance for review of the Trexima NDA.

In addition to our Phase 3 pivotal studies and three standard pharmacokinetic studies, we completed two additional pharmacokinetic Phase 1 studies requested by the FDA and these were submitted to the FDA within the Trexima NDA. We also completed a long−term, twelve−month open label safety study for Trexima. The final results of this study were submitted to the NDA, as previously agreed with FDA, in December 2005 with the 120−day safety update report to the NDA. Additional safety data from two GSK−sponsored studies were submitted to the FDA within the 120−day safety update report, and the final reports of those studies were filed to the IND during the first quarter of 2006. GSK has funded and continues to conduct pre−approval market support studies for Trexima under our IND.

We cannot reasonably estimate or know the amount or timing of the costs necessary to complete the development of Trexima or when, if and to what extent we will receive future cash inflows from Trexima. The additional costs that we may incur include expenses relating to clinical trials and other research and development activities and the cost and timing of activities necessary to obtain regulatory approval.

We incurred $79,000 in direct development costs associated with the development of MT 400/Trexima for the nine−month period ended September 30, 2006 and we have incurred $24.5 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 100

In May 2004, we received a not−approvable letter from the FDA with respect to our NDA for MT 100, our proprietary combination of metoclopramide hydrochloride and naproxen sodium. In September 2005, after an FDA advisory committee concluded that the potential but unquantified risk of the occurrence of an involuntary neurological movement disorder known as tardive dyskinesia associated with the use of metoclopramide would outweigh the benefits of the MT 100 combination, we decided to discontinue further development of MT 100 in the U.S. and to reevaluate our MT 100 European strategy. As a part of that reevaluation, in September 2005 we terminated our license agreement with Nycomed for the development and commercialization of MT 100 in Denmark, Norway, Sweden and Finland in exchange for a payment to Nycomed of $250,000. We are exploring the possibility of selling or otherwise disposing of the MT 100 asset to a third party, although there can be no assurance that we will, or will be able to, consummate such a transaction.

In October 2002, we submitted a Market Authorization Application (MAA) for MT 100 for the acute treatment of migraine to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK). In November 2005, we received notification that the MHRA had granted us marketing approval for MT 100 in the UK.

We are not currently conducting and do not plan to conduct any clinical trials for MT 100 and do not expect to incur any additional significant development costs related to MT 100. We incurred $82,000 in direct development costs associated with the development of MT 100 for the nine−month period ended September 30, 2006 and we have incurred $39.8 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

MT 300

In October 2003, we received a not−approvable letter from the FDA related to our NDA for MT 300, which we had submitted in December 2002. Subsequently, we continued our communications with the FDA relative to the NDA. Based upon our most recent discussions with the FDA, in which the FDA affirmed its previously stated concerns that approval of the NDA was problematic due to the higher incidence of nausea at two hours following dosing in patients treated with MT 300 compared with placebo, and our understanding of the current FDA standards for approving migraine drugs, we believe it is not possible to reverse the not approvable status of the NDA for MT 300.

We therefore, began discussions with Valeant NA regarding termination of our MT 300 commercialization agreement. 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. Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may elect to withdraw the NDA. If we notify Valeant NA of this situation and Valeant NA elects not to assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA the agreement will terminate and we would be required to pay Valeant NA a termination fee of $1.0 million. If Valeant NA decides to assume development, it would be credited $1.0 million in development expense. We do not believe that the withdrawal fee is payable under the circumstances of receipt of a 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. 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.

We are not currently conducting any clinical trials for MT 300 and do not expect to incur any additional significant development costs related to MT 300. Given our current assessment that we do not believe we can reverse the not−approvable status of the NDA for MT 300, we believe that we will not receive any cash inflows from MT 300.

We incurred $40,000 in direct development costs associated with the development of MT 300 for the nine−month period ended September 30, 2006 and we have incurred $14.6 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

PN Program

Under our PN program, we have completed formulation development and clinical studies for combinations of a proton pump inhibitor (PPI) and an 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 an NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. To date, we have 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. Our future development and commercialization efforts under the PN program will be covered under our exclusive collaboration agreement with AstraZeneca, which we entered into on August 1, 2006. Under our agreement with AstraZeneca, we and AstraZeneca will co−develop and AstraZeneca will commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the non−steroidal anti−inflammatory drug (NSAID) naproxen, in a single tablet. The initial product to be developed under the agreement, PN 400, will be indicated 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.

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 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 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 enteric−coated naproxen. This study demonstrated that the PN formulation was bioequivalent to the reference drug, EC Naprosyn®.

In early 2006, we submitted a Special Protocol Assessment (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, expect to meet with the FDA during the next few months to confirm whether, notwithstanding the use of a different PPI, the core development program and the SPA already agreed upon will apply to the new product consisting of proprietary fixed dose combinations of esomeprazole magnesium with naproxen. We commenced certain PN 200 trials in the third quarter of 2006 to test longer−term gastro−protection of the PN product concept. Additional trials with PN 400, the naproxen/esomeprazole fixed combination, will begin once the new product is formulated and clinical supplies are manufactured, with Phase 3 clinical trials expected to begin in the third quarter of 2007.

In 2005, we also had discussions with the FDA concerning the implications of the FDA's guidance issued in June 2005 concerning labeling of NSAID−containing products, which resulted from an FDA advisory committee meeting held in February 2005. The advisory committee addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX−2 selective NSAIDs. Based on our discussions with the FDA reviewing division for PN products, we believe that, unless new information about naproxen safety concerns becomes available, long−term cardiovascular safety studies will not be required at this time for FDA approval of our PN product candidates containing naproxen. However, we cannot guarantee that such studies will not be required. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements and study design necessary to support approval of NDAs for our PN and PA product candidates.

Additionally, we have met with four national European regulatory agencies to discuss the proposed development program for PN. While further clarification will be needed, based on the intention to develop the esomeprazole combination, further clinical studies, beyond those specifically required for the NDA submission in the U.S., will need to be conducted. In part, these studies will be required as the naproxen−containing products on the European market differ in strength and formulation from those available in the U.S.

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 PN product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PN products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our PN program of $6.5 million during the nine−month period ended September 30, 2006 and we have incurred $14.7 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

PA Program

In 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 have fewer gastrointestinal complications compared to an aspirin taken alone, in patients at risk for developing aspirin associated gastric ulcers. Our PA product candidates are not covered under the AstraZeneca agreement, and we have retained all rights to this program.

Our PA product candidate, PA 325, is currently in formulation development. We plan to commence a Phase 1 proof of concept study of PA 325 in the fourth quarter of 2006.

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 incurred direct development costs associated with the development of our PA program of $0.2 million during the nine−month period ended September 30, 2006 and we have incurred $0.6 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Lornoxicam Program

In this program, we have begun development work and conducted clinical studies to investigate the development of novel product candidates containing lornoxicam, alone or in combination with other active ingredients, as potential treatments for pain or other indications. Our exploratory and development work is being conducted under an exclusive license agreement with Nycomed, pursuant to which Nycomed licensed to us certain rights to develop and commercialize products containing lornoxicam in the U.S. As a part of our agreement with Nycomed, we have also granted certain exclusive rights to Nycomed to supply us, or our commercialization partners, if any, with lornoxicam active drug substance for use in the manufacture of any of our lornoxicam product candidates.

Oral Tablet Formulation. We filed an IND with the FDA in 2003 for an oral lornoxicam tablet formulation and completed our first human study with this formulation in 2004 in patients undergoing dental surgery. The data from this study confirmed the acute safety profile for lornoxicam in these patients and provided preliminary evidence of efficacy in this pain model. As a result of the FDA advisory committee meeting held in February 2005 addressing the safety and cardiovascular risks of NSAIDs, described above, the FDA has indicated that long−term cardiovascular safety studies will be required prior to NDA approval of new NSAID products that may be used on an intermittent or chronic basis, such as our oral tablet lornoxicam product candidate.

Injectable Formulation. We filed an IND with the FDA for an injectable lornoxicam formulation in May 2005, and during 2005 we initiated the first human studies with this formulation under our IND. We have completed a Phase 1 pharmacokinetic study as well as two Phase 2 studies to evaluate lornoxicam for management of acute post−operative bunionectomy pain and for management of migraine pain. In the Phase 2 bunionectomy study, both active doses of lornoxicam were significantly better than placebo in the acute management of pain following bunionectomy. Based on the results of our Phase 2 migraine study, we currently do not intend to pursue the migraine indications.

We will likely reassess the direction of our lornoxicam product candidates in the fourth quarter based on the results of our clinical studies, the regulatory environment and commercial opportunities. 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 lornoxicam product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any lornoxicam products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals.

We incurred direct development costs associated with the development of our lornoxicam program of $3.3 million during the nine−month period ended September 30, 2006, and we have incurred $8.5 million from inception to date. Our direct development costs do not include the cost of research and development personnel or any allocation or our overhead expenses.

Collaborative Arrangements

We have entered into and plan to 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 are responsible for development of the first combination product, while GSK is to provide formulation development and manufacturing. GSK has proposed Trexima as the brand name of the combination of sumatriptan succinate, formulated with GSK's RT Technology™, and naproxen sodium in a single tablet, being developed under the agreement. 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 Trexima NDA. Additionally, GSK is obligated to make payments to us in an aggregate amount of up to $20.0 million upon FDA approval of the Trexima NDA and upon notification of intent to commercialize Trexima. 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. GSK will also pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (August 14, 2017 based upon the scheduled expiration of currently issued patents). GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre−determined share of the market for the 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 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.

AstraZeneca AB (AstraZeneca)

In August 2006, we entered into a collaboration and license agreement with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose combinations of the proton pump inhibitor (PPI) esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers. Under the terms of the agreement, we granted to AstraZeneca an exclusive, fee−bearing license, in all countries of the world except Japan, under our patents and know−how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). AstraZeneca may, at no additional cost, elect to include Japan in the licensed territory within two years after the effective date of the agreement.

Pursuant to the terms of the agreement, we received an upfront license fee of $40 million from AstraZeneca following termination of the waiting period under the Hart−Scott−Rodino notification program. In addition, AstraZeneca has agreed to make milestone payments upon the achievement of certain development events and sales events. If all development milestones are achieved, total development milestone payments due us under the agreement will be $160 million. If all sales milestone events are achieved, total sales milestone payments due us under the agreement will be $175 million. We will also receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees under the agreement during the royalty term. The royalty rate varies based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, with percentages ranging from the mid−single digits to the mid−teens. In addition, the agreement provides for certain reductions to the royalty rate based on qualified royalty payments to other third parties and loss of market share due to generic competition. Our right to receive royalties from AstraZeneca for the sale of such products 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 retain responsibility for the development and filing of the New Drug Application (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 establishes joint committees with representation of both us and AstraZeneca to manage the development and commercialization of the product. The committees will operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

The agreement, unless earlier terminated, shall 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 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.

Nycomed Danmark ApS (Nycomed)

Lornoxicam

In May 2003, we entered into a development, option and license agreement with Nycomed pursuant to which we obtained an exclusive license to certain development rights during the option period and an exclusive option to license certain rights to develop, manufacture and commercialize products containing lornoxicam. In July 2005, we exercised the option and were granted an exclusive license, with the right to sublicense, develop, manufacture and commercialize single−entity products and combination products containing lornoxicam in the U.S. (and its territories) and Canada (the Exclusive Territory). We were granted a non−exclusive license to develop and commercialize combination products containing lornoxicam in Belgium, Germany, Greece, France, Ireland, Luxembourg, The Netherlands, Austria, Finland, Denmark, United Kingdom, Sweden, Armenia, Azerbaijan, Belarus, Estonia, Georgia, Iceland, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Moldova, Norway, Russia, Switzerland, Tajikistan, Turkmenistan, Ukraine and Uzbekistan (the Limited Territory). We were granted a non−exclusive license to manufacture single−entity and combination products containing lornoxicam outside of the Exclusive Territory, excluding certain countries. We granted Nycomed a right of first refusal with respect to the development, manufacturing and commercialization, in Iceland, Denmark, Norway, Finland, Sweden, Lithuania, Latvia, Estonia, Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Uzbekistan and Ukraine, of certain combination lornoxicam products that we may develop under the agreement.

Pursuant to the agreement, we paid Nycomed a total of $500,000 for upfront and milestone payments during the option period. We paid Nycomed a non−refundable $500,000 payment in August 2005 to exercise our option under the agreement. We will be obligated to pay additional milestone payments in an aggregate amount of up to $500,000 upon the occurrence of certain regulatory approvals. In addition, we will be obligated to pay Nycomed specified single digit royalties on all net sales of any licensed single−entity or combination lornoxicam products, with the amount of such royalties for single−entity lornoxicam products subject to reduction upon the occurrences of certain specified events. The obligation to pay such royalties expires on a product−by−product and country−by−country basis ten (10) years from the first commercial sale of a product in a given country. We are also obligated to pay Nycomed a specified single digit percentage of any upfront and milestone payments we may receive from our sublicensees up to a preset maximum amount per sub−licensee.

As a part of the agreement, Nycomed will supply us with all of our required clinical supply of active drug substance, and may also supply some clinical trial materials under certain conditions. Under the agreement, subject to Nycomed's ability to meet a specified percentage of our and each of our sublicensee's requirements, we and each of our sublicensees (each, a buyer) must purchase all of their required commercial supply of active drug substance from Nycomed for a minimum of five years. For each buyer, this exclusive 5−year purchase commitment for each of the Exclusive Territory and the Limited Territory begins with the buyer's first commercial sale of its first licensed lornoxicam product in a particular specified country within the Exclusive Territory and the Limited Territory, respectively, as applicable.

Each party generally has the duty to indemnify the other for damages arising from each party's breach of its representations, warranties and obligations under the agreement, as well as for gross negligence or willful misconduct. In addition, we must indemnify Nycomed for any claim brought by a third party arising from our development, testing, manufacture or sale of any licensed product. Further, each party has a duty to maintain commercially reasonable insurance coverage commensurate with its obligations under the agreement. Nycomed has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If Nycomed does not bring any such action within a certain time frame, we have the right, but not the obligation, at our own expense, to bring the appropriate action. The agreement terminates upon the date of expiration of all royalty obligations unless terminated earlier by either party for material breach or upon the bankruptcy, insolvency or dissolution of either party, or by us if we determine in good faith that it is not commercially or scientifically feasible to continue development and commercialization efforts with respect to products using the licensed technology. Nycomed also may terminate the agreement if we or any sublicensee initiates a lawsuit challenging the validity of any licensed patent.

MT 100

In June 2003, we signed a license agreement with Nycomed for the commercialization of MT 100 in four Nordic countries and received an initial license fee of $500,000. As a result of our decision to discontinue development of MT 100 in the U.S. and to re−evaluate our MT 100 European strategy, we terminated this agreement and the related supply agreement with Nycomed in September 2005 pursuant to the terms of a termination agreement. The termination agreement provided for the immediate termination of the license and supply agreements and all rights and obligations of the parties under those agreements, subject to the survival of certain specified provisions, including under the license agreement, those related to confidentiality and indemnification obligations, ownership rights, and limitation of warranty and liability, and under the supply agreement, those related to confidentiality obligations. Subject to these surviving provisions and the parties' obligations under the termination agreement, the parties also agreed to mutually release each other from any and all present and future claims resulting from events existing as of the date of the termination agreement. As consideration for Nycomed's consent to enter into the termination agreement and the mutual release, we paid Nycomed $250,000.

Valeant Pharmaceuticals North American (Valeant NA) (formerly Xcel Pharmaceuticals Inc.)

In September 2003, we signed an agreement with Valeant NA for the further development and commercialization of MT 300. In March 2005, Valeant Pharmaceuticals International (Valeant International) acquired Valeant NA. Under the terms of the agreement, Valeant NA would have exclusive rights in the United States to commercialize MT 300 subject to certain minimum commercialization obligations. Pursuant to the terms of the agreement, Valeant NA paid us an upfront fee of $2.0 million. Upon certain future regulatory approvals, including the FDA's approvals relating to MT 300, and the achievement of a predetermined sales threshold on MT 300, potential milestone payments of up to $8.0 million would be due. Valeant NA is also obligated to pay us royalties on all combined net sales of MT 300 and Valeant NA's D.H.E. 45® (dihydroergotamine mesylate) Injection, upon commercialization of MT 300, until at least the expiration of the last to expire issued applicable patent (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent), subject to reduction in certain instances of generic competition, or in the event that Valeant NA pays royalties to one or more third parties to license rights from such third parties to commercialize MT 300. The agreement terminates on the date of expiration of all royalty obligations (2020, based upon the scheduled expiration of the last to expire currently issued applicable patent) unless earlier terminated by either party for a material breach or in the event that either party determines not to pursue approval of MT 300, under the conditions described below. Under certain circumstances, the agreement provides for the terminating party to facilitate the assumption of its responsibilities by the non−terminating party. Generally, each party must indemnify the other for damages arising from such party's breach of its representations, warranties and obligations under the agreement, as well as for the gross negligence or willful misconduct by either party. Additionally, Valeant NA must indemnify us for damages arising from the development, manufacture or use of any product after the effective date of the agreement, while we must indemnify Valeant NA for any damages arising from such development, manufacture or use prior to the effective date. We must also indemnify Valeant NA for any use by us or any sub licensee of certain technology owned by Valeant NA.

Under the agreement, if we determine that additional studies or data that are required by the FDA for approval of the NDA for MT 300 would jeopardize the commercial viability of MT 300 or exceed our financial resources available for MT 300, we may elect to withdraw the NDA. If we notify Valeant of this situation and Valeant NA does not assume control of efforts to seek approval of the NDA, then, under the conditions outlined in the agreement, upon notice from Valeant NA the agreement will terminate and we would be required to pay Valeant NA a withdrawal fee of $1.0 million. If Valeant decides to assume development, it would be credited $1.0 million in development expense. Based upon our understandings from our most recent communications with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we believe it is not possible to reverse the not approvable status of the NDA for MT 300 and we have begun discussions regarding termination of our commercialization agreement with Valeant NA. In July 2005, we received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee. We do not believe that the withdrawal fee is payable based on our receipt of a not−approvable letter from the FDA with respect to our NDA for MT 300. 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 in the agreement. We intend to vigorously defend our position under the agreement. At this time, it is not possible to determine if any withdrawal fee will be required to be paid to Valeant NA upon the ultimate resolution of this dispute.

Based upon the delays related to commercialization of MT 300 due to our receipt of the not−approvable letter for MT 300 and our efforts to address with the FDA the issues raised in that letter, we and Valeant NA had previously agreed to extend the time for certain activities under our agreement with Valeant NA that are dependent on the FDA's actions with respect to MT 300. In the event of termination of the agreement, these obligations will not be relevant.

We can give no assurance that Valeant NA or Valeant International will agree to termination terms acceptable to us or that we will not be required to pay Valeant NA the withdrawal fee of $1.0 million described above.

Critical Accounting Policies and Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the United States in the preparation of our financial statements. The development and selection of the critical accounting policies, and the related disclosure about these policies, have been reviewed by the audit committee of our board of directors. We evaluate our estimates and judgments on an ongoing basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We have a discussion below of four critical accounting estimates: revenue recognition, accrued expenses, stock−based compensation and income taxes.

Revenue Recognition

Our licensing and other collaborative agreements have terms that include up−front payments upon contract signing, additional payments if and when certain milestones in the product's development are reached, royalty payments based on future product sales and withdrawal fees if certain conditions are met. We recognize revenue under these agreements in accordance with SEC Staff Accounting Bulletin 101, “Revenue Recognition” as amended by SAB 104, “Revenue Recognition” (“SAB 101”), and Emerging Issues Task Force 00−21 (“EITF 00−21”), “Revenue Arrangements with Multiple Deliverables.”

Under SAB 101 recognition of revenue from non−refundable up−front payments is deferred by us upon receipt and recognized over the period ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates. If regulatory approvals or other events relating to our product candidates are accelerated, delayed or not ultimately obtained, then the amortization of revenues for these products would prospectively be accelerated or reduced accordingly.

We recognize milestone payments as 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 will be recorded as deferred revenue and only recognized as revenue when both criteria are met.

Additionally, our licensing agreements may include payment for services provided by us on an hourly rate and direct expenses. We record such revenue in accordance with the agreements which would generally be based upon time spent and materials used on the project and the direct costs and certain personnel−related expense incurred in performing additional development activities described within the agreement.

We have not previously received royalty revenue but we anticipate such revenue will be recognized related to the manufacture, sale or use of our products or technology. For those arrangements where royalties are reasonably estimable, we will recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following period.

Management believes that its current assumptions and other considerations used to estimate the periods for revenue recognition described above are appropriate, and historical changes in our estimates of these periods have not resulted in material changes in the revenue we recognized. However, we continually review these estimates, which could result in a change in the deferral period and might impact the timing and amount of revenue recognition. Further, if regulatory approval of Trexima is accelerated, delayed or not ultimately obtained, then the amortization of revenues for this product would prospectively be accelerated or reduced accordingly. For example, as a result of our receipt in June 2006 of an approvable letter from the FDA related to our Trexima NDA, we have extended the amortization period for completion of our obligations under our Trexima collaboration agreement with GSK.

As of September 30, 2006, we had deferred $42.6 million of revenue, of which $1.0 million is refundable under certain termination or cancellation provisions within our licensing agreements. We recognized revenue related to our collaborations of $6.5 million for the nine month period ended September 30, 2006, $28.6 million for the fiscal year ended December 31, 2005, $23.1 million for the fiscal year ended December 31, 2004 and $3.7 million for the fiscal year ended December 31, 2003.

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 our clinical trials. Specifically, our management must make estimates of costs incurred to date but not yet invoiced in relation to contracted, external costs. Management analyzes the progress of product development, clinical trial and toxicology and related activities, invoices received and budgeted costs when evaluating the adequacy of the accrued liability for these related costs. Material differences in the amount and timing of the accrued liability for any period may result if management made different judgments or utilized different estimates.

Management 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 level of services performed on or before a given date and the cost of such services involves subjective judgments and often must be based upon information provided by third parties. In the event that we do not identify certain contract costs which have begun to be incurred or we under− or over−estimate the level of services performed or the costs of such services, our reported accrued expenses for such period would be too low or too high, as the case may be.

We recognized accrued costs related to product development and operating activities, including clinical trials, based upon the progress of these activities covered by the related contracts, invoices received and estimated costs, of $1.0 million for the fiscal year ended December 31, 2005, $1.4 million for the fiscal year ended December 31, 2004 and $0.8 million for the fiscal year ended December 31, 2003. The variance, at each of these ending periods, between the actual expenses incurred and the expenses accrued has been less than $125,000.

Stock−Based Compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards (“SFAS”) No. 123(R), “Share−Based Payment,” which requires us to account for share−based payment transactions using a fair value−based method and recognize the related expense in our results of operations. Prior to our adoption of SFAS No. 123(R), as permitted by SFAS No. 123, we accounted for share−based payments to employees using the Accounting Principles Board Opinion No. 25 (“APB 25”), “Accounting for Stock Issued to Employees,” intrinsic value method. Therefore, prior to January 1, 2006 we generally recognized compensation expense for restricted stock awards and did not recognize compensation cost for employee stock options, as all such options had an exercise price equal to the market value of the underlying common stock on the date of the grant. SFAS No. 123(R) allows companies to choose one of two transition methods: the modified prospective transition method or the modified retrospective transition method. We chose to use the modified prospective transition methodology. Under this transition method, our compensation cost recognized includes compensation costs for all share−based payments granted prior to, but not yet vested as of, January 1, 2006 based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and compensation cost for all share−based payments granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Accordingly, we have not restated our financial results for prior periods.

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

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates, and expected terms. The expected volatility rate was estimated based on an equal weighting of the historical volatility of our common stock over a six year period. The expected term was estimated based on a simplified method as allowed under SEC Staff Accounting Bulletin No. 107 averaging the vesting term and original contractual term. 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 nine months ended September 30, 2006 was based on historical rates.

Determining the appropriate amount to expense for performance−based awards based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

Income Taxes

We record deferred tax assets and liabilities based on the net tax effects of tax credits, operating loss carry−forwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. We then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we establish an annual valuation allowance. We have not recorded any tax provision or benefit for the years ended December 31, 2005, 2004, or 2003 and have provided a valuation allowance for the full amount of our net deferred tax assets. If results of operations in the future indicate that some or all of the deferred tax assets will be recovered, the reduction of the valuation allowance will be recorded as a tax benefit during one or more periods. Until we record a tax provision or benefit based upon anticipated utilization of the prior operating loss carry−forwards, no estimate of the effect of a change in our estimated effective tax rate will be made.

Results of Operations

Three months ended September 30, 2006 compared to the three months ended September 30, 2005

Net loss per share: Net loss attributable to common stockholders for the quarter ended September 30, 2006 was $(4.1) million or $(0.14) per share as compared to a net loss of $(4.7) million, or $(0.16) per share, for the quarter ended September 30, 2005. The net loss for the quarter ended September 30, 2006 included a $1.5 million or ($0.05) per share charge for non−cash stock−based compensation expenses resulting from our adoption of SFAS No. 123(R) on January 1, 2006.

Revenue: We recognized $3.4 million of revenue for the quarter ended September 30, 2006 as compared to $2.4 million for the quarter ended September 30, 2005. The increase in revenue was primarily due to the amortization of upfront payments we received and other revenue from development activities we completed in the period pursuant to our development and commercialization agreement with AstraZeneca. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non−refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $42.6 million remains in deferred revenue at September 30, 2006. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development total expenses decreased by $0.6 million to $4.3 million for the quarter ended September 30, 2006, as compared to the same period of 2005. The decrease was due primarily to a decrease in direct development costs for Trexima and the lornoxicam program, partially offset by an increase in direct development costs for the PN program, as compared to the same period of 2005. Direct development costs for Trexima decreased by $1.2 million to $0.1 million, primarily due to the completion of Phase 3 clinical trial activities and regulatory fees incurred for submission of the NDA to the FDA during 2005 as compared to the same period of 2006. Direct development costs for lornoxicam decreased by $0.7 million primarily due to a $500,000 payment to Nycomed for exercise of the lornoxicam option in 2005 as compared to the same period of 2006. Direct development costs for the PN program increased by $1.2 million to $2.2 million, primarily due to Phase 3 clinical trial activities during the third quarter of 2006, as compared to the same period of 2005. Direct development costs for the PA program were $0.1 million during the third quarter of 2006, as compared to $0.2 million during the same period of 2005. Research and development departmental expenses increased by $0.3 million as compared to the same period of 2005, primarily due to a $0.2 million increase in non−cash compensation charges for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006 and bonus payments made to certain company employees in recognition of their efforts in connection with the AstraZeneca licensing agreement. 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 $1.2 million to $3.7 million for the third quarter of 2006, as compared to the same period of 2005. The increase was due primarily to a $0.7 million increase in non−cash compensation charge for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. Cost associated with our business development activities increased by $0.5 million to $1.1 million, primarily due to increased legal expenses and other consulting expenses related to our licensing activities and bonus payments made to certain company employees in recognition of their efforts in connection with the AstraZeneca licensing agreement. Costs associated with our public company activities decreased by $0.3 million primarily due to a decrease in the cost of directors' and officers' liability insurance, as compared to the same period of 2005. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $0.3 and $0.1 million for the quarters ended September 30, 2006 and $0.4 million for 2005, respectively. Investment income from bond amortization for the period ended September 30, 2006 totaled $0.1 million as compared to $0.2 million during the same period of 2005.

Nine months ended September 30, 2006 compared to the nine months ended September 30, 2005

Net income (loss) per share: Net loss attributable to common stockholders for the nine months ended September 30, 2006 was $(18.9) million, or $(0.65) per share, as compared to a net loss of $(14.2) million, or $(0.49) per share, for the same period of 2005. The net loss for the period ended September 30, 2006 included $4.7 million, or $(0.15) per share, charge for non−cash stock−based compensation expenses resulting from our adoption of SFAS No. 123(R) on January 1, 2006.

Revenue: We recognized $6.5 million of revenue for the nine months ended September 30, 2006, as compared to $6.4 million for the same period of 2005. Revenue for the period included $2.6 million of amortization of upfront payments we received and other revenue from development activities we completed in the period pursuant to our development and commercialization agreement with AstraZeneca and amortization of other revenue from our collaboration agreement with GSK. In the second quarter of 2006, we extended the amortization period of the upfront payments we received pursuant to our development and commercialization agreement with GSK related to Trexima. Based upon our receipt in June 2006 of an approvable letter from the FDA related to our Trexima NDA, the remaining Trexima amortization period was extended to the end of the second quarter of 2007, which we believe represents our best estimate of the period required to conclude any obligations on our part under the agreement. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product development or related milestones are achieved. All upfront payments were deferred and the non−refundable portions are being amortized over the periods ending on the anticipated dates of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on our part. Approximately $42.6 million remains in deferred revenue at September 30, 2006. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development total expenses increased by $2.2 million to $16.4 million for the nine months ended September 30, 2006, as compared to the same period of 2005. The increase was due primarily to a $1.2 million increase in non−cash compensation charges for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006 and an increase in direct development costs for the lornoxicam and the PN programs, partially offset by a decrease in direct development costs for Trexima, as compared to the same period of 2005. Direct development costs for the lornoxicam program increased by $2.0 million to $3.3 million, primarily due to Phase I/II clinical trial activities during the first half of 2006 as compared to the same period of 2005. Direct development costs for the PN program increased by $4.4 million to $6.5 million, primarily due to product development activities including the formulation and development of clinical trial materials and PN clinical trial activities during the period ended September 30, 2006, as compared to the same period of 2005. Direct development costs for the PA program were $0.2 million during the period ended September 30, 2006, as compared to $0.4 million during the same period of 2005. Direct development costs for Trexima decreased by $5.1 million, primarily due to the completion of clinical trial activities for Trexima and the regulatory submission of the Trexima NDA to the FDA during 2005. Research and development departmental expenses increased by $1.4 million to $5.7 million as compared to the same period of 2005, primarily due to a $1.2 million increase in non−cash compensation charge for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. We have included in our research and development total expenses the personnel costs associated with our departmental research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

General and administrative: General and administrative expenses increased by $3.2 million to $10.4 million for the nine months ended September 30, 2006, as compared to the same period of 2005. The increase was due primarily to a $2.6 million increase in non−cash compensation charges for stock option expense resulting from our adoption of SFAS No. 123(R) on January 1, 2006. Costs associated with our business development activities increased by $0.9 million to $2.4 million, primarily due to increased legal expenses and other consulting expenses related to our licensing activities and bonus payments made to certain company employees in recognition of their efforts in connection with the AstraZeneca licensing agreement. General and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses and public company activities.

Other income: Interest income was $0.7 million and $0.4 million for the nine months ended September 30, 2006 and 2005, respectively. Investment income from bond amortization for the period ended September 30, 2006 totaled $0.6 million as compared to $0.4 million during the same period of 2005.

Income Taxes

As of December 31, 2005, we had net operating loss carry−forwards of approximately $96.3 million and $80.7 million for federal and state income tax purposes, respectively, which expire between 2011 and 2020. We also have research and development tax credit carry−forwards of approximately $8.7 million for federal income tax reporting purposes that expire between 2012 and 2020. We currently estimate net operating loss, for tax purposes, of approximately $19.2 million for the twelve months ending December 31, 2006 and we estimate an effective tax rate of 0% for the nine month period ended September 30, 2006 based upon financial results available at September 30, 2006. Our effective tax rate was 0% for the nine month period ended September 30, 2005. The estimated effective rate was based upon estimates of loss for the fiscal year and our ability to use remaining net operating loss carry−forwards and other tax credits. However, the actual effective rate may vary depending upon actual licensing fees and milestone payments received, specifically the pre−tax book income for the year, and other factors. Income taxes have been accounted for using the liability method in accordance with SFAS 109, “Accounting for Income Taxes.” Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Tax Reform Act of 1986 (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 significantly 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 U.S. 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 income tax purposes. In July 2006, the FASB issued interpretation No. 48 “Accounting for Uncertainty in Income Taxes”, ("FIN 48"). FIN 48 clarifies SFAS No. 109 “Accounting for Income Taxes” by providing specific guidance in reporting uncertain income taxes recognized in a company's financial statements, including consistent recognition threshold, classification, interest and penalties and disclosures. FIN No. 48 is effective for us as of January 1, 2007. We have not yet determined the future impact of the adoption of FIN No. 48 on our financial position, results of operations or cash flows; however, there is no impact on our current financial statements.

Liquidity and Capital Resources

Since our inception, we have financed our operations and internal growth primarily through private placements of preferred stock and our initial public offering, resulting in cash inflows of $133.9 million, and since 2003, from upfront and milestone payments from our collaborators, resulting in cash inflows of $103.3 million. At September 30, 2006, cash and cash equivalents, along with short−term investments, totaled $66.6 million, an increase of $20.8 million compared to December 31, 2005. The increase in cash was primarily due to our receipt of a $40 million upfront license fee payment in September 2006 pursuant to our global collaboration agreement with AstraZeneca. Our cash and cash equivalents are 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.

During the nine month period ended September 30, 2006, we moved $25.0 million into 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. 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 in market value and cost is reported in the stockholder's equity section of our financial statements as comprehensive income or loss.

We received $40 million in operating cash during the nine month period ended September 30, 2006 pursuant to the terms of our collaboration agreement with AstraZeneca. In addition, we recorded a $1.6 million accounts receivable for invoiced development activities under the terms of the agreement. Cash received from financing activities during the period totaled $2.0 million reflecting net proceeds from the exercise of stock options.

Based upon the direct method of presenting cash flow, cash used in operating activities totaled $20.0 million for the nine−month period ended September 30, 2006. The indirect method for presenting cash flow is used in the Statement of Cash Flows included in our financial statements. Cash used in operating activities was $27.4 million for the fiscal year ended December 31, 2005, $26.4 million for the fiscal year ended December 31, 2004 and $18.4 million for the fiscal year ended December 31, 2003. Net cash provided by investing activities during the nine month period ended September 30, 2006 totaled $0.6 million, reflecting investing activities associated with the sale of short−term securities. Cash required for our operating activities during 2006 is projected to approximate our 2005 requirements. During the nine month period ended September 30, 2006 we recorded non−cash stock−based compensation expense of $4.7 million as a result of adopting SFAS No. 123(R) on January 1, 2006. We also reclassified, from current liabilities to additional paid−in capital, $1.4 million of prior year accrued compensation related to the expensing of restricted stock units and performance based options granted under the Trexima incentive program. This reclassification also resulted from our adoption of SFAS No. 123(R).

As of September 30, 2006, we had $33.2 million in cash and cash equivalents and $33.5 million in short−term investments. If our operating expenses for 2006 and 2007 remain at the level of our operating expenses in 2005, we believe that we will have sufficient cash reserves to maintain that level of business activities throughout 2007 provided that certain development expenses are paid by AstraZeneca, as outlined in the agreement.

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 issue 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 (SEC), and the SEC has declared effective, a shelf registration statement on Form S−3 under which we may register up to 8,540,000 shares of our common stock for sale in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to an aggregate of 540,000 of such shares, and we will not receive any of the proceeds from the sales of shares made by the selling stockholders. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

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

- the number and progress of our clinical trials and other trials and studies;
- our success in obtaining, and 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;
- 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 the class action lawsuit that is pending against us and our president and chief executive officer relating to MT 100 and MT 300.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The proceeds from our initial public offering and, private placements and revenue from our collaboration agreements have been invested, in accordance with our investment policy, 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

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness our disclosure controls and procedures 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 were designed and 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 recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. We believe that 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.

(b) Change in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during our most recent 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

Five purported class action lawsuits were filed during 2004 by holders of our securities against us and certain of our current and former officers, in the U. S. District Court for the Middle District of North Carolina, alleging violations of securities laws. These actions were filed as a single consolidated amended complaint on December 20, 2004. The amended complaint alleges, among other claims, violations of federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b−5 and Section 20(a) of the Exchange Act against us and Dr. John R. Plachetka, our chairman and chief executive officer, arising out of allegedly false and misleading statements made by us concerning our product candidates, MT 100 and MT 300, during the class period. The amended complaint requests certification of a plaintiff class consisting of purchasers of our stock between October 4, 2002 and May 28, 2004. On January 27, 2005, we filed a motion to dismiss the amended complaint. On August 30, 2005, our motion to dismiss was denied and the case is now in the discovery phase. On March 27, 2006, a motion for class certification was filed. We filed our brief in opposition to class certification on June 30, 2006.

We believe that the allegations in the class action lawsuit are without merit and intend to defend this action vigorously. While we cannot predict the outcome or reasonably estimate the range of potential loss, if any, from this litigation, it is the current judgment of management that it is unlikely that this litigation will have a material adverse effect on our results of operation or financial condition.

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 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 development, approval and commercialization of our current product candidates. Many factors could negatively affect our ability to obtain regulatory approval for our product candidates. For example, in June 2006 we received an approvable letter relating to our NDA for Trexima, in which the FDA requested additional safety information on Trexima which will require some additional studies. We expect to submit a full response to the FDA's approvable letter in the fourth quarter of 2006. However, there can be no guarantee that the FDA will approve our NDA based on the information contained in our response to the approvable letter, or at all. Further, we have decided to discontinue development of MT 100 in the U.S. and to explore the possibility of selling or otherwise disposing of the MT 100 asset, based upon the determination of an FDA Advisory Committee in August 2005. The FDA Advisory Committee determined, following our receipt of a not approvable letter from the FDA in 2004 for our NDA for MT 100, that the potential, but unquantified, risk of tardive dyskinesia, an involuntary movement disorder associated with the use of metoclopramide, one of the components of MT 100, outweighed the benefits, as defined by the FDA, of metoclopramide hydrochloride in combination with naproxen sodium. Further, based upon our understandings from our recent communications with the FDA, in which the FDA restated its concerns that approval of MT 300 was problematic due to the higher incidence of nausea at two hours following dosing in patients treated with MT 300 compared with placebo, we do not believe it is possible to reverse the not approvable status of MT 300 stated in the not approvable letter we received from the FDA in 2003. 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.

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. We do not have a current source of product revenue.

We have incurred significant losses since our inception. As of September 30, 2006, we had an accumulated deficit of approximately $131.5 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 of payments that we may receive from others. We expect to continue to incur significant operating losses and do not know when, if and to what extent we will generate product revenue.

Our only current potential sources of revenue are the payments that we may receive pursuant to our collaboration agreements with GSK and AstraZeneca. Our remaining milestone payments under our collaboration agreement with GSK related to Trexima are payable upon FDA approval of and GSK's intent to commercialize Trexima. As a result of our receipt in June 2006 of an approvable letter relating to our NDA for Trexima requesting certain additional safety information, we cannot guarantee when or if we will receive future payments under that agreement. Further, we may have to pay Valeant NA a $1.0 million withdrawal fee if we do not prevail in our current dispute with them as to whether the withdrawal fee is payable. This amount is currently reflected in our financial statements as deferred revenue and will never be recognized as revenue if repaid.

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

The process of drug development and regulatory approval for product candidates takes many years, during which time the FDA's interpretations of the standards against which drugs are judged for approval may evolve or change. The FDA can also change its approval policies based upon changes in laws and regulations. In addition, it can decide, based on its then current approval policies, any changes in those policies and its broad discretion in the approval process, to weigh the benefits and the risks of every drug candidate. As a result of any of the foregoing, the FDA may decide that the data we submit in support of an application for approval of a drug candidate are insufficient for approval. 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 and 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 (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. For example, we believe that long−term cardiovascular safety studies will be required for NDA approval of our oral lornoxicam product candidate. We do not know to what extent the FDA's actions may otherwise adversely affect or delay the approvability of our product candidates which 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 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 United States. 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. None of our product candidates have been approved for sale in the U.S. or any foreign market (except for MT 100, which has been approved for sale in the UK) and they may never be approved. For example, in June 2006, we received an approvable letter relating to our NDA for Trexima, in which the FDA requested additional safety information on Trexima thereby delaying regulatory approval, and any subsequent commercial sales, if at all. We 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. Further, under our MT 300 collaboration agreement with Valeant NA, we may elect 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. If we notify Valeant NA of this situation and Valeant NA elects not to assume control of efforts to seek approval of the NDA, then upon notice from Valeant, the agreement would terminate and we would be required to pay to Valeant NA a withdrawal fee of $1.0 million. In 2005 we began discussions regarding termination of our commercialization agreement with Valeant NA. On July 21, 2005, we received a letter from Valeant NA seeking payment of the $1.0 million withdrawal fee required under certain conditions under the agreement. We do not believe that the withdrawal fee is payable based on our receipt of a not−approvable letter from the FDA with respect to our NDA for MT 300. 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 in the agreement. 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 $1.0 million withdrawal fee.

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 (“cGMP”) regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation.

Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product candidates, and are subject to additional FDA inspection. We, or our third−party manufacturers, may not be able to comply with cGMP regulations or other FDA regulatory requirements, which could result in a delay or an inability to manufacture the products.

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 impair our ability to effectively 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 believe are necessary or desirable for the promotion of our product candidates.

Because we do not believe it is possible to convince the FDA to reverse its conclusion as stated in its not−approvable letter for MT 300, we do not expect to receive any revenue from sales of MT 300 in the United States.

In October 2003, we received a not−approvable letter from the FDA related to our NDA for MT 300. The letter was issued based on the FDA's conclusion that we had not submitted substantial evidence of effectiveness for MT 300 as an acute treatment for migraine. The FDA noted that, although MT 300 provided a statistically significant improvement over placebo on the pre−defined endpoint of sustained pain relief at 24 hours post dose as well as relief of pain at two hours post dose, MT 300 failed to achieve statistical significance versus placebo for the relief of all of the ancillary symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Further, the FDA noted that the incidence of nausea, one of the associated symptoms of migraine, was statistically significantly higher following MT 300 treatment versus placebo at two hours. Since our receipt of the not−approvable letter, we have had continuing communications with the FDA regarding the MT 300 NDA. Based upon our understandings from our most recent communications 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 MT 300 NDA. Therefore, we do not believe that we will receive any revenue from sales of MT 300 in the U.S.

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

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

In addition, 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 as our license and development agreement with Nycomed pursuant to which we obtained an exclusive license to certain rights to develop, manufacture and commercialize products containing lornoxicam. 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 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 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, as well as under our lornoxicam license agreement with Nycomed described above, our collaborators have the right to terminate the agreement upon a default by us. In addition, GSK and AstraZeneca are entitled to terminate their agreements upon 90 days' notice for any reason. Substantial delays in obtaining regulatory approval to market Trexima, such as may result from our receipt in June 2006 of an approvable letter relating to our NDA for Trexima in which the FDA requested additional safety information, could increase this risk of termination of the GSK agreement. Additionally, both GSK and AstraZeneca have the right to reduce the royalties on net sales of products payable to us under the 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. Valeant NA is entitled to terminate its agreement with us and a $1.0 million withdrawal fee 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, we began discussions with Valeant NA regarding termination of our agreement. Valeant NA has demanded payment of the $1.0 million withdrawal fee, which POZEN is 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 Trexima clinical trials. 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 commercialization we are currently experiencing as a result of the approvable letter we received from the FDA in June 2006 related to our Trexima NDA, would delay or 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 the respective agreements and would have exclusive control over such enforcement litigation.

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;

- 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 instead.

We have entered into collaboration and license agreements, and expect to continue to enter into such agreements, with companies that have products and are developing new product candidates that compete or may compete with our product candidates. 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 agreement with GSK is subject to this risk. GSK has publicly disclosed that it is exploring the development of several early−stage compounds for the treatment of migraine. If GSK decides to focus its development and commercialization efforts on its own products rather than continuing to work with us on Trexima or any other product candidates that may be developed under the agreement, it has the ability to terminate our agreement upon 90 days' written notice. Any substantial delays in obtaining, or failure to obtain, regulatory approval from the FDA to market Trexima, including as a result of our receipt in June 2006 from the FDA of an approvable letter requesting additional safety information for Trexima, would exacerbate this risk. In such a case, we would need to enter into a new development and commercialization agreement and would need to start the development process all over again. If we were able to negotiate a new development and commercialization agreement to develop our MT 400 technology, which is not certain, we would face delays and redundant expenses in that development.

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

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

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, and clinical trials for our product candidates. Any negative or unanticipated results, unforeseen costs or delays in the conduct of these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could cause us to discontinue development of a product candidate or reduce, delay or eliminate our receipt of 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, 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 Trexima 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 Trexima failed to achieve statistical significance at two hours compared to placebo in the relief of nausea. In the second Phase 3 pivotal clinical trial, Trexima 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 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 is unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. For example, even though we are entitled to submit an NDA for Trexima as a 505(b)(2) application, the FDA may require us to conduct more studies or trials than we now believe are necessary or required.

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 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 a have 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, results from a genotoxicity study involving MT 400 may require us to conduct chronic toxicology and carcinogenicity studies for Trexima or other MT 400 product candidates we may develop.

Once submitted, an NDA requires FDA approval before we can distribute or commercialize the product described in the application. 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 has requested additional safety information on Trexima in the approvable letter we received in June 2006 relating to our NDA for Trexima, which will require some additional studies. There is no guarantee that such studies will be successful or that the FDA will approve the NDA based on the additional information and study results contained in our submission in response to the FDA's approvable letter, or at all. Further, although we believe that we provided the necessary data to support approval of the NDAs for MT 100 and MT 300, the FDA issued not−approvable letters for the MT 100 and MT 300 NDAs on May 28, 2004 and October 17, 2003, respectively, and based upon our understandings from our most recent communication with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the NDA for MT 300. In addition, based upon our receipt of the not approvable letter for MT 100 and the outcome of an August 2005 FDA Advisory Committee meeting relating to the potential risk of tardive dyskinesia associated with the use of one of the components of MT 100, we made the decision to discontinue further development of MT 100 in the U.S.

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

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

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

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 are currently experiencing as a result of the approvable letter we received from the FDA in June 2006 relating to the Trexima NDA, and as we previously experienced as a result of the not−approvable letters we received from the FDA on MT 100 and MT 300, increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non−competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

If there is an adverse outcome in the securities class action lawsuits that have been filed against us or our current or former directors and officers, our business may be materially harmed. Further, defending against these lawsuits may be expensive and will divert the attention of our management.

Four purported class action lawsuits claiming violations of securities laws were filed between June 4 and July 28, 2004 in the U.S. District Court for the Middle District of North Carolina by holders of our securities against us and certain of our current and former officers. These actions have been consolidated for pre−trial purposes. A fifth case filed on August 6, 2004 has also been consolidated with those actions for pre−trial purposes. By order dated November 4, 2004, the court appointed a lead plaintiff, who filed a consolidated amended complaint (amended complaint) on December 20, 2004. The defendants named in the amended complaint are POZEN and John R. Plachetka, our chairman and chief executive officer. The complaint alleges violations of federal securities laws, including violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b−5, and violations of Section 20(a) of the Exchange Act against Dr. Plachetka. The amended complaint alleges that we made false and misleading statements concerning our product candidates MT 100 and MT 300 during the class period. The amended complaint requests certification of a plaintiff class consisting of purchasers of our stock between October 4, 2002 and May 28, 2004. In January 2005, we moved to dismiss the amended complaint. On August 30, 2005, our motion to dismiss the complaint was denied and the case is now in the discovery phase. On March 27, 2006, a motion for class certification was filed. We filed our brief in opposition to class certification on June 30, 2006.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of the pending class action lawsuit described above. Furthermore, we will have to incur expenses in connection with this lawsuit, which may be substantial. In the event of an adverse outcome, our business could be materially harmed. Moreover, responding to and defending the 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. In addition, due to the extensive time needed to develop and test our products, any patents that we obtain may expire in a short time after commercialization. This would reduce or eliminate any 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. 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. Such opposition proceedings may not be resolved for several years, and may result in the revocation of the issued patent.

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 a risk exists 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.

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. As a result of such litigation, our patent claims may be found to be invalid, unenforceable or not of sufficient scope to cover the activities of an alleged infringement. 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 have the first right to enforce our patents under their respective agreements.

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

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

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

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

None of our future products may be accepted by the market.

Even if our product candidates perform successfully in clinical trials and are approved by the FDA and other regulatory authorities, our future products may not achieve market acceptance and may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

- 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 us and third−party distributors and agents;
- the existence of adverse publicity regarding our products or similar products; and
- the extent and severity of side effects as compared to alternative therapies.

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

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

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

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

The testing and marketing of pharmaceutical products entails 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 human clinical trials in an amount equal to up to $10.0 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 intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our products and commercial sales of the product 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.

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 arrange for the commercialization of our product candidates.

Our operating expenses for the nine−month period ended September 30, 2006 totaled $26.8 million, including non−cash compensation expense of $4.7 million related to stock options and other stock−based awards, primarily associated with our adoption of SFAS No. 123(R) on January 1, 2006. For fiscal years 2003 through 2005, our average annual operating expenses (including average non−cash deferred compensation of $0.6 million) were $25.4 million. We are currently expecting operating expenses for the 2006 fiscal year to be between $35.0 million and $36.0 million, including non−cash compensation expenses, related to stock options and other stock−based awards expected to be $6.5 million, resulting from our adoption of SFAS 123(R) on January 1, 2006. As of September 30, 2006, we had an aggregate of $66.6 million in cash and cash equivalents and short−term investments. If our operating expenses for 2006 and 2007 remain at the level of our operating expenses in 2005, we believe that we will have sufficient cash reserves to maintain that level of business activities throughout 2007 provided that certain development expenses are paid by AstraZeneca, as outlined in the agreement. However, our expenses might increase in 2007 and 2008 beyond currently expected levels if any regulatory agency requires us to conduct additional clinical trials, studies or investigations, including in connection with their consideration, or reconsideration, of our regulatory filings for our product candidates. In addition, we may be required to pay Valeant NA a withdrawal fee of $1.0 million if we do not prevail in our current dispute with them as to whether the withdrawal fee is payable under our MT 300 collaboration agreement.

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

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

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

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an amended and restated employment agreement with us on March 14, 2006, 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. 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. Marshall E. Reese, Executive Vice President, Product Development, William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer, or Kristina M. Adomonis, Senior Vice President, Business Development or if we fail to recruit other key scientific personnel, we may be unable to achieve our business objectives. There is intense competition for qualified scientific personnel. Since our business is very science−oriented, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

Factors That May Affect Our Stockholders

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

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

- fluctuations in our operating results;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- 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, through September 30, 2006, the high and low closing prices of our common stock ranged from $2.25 to $21.75. Broad market fluctuations may also adversely affect the market price of our common stock.

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

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market and four of our stockholders and their affiliates beneficially hold approximately 34% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, as we recently announced, beginning in September 2006 our chief executive officer and one of our directors may sell up to an aggregate of 1,010,000 shares pursuant to Rule 10b5−1 trading plans. Further, stockholders' ownership will be diluted if we raise additional capital by issuing equity securities. We have filed with the SEC, and the SEC has declared effective, a shelf registration statement on Form S−3 under which we may register up to 8,540,000 shares of our common stock for sale to the public in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to 540,000 of such shares, and we would not receive any of the proceeds from sales of those shares.

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

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

- authorize the issuance of “blank check” preferred stock without any need for action by stockholders;
- provide for a classified board of directors with staggered three−year terms;
- require supermajority stockholder approval to effect various amendments to our charter and bylaws;

- eliminate the ability of stockholders to call special meetings of stockholders;

- prohibit stockholder action by written consent; and

- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

Item 6. Exhibits

Exhibit Number	Description
10.1	Collaboration and License Agreement dated August 1, 2006 between the Registrant and AstraZeneca AB.
10.2	Side Letter dated September 19, 2006 Re: Collaboration and License Agreement dated as of August 1, 2006 by and between POZEN INC. and AstraZeneca AB
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.

Confidential treatment requested as to certain portions.

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)	
November 3, 2006	By:	/s/ JOHN R. PLACHETKA John R. Plachetka President and Chief Executive Officer
November 3, 2006	By:	/s/ WILLIAM L. HODGES William L. Hodges Chief Financial Officer
November 3, 2006	By:	/s/ JOHN E. BARNHARDT John E. Barnhardt Principal Accounting Officer

EXHIBIT INDEX

Exhibit Number	Description
10.1	Collaboration and License Agreement dated August 1, 2006 between the Registrant and AstraZeneca AB.
10.2	Side Letter dated September 19, 2006 Re: Collaboration and License Agreement dated as of August 1, 2006 by and between POZEN INC. and AstraZeneca AB
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.

Confidential treatment requested as to certain portions.

EXHIBIT 10.1

Execution Copy

COLLABORATION AND LICENSE AGREEMENT

by and between

POZEN INC.

and

ASTRAZENECA AB

August 1, 2006

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COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (**"Agreement"**) is made and entered into effective as of August 1, 2006 (the **"Execution Date"**), by and between **POZEN INC.**, a Delaware corporation having offices at 1414 Raleigh Road, Suite 400, Chapel Hill, North Carolina (**"POZEN"**), and ASTRAZENECA AB, a Swedish corporation having an office at SE−431 83, Mölndal, Sweden (**"AstraZeneca"**). POZEN and AstraZeneca each may be referred to herein individually as a **"Party**,**"** or collectively as the **"Parties**.**"**

RECITALS

A. POZEN controls certain patents and other intellectual property pertaining to pharmaceutical products having gastroprotective agents in single fixed combination oral solid dosage form with non−steroidal anti−inflammatory drugs.

B. AstraZeneca desires to obtain a license to POZEN's intellectual property and to enter into a collaboration with POZEN for the purpose of developing and commercializing certain pharmaceutical products.

C. POZEN desires to grant AstraZeneca such a license and to enter into such a collaboration on the terms and conditions set forth in this Agreement.

In consideration of the foregoing premises, the mutual promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, POZEN and AstraZeneca hereby agree as follows:

AGREEMENT

1. DEFINITIONS

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement. All financial and accounting terms not otherwise defined in this Agreement, whether capitalized or not, shall have the meanings assigned to them in accordance with generally accepted accounting principles based on International Accounting Standards/International Financial Reporting Standards as in effect from time to time (**"IFRS"**).

1.1 "ADA Budget" has the meaning set forth in Section 3.3.3 (Expenses).

1.2 "Additional Development Activities" means any activities related to the Development of the Initial POZEN Product that are not Core Development Activities. Additional Development Activities agreed upon as of the Execution Date are included in the Initial U.S. Development Plan and Initial ROW Development Plan.

****** Portion for which confidential treatment requested.

1.3 "Adverse Event" means any adverse medical occurrence in a patient or clinical investigation subject that is administered a pharmaceutical product, as designated under 21 CFR § 312.32 and any other Applicable Law in the Territory.

1.4 "Affiliate" means a legal entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with an entity. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a legal entity; provided, that if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

1.5 "Applicable Law" means the laws, rules, and regulations, including any statutes, rules, regulations, guidelines, or other requirements that may be in effect from time to time and apply to the activities contemplated by this Agreement in the Territory.

1.6 "AstraZeneca House Marks" means any trademarks, trade names, domain names, or other names or marks used or registered by AstraZeneca or its Affiliates at any time during the Term to identify itself.

1.7 "AstraZeneca Invention" means any Invention that is conceived solely by one or more employees, agents, or independent contractors of AstraZeneca or its Affiliate(s).

1.8 "Blocking Patent" means a Patent owned or controlled by a Third Party, one or more Valid Claims of which, in the absence of a license thereunder, would be infringed by the making, use, sale, offering for sale, or importation of a POZEN Product.

1.9 "Budgeted Development Activities" means the Additional Development Activities described in the first ADA Budget approved by the GPT pursuant to Section 3.3.3 (Expenses) and the first U.S. Development Plan and first ROW Development Plan approved by the GPT pursuant to Section 3.1 (Development Plans), in each case consistent with the Initial U.S. Development Plan and Initial ROW Development Plan.

1.10 "Business Combination" means any merger, consolidation, sale of stock, sale or transfer of all or substantially all of the assets, or other similar transaction to which POZEN is a party, other than any merger, consolidation, or similar transaction following which the individuals and entities who were the beneficial owners of the outstanding voting securities of POZEN immediately prior to such transaction still beneficially own, directly or indirectly, more than fifty percent (50%) of the voting power of the surviving entity immediately after such transaction.

1.11 "Business Day" means any day other than (i) Saturday or Sunday or (ii) any other day on which banks in New York, New York, United States, the United Kingdom or Sweden are permitted or required to be closed.

****** Portion for which confidential treatment requested.

1.12 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.13 "cGCP" means current good clinical practices as defined in U.S. Regulations 21 CFR §§ 50, 54, 56, 312 and 314, (or in the case of foreign jurisdictions, comparable regulatory standards), the International Conference of Harmonization (ICH) E6 "Good Clinical Practice: Consolidated Guidance," and in any successor regulation or any official guidance documents issued by an applicable Regulatory Authority.

1.14 "cGLP" means current good laboratory practice standards as defined by the FDA pursuant to 21 CFR Part 58 (or in the case of foreign jurisdictions, comparable regulatory standards), and in any successor regulation or any official guidance documents issued by a Regulatory Authority.

1.15 "cGMP" means current good manufacturing practices as contained in 21 CFR Parts 210 and 211 as amended from time to time and any equivalents contained in regulations in countries outside the U.S.

1.16 "Change of Corporate Control" means the occurrence of either of the following:

(a) a Business Combination involving POZEN; or

(b) the acquisition (whether in a single transaction or series of related transactions) after the Effective Date by a Third Party or Group of beneficial ownership of ******* percent (*******%) or more of POZEN's voting securities.

1.17 "Clinical Trial Materials" means the Initial POZEN Product formulated in accordance with the specifications of Schedule 6.1, matching placebo and matching individual ingredients and comparators, each packaged and labeled for use in the applicable clinical trial.

1.18 "Combination Product" means a Product that includes one or more pharmaceutically active ingredients (in addition to a single Gastroprotective Agent and a single NSAID) and is sold in final form either in a single fixed combination oral solid dosage or as separate doses in a single package and priced as one item.

1.19 "Commercial Launch" means the nationwide commercial sale, promotion and distribution of POZEN Product in a particular country of the Territory following receipt of Marketing Approval in such country.

****** Portion for which confidential treatment requested.

1.20 "Commercialization" means all activities relating to the manufacture, marketing, promotion, advertising, selling and distribution of Product in any country of the Territory, including pre−Commercial Launch market development activities conducted in anticipation of Marketing Approval of Product, including, without limitation, seeking pricing and reimbursement approvals for Product, preparing advertising and promotional materials, sales force training, and all interactions and activities (*e.g.*, dossier preparations and filings) associated with Regulatory Authorities regarding the commercialization of Product and the maintenance of Marketing Approvals. The term "Commercialize" has a correlative meaning.

1.21 "Commercialization Plan" has the meaning set forth in Section 5.4.1.

1.22 "Commercialized POZEN Product" has the meaning set forth in Section 12.6.4(b)(ii).

1.23 "Competing Product" means, with respect to a particular Product being Commercialized by AstraZeneca or any of its Affiliates or Sublicensees in any country of the Territory, a product being marketed by or on behalf of a Third Party (other than a Sublicensee) in the same country containing at least ****** that are ****** those in the ******and are ******.

1.24 "Controlled" means, with respect to any Know−How, Patent, or other intellectual property right, the possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Know−How, Patent or right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party.

1.25 "Core Development Activities" means any activities identified on Exhibit B as being paid for by POZEN.

1.26 "DDMAC" means the FDA's Division of Drug Marketing, Advertising, and Communications.

1.27 "Develop" or "Development" means all activities relating to pre−clinical and clinical development of a Product and all development activities relating to the preparation and filing of NDAs and obtaining of Marketing Approvals, price and reimbursement approvals, including, without limitation, preparing and conducting pre−clinical testing, toxicology testing, human clinical studies, regulatory affairs.

1.28 "Development Program" means the program of Development described in the U.S. Development Plan and ROW Development Plan, each as amended from time to time.

****** Portion for which confidential treatment requested.

1.29 "Diligent Efforts" means, (A) with respect to the Development, Manufacture or Commercialization by AstraZeneca of a product, at any given time as the case may be, efforts and resources reasonably used by AstraZeneca or its Affiliates (giving due consideration to relevant industry standards) for AstraZeneca's own products (including internally developed, acquired and in−licensed products) with similar commercial potential at a similar stage in their lifecycle (assuming continuing development of such product), taking into consideration their safety, tolerability and efficacy, the profitability (taking into account any payments payable under this Agreement), the extent of market exclusivity, patent protection, cost to develop the product, promotable claims, and health economic claims, and (B) with respect to the Development by POZEN of a product, at any given time as the case may be, efforts and resources reasonably used by an entity in the pharmaceutical industry of similar resources and expertise as POZEN, for such similar entity's own products (including internally developed, acquired and in−licensed products) with similar commercial potential at a similar stage in their lifecycle (assuming continuing development of such product), taking into consideration their safety, tolerability and efficacy, the profitability (taking into account any payments payable under this Agreement), the extent of market exclusivity, patent protection, cost to develop the product, promotable claims, and health economic claims.

1.30 "Direct Costs" means all amounts which POZEN disburses to vendors for services rendered or product supplied in conducting studies pursuant to this Agreement. For clarification, no POZEN employee compensation, internally consumed supplies, utility charges, recoverable Indirect Taxes or other indirect costs will be included in Direct Costs.

1.31 "Effective Date" has the meaning as defined in Section 12.1 (HSR Act).

1.32 "**EMEA**" means the European Medicines Agency, or any successor agency thereto.

1.33 "Esomeprazole" means that certain pharmaceutical compound with the name (5−methoxy−2−{(S)−[(4−methoxy−3,5−dimethylpyridin−2−yl)methyl]sulfinyl}−1H−benzimidazole), including any ******.

1.34 "FDA" means the United States Food and Drug Administration, or any successor agency thereto.

1.35 "Field of Use" means the treatment of human diseases and conditions by means of a pharmaceutical product.

1.36 "First Commercial Sale" means, with respect to a Product and on a country−by−country basis, the date on which AstraZeneca or its Affiliate or Sublicensee first sells the Product intended for commercial distribution to any Third Party after receipt of NDA Approval of such Product in such country (including, without limitation, sale in an individual state, province or similar sub−national political subdivision in which Marketing Approval may be received). Sale of a Product for clinical studies, compassionate use, named patient programs, under a treatment IND, test marketing, any clinical studies, or any similar instance where the Product is supplied with or without charge will not constitute a First Commercial Sale.

****** Portion for which confidential treatment requested.

1.37 "Formulation Budget" has the meaning set forth in Section 6.1.4 (Expenses).

1.38 "Formulation Development Activities" has the meaning set forth in Section 6.1.4 (Expenses).

1.39 "Formulation Technology" means any Know−How Controlled by AstraZeneca in the AstraZeneca Inventions that are used by AstraZeneca in the manufacture, use, sale or import of the formulation of a Commercialized POZEN Product, and any Patents Controlled by AstraZeneca claiming such AstraZeneca Inventions; provided, that Formulation Technology will not include any Patents or Know−How to the extent directed to a Gastroprotective Agent, non−steroidal anti−inflammatory, or other drug or chemical agent, or any methods of manufacture or use thereof.

1.40 "FTE Costs" means an amount equal to $****** multiplied by the total number of hours spent by POZEN development personnel ****** conducting Additional Development Activities for the Development of Initial POZEN Products pursuant to this Agreement in accordance with a Development plan and budget approved by the GPT.

1.41 "Gastroprotective Agent" means proton pump inhibitors and H2 receptor antagonists for the treatment, prevention or amelioration of injury to the gastrointestinal tract.

1.42 "GPT" means AstraZeneca's global product team operating pursuant to AstraZeneca's instructions for global product teams for the Initial POZEN Product with representatives of AstraZeneca having expertise in the areas of research & development, marketing, regulatory, intellectual property, finance, toxicology, and other areas.

1.43 "GPT Chair" will have the meaning set forth in Section 2.2.1 (GPT) .

1.44 "Group" means a group of related persons or entities deemed a "person" for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended.

1.45 "IND" means an Investigational New Drug Application filed with the FDA pursuant to 21 CFR § 312.20, or the corresponding filing in any country or regulatory jurisdiction other than the United States required for the clinical testing in humans of a pharmaceutical product.

1.46 "Indirect Tax" means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.47 "Initial POZEN Product" means the POZEN Product containing non−enteric coated Esomeprazole and enteric−coated Naproxen that is the subject of the Initial U.S. Development Plan and Initial ROW Development Plan, subject to substitution (either throughout the Territory or in any one or more countries of the Territory) in accordance with Section 3.4.2 (Substitution) hereof.

1.48 "Initial ROW Development Plan" means the outline for the ROW Development Plan, as set forth in Exhibit D as of the Effective Date.

****** Portion for which confidential treatment requested.

1.49 "Initial ROW Development Plan Timeline" means the ROW Development Plan Timeline attached to this Agreement as Exhibit E as of the Effective Date.

1.50 "Initial U.S. Development Plan" means the outline for the U.S. Development Plan, as set forth in Exhibit B as of the Effective Date.

1.51 "Initial U.S. Development Plan Timeline" means the U.S. Development Plan Timeline attached to this Agreement as Exhibit C as of the Effective Date.

1.52 "Invention" means any invention, discovery or Know−How that is conceived during the Term in the performance of activities undertaken pursuant to this Agreement by employees, agents, or independent contractors of either Party, its Affiliates or Sublicensees and is Controlled by such Party, Affiliates or Sublicensees.

1.53 "Joint Invention" means any Invention that is conceived jointly by one or more employees, agents, or independent contractors of AstraZeneca or its Affiliate(s) and one or more employees, agents, or independent contractors of POZEN or its Affiliate(s).

1.54 "Joint Patent" means a Patent claiming a Joint Invention.

1.55 "JSC" has the meaning set forth in Section 2.1.2 (Joint Steering Committee).

1.56 "Know−How" means any non−public, documented or otherwise recorded or memorialized knowledge, experience, know−how, technology, information, and data, including formulas and formulations, processes, techniques, unpatented inventions, discoveries, ideas, and developments, test procedures, and results, together with all documents and files embodying the foregoing.

1.57 "Licensed Know−How" means any Know−How that is necessary or useful for the Development, Manufacture or Commercialization of Product in the Field of Use and that is Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term.

1.58 "Licensed Patents" means: (a) the Patents set forth on Schedule 1.58, and any substitutions, divisions, continuations, continuations−in−part, reissues, renewals, registrations, confirmations, re−examinations, or extensions of such Patents, (b) any Patents Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that claim Inventions (including without limitation POZEN's interest in Joint Inventions), (c) all other Patents Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that are necessary or useful for the Development, Manufacture or Commercialization of a Product; and any foreign counterparts of any of the foregoing.

1.59 "Licensed Technology" means the Licensed Patents and the Licensed Know−How.

1.60 "Major Ex−U.S. Market" means the following countries: ******, or any country substituted for one of the foregoing countries pursuant to Section 4.1.2. (Outside the U.S.).

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1.61 "Manufacture" means all activities related to the manufacturing of a Product, or any ingredient thereof, including but not limited to formulation development and process development for the manufacture of a Product, manufacturing supplies for Development, manufacturing for commercial sale, packaging, in−process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing. "Manufacture" shall not include any of the above activities with respect to Esomeprazole as an active ingredient.

1.62 "Market Reduction" has the meaning set forth in Section 8.4.3 (Rate Step Down for Competing Product Entrants).

1.63 "Marketing Approval" means all approvals (including NDA Approvals and, where available under Applicable Law, pricing and reimbursement approvals in accordance with Applicable Law) of any Regulatory Authority in a country, that are necessary or useful to be obtained prior to the manufacture or Commercialization of a Product in that country. For purposes of clarification, "Marketing Approval" in the U.S. shall have the same meaning as NDA Approval in the U.S.

1.64 "Milestone Events" means the events listed under the heading "Milestone Events" in the table in Section 8.2 (Development Milestone Payments).

1.65 "Naproxen" means that certain pharmaceutical compound with the chemical name (S)−6−methoxy−(alpha)−methyl−2−naphthaleneacetic acid, including any ******.

1.66 "NDA" means a New Drug Application filed with the FDA as described in 21 CFR § 314, or any corresponding application for Regulatory Authority approval (not including pricing and reimbursement approval) in any country or regulatory jurisdiction other than the U.S.

1.67 "NDA Approval" means receipt of a letter from the FDA, or equivalent Regulatory Authority in jurisdictions outside the U.S., approving an NDA.

1.68 "Net Sales" means with respect to any Product, the gross amounts recognized by AstraZeneca, its Sublicensees or its Affiliates from Third Party customers for sales of a Product in the Territory, less the following deductions made by AstraZeneca (to the extent not already taken by AstraZeneca in the Product invoice or in amounts recognized), its Sublicensees or its Affiliates in arriving at net sales as reported in the AstraZeneca statutory accounts prepared in accordance with IFRS:

(a) actual credited allowances to such Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned Product and for retroactive price reductions;

(b) the amounts of trade and cash discounts actually granted to Third Party customers, to the extent such trade and cash discounts are specifically allowed on account of the purchase of such Product;

****** Portion for which confidential treatment requested.

(c) sales taxes, excise taxes and import/export duties actually due or incurred in connection with the sales of a Product to any Third Party customer;

(d) allowances, adjustments, reimbursements, discounts, chargebacks and rebates actually granted to Third Party customers (not in excess of the selling price per unit of such Product);

(e) other deductions from gross sales made in arriving at net sales as reported in the AstraZeneca statutory accounts; and

(f) allowance for transportation costs, distribution expenses, special packaging and related insurance charges in the amount of ****** percent (*******%) of the Net Sales calculated after applying the deductions of items (a)−(e) above.

Net Sales shall be calculated using AstraZeneca's internal audited systems used to report such sales as adjusted for any of items (a)−(f) above not taken into account in such systems. Notwithstanding the foregoing, if Product is sold as a Combination Product, the Net Sales used for the calculation of the royalties under Section 8.4 (Royalties) shall be determined as follows:

****** Portion for which confidential treatment requested.

$\frac{A}{A+B}$ X Net Sales of the Combination Product, where:

A = Standard Sales Price of the ready−for−sale form of the Product if sold separately from the Combination Product in question, in the given country.

B = Standard Sales Price of the ready−for−sale form of a product containing the same amount of the other therapeutically active ingredient(s) that is contained in the Combination Product in question, in the given country.

If, in a specific country, (a) the other therapeutically active ingredient(s) in such Combination Product are not sold separately in such country, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A/C, where C is the Standard Sales Price in such country of such Combination Product, and (b) if a Product contained in the Combination Product is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction (C−B)/C, where B is the Standard Sales Price in such country of the other therapeutically active ingredient(s) in the Combination Product and C is the Standard Sales Price in such country of the Combination Product. If, in a specific country, both a Product in a Combination Product and a product containing the other active ingredients in such Combination Product are not sold separately, a market price for such Product and such other active ingredients shall be negotiated by the Parties in good faith based upon the market price of products that are comparable to such Product or such other active ingredients, as applicable. In each country where the Product in the Combination Product is marketed, the Standard Sales Price of the Product in such Combination Product for purposes of calculating the royalty payable to POZEN will be no less than ****** percent (******%) of the Standard Sales Price of the Product sold outside of such Combination Product in such country.

In addition, and notwithstanding the foregoing, if a Product is sold together with other goods with or without a separate price for such Product (such group of products including the Product a **"Product Set"**), then the Net Sales applicable to the quantity of such Product included in any such transaction will be calculated as follows:

$\frac{A}{A+B}$ X Net Sales of the Product Set, where:

A = Standard Sales Price of the Product if sold separately from the Product set in question, in the given country.

B = The total of the Standard Sales Prices of all products in the Product Set other than the Product, in the given country.

****** Portion for which confidential treatment requested.

1.69 "Nexium" means AstraZeneca's products containing Esomeprazole as the sole active ingredient in any presentation form.

1.70 "Nexium Business" means AstraZeneca's development and commercialization activities pertaining to Esomeprazole and Esomeprazole based products.

1.71 "NSAID" means any non−steroidal anti−inflammatory drug, the primary mechanism of action of which is inhibition of cyclooxygenase, but excluding acetyl salicylic acid (including salts and derivatives thereof).

1.72 "Patent Challenge" has the meaning set forth in Section 9.9.

1.73 "Patents" means (a) all patents and patent applications in any country or supranational jurisdiction, and (b) any substitutions, divisions, continuations, continuations−in−part, reissues, renewals, registrations, confirmations, re−examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent applications.

1.74 "****"** has the meaning set forth in Section 6.1.3.

1.75 "PDUFA Date" means the date identified in an official communication from the FDA as the target date by which the FDA expects to issue an action letter, as required under the Prescription Drug User Free Act of 1992 (P.L. 102−571), as amended and in effect from time to time.

1.76 "**** Study"** means the ****** study described in the Initial U.S. Development Plan.

1.77 "****** Studies**" means the ****** studies described in the U.S. Development Plan.

1.78 "Post−Approval Failure" means: (a) a mandatory withdrawal or recall of a Product by a Regulatory Authority in any country in the Territory, or (b) any voluntary withdrawal or recall of a Product in the U.S. or a Major Ex−U.S. Market country that arises from risks associated with a serious adverse health consequence or death reported to a Regulatory Authority anywhere in the world. Notwithstanding the foregoing, any such recall that results primarily from AstraZeneca's or its Affiliate's or Sublicensee's gross negligence, willful misconduct, or failure to comply with Applicable Law in the Development, Manufacture or Commercialization of a Product shall not be considered a Post−Approval Failure for purposes of this Agreement.

1.79 "POZEN House Marks" means any trademarks, trade names, domain names, or other names or marks used or registered by POZEN or its Affiliates at any time during the Term to identify itself.

1.80 "POZEN Invention" means any Invention that is conceived solely by one or more employees, agents, or independent contractors of POZEN or its Affiliate(s).

****** Portion for which confidential treatment requested.

1.81 "POZEN Product" means any product that combines a Gastroprotective Agent and any NSAID in a single fixed combination dosage form, that would, if made, used, sold, offered for sale, had made, imported or exported without a license from POZEN of the Licensed Patents, infringe one or more Valid Claims of the Licensed Patents.

1.82 "Pre−Approval Failure" means any of the following:

(a) POZEN's failure to deliver the formulation, manufacturing process, data and materials for the Initial POZEN Product in accordance with the terms of Section 6.1.1 (Initial POZEN Product) or Section 6.1.2 (ROW POZEN Products);

(b) the receipt of notice from the FDA, EMEA or other Regulatory Authority in the EU that successful completion of the Budgeted Development Activities and Core Development Activities would be insufficient to achieve NDA Approval of the Initial POZEN Product without the performance of Additional Development Activities that are not included in the Budgeted Development Activities and that would be reasonably expected, in the aggregate, to either (i) delay the anticipated date of NDA Approval of the Initial POZEN Product by more than ****** past the dates set forth in the Initial U.S. Development Plan Timeline or for any country of the EU set forth in the Initial ROW Development Plan Timeline, or (ii) require AstraZeneca to spend more than an aggregate of $****** to perform; provided that, the cost of any such Additional Development Activities conducted pursuant to the ****** and ****** Studies shall not be counted toward such $****** limit;

(c) either (i) the failure of the ****** Study described in the Initial U.S. Development Plan to satisfy its primary endpoint for all doses of the Initial POZEN Product, or (ii) the failure of the ****** of the ****** Study described in the Initial U.S. Development Plan to satisfy its primary endpoint, ******;

(d) receipt of results of a clinical trial of the Initial POZEN Product that show that such Initial POZEN Product is unsafe;

(e) TPP Failure;

(f) the receipt of notice from the FDA, the EMEA or a Regulatory Authority in a country in the Major Ex−U.S. Market that the NDA for the Initial POZEN Product in such country is not approvable;

(g) after the submission of an NDA for the Initial POZEN Product, receipt of notice from the FDA, EMEA or other Regulatory Authority in the EU that such NDA will not be approved without the performance of Additional Development Activities that would be reasonably expected, in the aggregate, to either (i) delay the anticipated date of NDA Approval of the Initial POZEN Product by more than ****** past the date set forth in the Initial U.S. Development Plan Timeline or for any country of the EU set forth in the Initial ROW Development Plan Timeline, or (ii) require AstraZeneca to spend more than an aggregate of $****** to perform; or

****** Portion for which confidential treatment requested.

(h) subject to the terms of Sections 2.3.5 (Interim Results of ******) and 4.3.3 (Label Negotiations and Approval), delay in Development activities not caused by AstraZeneca's failure to comply with its obligations under this Agreement that, in the aggregate, will delay NDA Approval for the Initial POZEN Product in either the U.S. or the EU at least ****** beyond the date for such NDA Approval set forth in the Initial U.S. Development Plan Timeline and the Initial ROW Development Plan Timeline.

1.83 "Product" means: (a) any POZEN Product, and (b) any other product that combines a Gastroprotective Agent and any NSAID in a single fixed combination oral solid dosage form (with or without one or more additional therapeutically active agents), which product is developed or commercialized by or for, invented or acquired by, or comes under the Control of AstraZeneca or its Affiliates during the Term. For the avoidance of doubt, "Product" does not include any product containing acetyl salicylic acid (including salts and derivatives thereof).

1.84 "Product Labeling" means (a) the full prescribing information for a POZEN Product approved by the applicable Regulatory Authority, and (b) all labels and other written, printed or graphic information included in or placed upon any container, wrapper or package insert used with or for the POZEN Product.

1.85 "Product Trademarks" means any trademarks, trade dress (including packaging design), logos, slogans, domain names and designs, whether or not registered in a country or territory, selected and owned by AstraZeneca and used to identify or promote a POZEN Product, but excluding any POZEN House Marks and AstraZeneca House Marks.

1.86 "Promotional Materials" means all sales representative training materials and all written, printed, graphic, electronic, audio or video presentations of information, including, without limitation, journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct−to−consumer advertising, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items) intended for use or used by AstraZeneca or its Affiliates in connection with any promotion of the Initial POZEN Product hereunder, but excluding Product Labeling.

1.87 "Proof of Concept Study" means the ****** Study and ****** Study described in the Initial U.S. Development Plan.

1.88 "Regulatory Authority" means, in a particular country or jurisdiction, any applicable government regulatory authorities involved in granting approval to market or sell a Product, including any pricing and reimbursement approvals, in such country or jurisdiction, including, (a) in the United States, the FDA, and any successor government authority having substantially the same function, (b) any non−United States equivalent thereof, and (c) in the EU, the EMEA and any national regulatory authority in any EU country.

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1.89 "Regulatory Materials" means regulatory applications, submissions, notifications, registrations, Marketing Approvals or other submissions made to or with a Regulatory Authority that are necessary or reasonably desirable in order to develop, manufacture, market, sell or otherwise Commercialize the Initial POZEN Product in a particular country, territory or possession. Regulatory Materials include, without limitation, INDs and NDAs, and amendments and supplements for any of the foregoing, and applications for pricing and reimbursement approvals.

1.90 "ROW Development Plan" means the plan for the Development of the Initial POZEN Product for Marketing Approval in the Territory outside the U.S. as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.91 "ROW Development Plan Timeline" means the estimated timeline for completion of the ROW Development Plan, as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.92 "Royalty Term" has the meaning set forth in Section 8.4.2 (Royalty Term).

1.93 "Specifications" has the meaning set forth in Section 6.1.1 (Manufacturing Development; Initial POZEN Product).

1.94 "Standard Sales Price" means, as reported by IMS (or ACNielsen in the case of over−the−counter products) in the relevant country, the average sales price for the preceding Calendar Quarter for the Product or, in the case of a Combination Product, the average sales price for the applicable presentation and dosage strength of all marketed brands of the other therapeutically active ingredient(s). As used herein, "presentation" means the method of administration of a pharmaceutical substance into the human body, including, but not limited to, solid oral (including tablets, capsules, gelcaps, sachets and caplets), other oral (including suspension and solution), parenteral (including intramuscular, subcutaneous and intravenous), transdermal, suppository and intranasal.

1.95 "Sublicense Agreement" means any agreement under which AstraZeneca grants a Third Party a sublicense, option or other right under the Licensed Technology to make, use, have made, sell, offer for sale, import and export Products in the Field of Use in the Territory.

1.96 "Sublicensee" means any Third Party that has entered into a Sublicense Agreement.

1.97 "Term" has the meaning assigned to it in Section 12.2 (Term).

1.98 "Territory" means all countries of the world, excluding Japan, unless and until AstraZeneca exercises the option under Section 7.6 (Japan Option), whereupon the Territory shall be all countries of the world.

1.99 "Third Party" means any entity other than POZEN, AstraZeneca, or any of their respective Affiliates.

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1.100 "Third Party Royalties" means upfront, commercialization milestone, royalty and any other similar payments paid by AstraZeneca or any AstraZeneca Affiliate to any Third Party in consideration for a license to a Blocking Patent for the Development or Commercialization of POZEN Products.

1.101 "TPP" shall mean the target product profile of the Initial POZEN Product as described in Exhibit F.

1.102 "TPP Endpoints" means the endpoints of the TPP Studies as described in Exhibit F.

1.103 "TPP Failure" means the failure of any TPP Study to achieve TPP Endpoint Success, as defined in Exhibit F.

1.104 "TPP Studies" means the studies entitled ****** in the Initial U.S. Development Plan.

1.105 "U.S." means the United States of America and its possessions and territories.

1.106 "U.S. Development Plan" means the plan for the Development of the Initial POZEN Product for Marketing Approval in the U.S. as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.107 "U.S. Development Plan Timeline" means the estimated timeline for completion of the U.S. Development Plan, as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.108 "Valid Claim" means any claim of any issued and unexpired patent or a patent application that has not been disclaimed or held invalid or unenforceable by judgment or decree entered in any judicial proceeding that is not further reviewable through the exhaustion of all permissible applications for rehearing or review by a superior tribunal, or through the expiration of the time permitted for such applications; provided, that any claim in a pending Patent application that does not issue as a patent claim within ****** (******) years after the earliest priority date of such application will not be a "Valid Claim" until such claim issues as a patent claim.

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2. COLLABORATION GOVERNANCE

2.1 Establishment.

2.1.1 Global Product Team. Within twenty (20) days after the Effective Date, the Parties will appoint representatives to the GPT in accordance with the terms of this Section 2.1 and convene the first GPT meeting. The GPT will coordinate and oversee the Development and Commercialization of the Initial POZEN Product hereunder. The purposes of the GPT will be, with respect to the Initial POZEN Product only, (a) to coordinate the management and implementation of the Parties' Development activities hereunder, (b) to update the U.S. Development Plan in a manner consistent with the Initial U.S. Development Plan by providing additional detail regarding the activities described therein and to amend the U.S. Development Plan from time to time, (c) to update the ROW Development Plan in a manner consistent with the Initial ROW Development Plan by providing additional detail regarding the activities described therein and to amend the ROW Development Plan from time to time, (d) to propose, approve, amend and allocate responsibility for performing any Additional Development Activities, and (e) to develop AstraZeneca's Commercial Launch and marketing plans for the Initial POZEN Product. The GPT will have the membership and will operate by the procedures set forth in Section 2.2 (Membership and Procedures).

2.1.2 Joint Steering Committee Promptly following the Effective Date, the Parties will create a joint steering committee (the **"JSC"**) to provide strategic guidance to the GPT in decisions pertaining to the Initial POZEN Product. The purposes of the JSC will be (a) to review and make recommendations to the GPT regarding the U.S. Development Plan, and (b) to resolve disputes of the GPT. The JSC will have the membership and will operate by the procedures set forth in Section 2.2 (Membership and Procedures).

2.2 Membership and Procedures.

2.2.1 GPT.

(a) Membership. In addition to members designated by AstraZeneca, the GPT shall have up to three (3) representatives designated by POZEN, attending, observing and participating in meetings of the GPT at POZEN's expense, such representatives having the relevant experience and skill appropriate for service on such team. Such representatives shall be regular working members of the GPT. AstraZeneca shall be entitled to have as many representatives serve as members of the GPT as it desires. POZEN may replace its representatives on the GPT at any time upon written notice to AstraZeneca. AstraZeneca shall provide POZEN office space at its facilities for such representatives to facilitate such participation; provided, that such representatives shall comply with all policies and reasonable restrictions imposed by AstraZeneca and provided to POZEN in writing. Upon prior written consent of AstraZeneca, which consent will not be unreasonably withheld, a reasonable number of employees, consultants, representatives or advisors of POZEN who are not POZEN's GPT representatives may attend GPT meetings as observers; provided, that such persons shall comply with all policies and reasonable restrictions imposed by AstraZeneca and provided to POZEN in writing.

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(b) Chairpersons. The global product director for the Initial POZEN Product designated by AstraZeneca will chair the GPT (**"GPT Chair"**).

(c) Meetings. The GPT will hold meetings when called by the GPT Chair but, in any event, at least once every Calendar Quarter. Meetings may be held in person at AstraZeneca's facilities or by means of telecommunication (telephone, video, or web conferences). Following any GPT meeting, the GPT Chair will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. Such minutes will not be finalized until a representative of the GPT designated by each Party has reviewed and confirmed the accuracy of such minutes in writing. If a disagreement regarding the accuracy of such minutes cannot be resolved, the minutes will reflect such disagreement.

2.2.2 JSC.

(a) Membership. Each Party will designate an equal number of representatives, but in no event less than three (3) each, with appropriate expertise to serve as members of the JSC. Each Party may replace its representatives on the JSC at any time upon written notice to the other Party.

(b) Co−Chairpersons. One of each Party's representatives to the JSC will be designated as a co−chairperson. The co−chairpersons will be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting, and preparing minutes of each meeting.

(c) Meetings. The JSC will hold meetings at least once every Calendar Quarter, or more frequently as the Parties may agree with at least two meetings held in person annually. Subject to the preceding sentence, meetings may be held in person at locations to be determined by the mutual agreement of the Parties (a majority of which must be outside the United States) or by means of telecommunication (telephone, video, or web conferences). Following any JSC meeting, the co−chairpersons will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. Such minutes will not be finalized until a representative of each Party has reviewed and confirmed the accuracy of such minutes in writing. If a disagreement regarding the accuracy of such minutes cannot be resolved, the minutes will reflect such disagreement.

2.2.3 Limitations of Powers. The GPT and JSC will have only such powers as are specifically delegated to them hereunder and will not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, the GPT and JSC will not have any power to amend this Agreement (except amendments to the U.S. Development Plan or ROW Development Plan). Any amendment to the terms and conditions of this Agreement may only be implemented pursuant to Section 15.6 (Entire Agreement; Modifications) below.

2.2.4 Expenses. Each Party will be responsible for all of its own expenses of participating in the GPT and JSC.

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2.3 Decision−Making.

2.3.1 GPT Decisions. Subject to the terms of this Section 2.3 (Decision−Making), the GPT will act by decision of the GPT Chair. If a POZEN representative objects to any decision, then such dispute will be referred to the JSC.

2.3.2 JSC Decisions. Subject to the terms of this Section 2.3 (Decision−Making), the JSC will take action by unanimous vote with each Party having a single vote, irrespective of the number of representatives actually in attendance at a meeting, or by a written resolution signed by the designated representatives of each of the Parties. If the JSC fails to reach unanimous consent on a particular matter within ****** (******) Business Days of POZEN having requested a formal vote on such matter (or any earlier period mutually agreed to by the Parties if a delay may reasonably be anticipated to have an adverse effect on the Development or Commercialization of the Initial POZEN Product), then such dispute will be subject to the resolution procedures described in Section 2.3.3 (Dispute Resolution) below.

2.3.3 Dispute Resolution. In the event of any dispute in the JSC that is not resolved pursuant to the terms of Section 2.3.2 (JSC Decisions), either Party may provide written notice of such failure (a **"Notice of Disagreement"**) to the Chief Executive Officer of the other Party (or his or her designee). The Chief Executive Officers or designees of each of the Parties will meet at least once in person or by means of live telecommunication (telephone, video, or web conferences) to discuss the matter on which the JSC failed to reach unanimous consent and use their good faith efforts to resolve the matter within ****** (******) Business Days after receipt of the Notice of Disagreement by the applicable Chief Executive Officer of a Party. If any such disagreement is not resolved by the Chief Executive Officers or designees within such ****** (******) day period, then (A) the Chief Executive Officer or designee of POZEN will have the final decision−making authority with respect to any such disagreement arising out of either (i) Core Development Activities (other than ****** or the ******) or (ii) subject to Section 3.3.3 (Expenses), Additional Development Activities but only to the extent that such activities are required by the FDA to obtain NDA Approval in the U.S. of the Initial POZEN Product, and (B) the Chief Executive Officer or designee of AstraZeneca will have the final decision−making authority with respect to disagreement relating to all other matters. Notwithstanding anything to the contrary in this Section 2.3.3 (Dispute Resolution):

(a) POZEN'S Chief Executive Officer or designee will not make a final determination that would ****** without AstraZeneca's prior written consent;

(b) POZEN'S Chief Executive Officer or designee will not make a final determination ****** without the prior written consent of AstraZeneca; provided, that AstraZeneca will not unreasonably withhold, condition or delay its consent;

(c) Neither Party's Chief Executive Officer or designee ******;

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(d) Neither Party's Chief Executive Officer or designee may make any decision without the prior written consent of the other Party that would ****** for the ******from the ****** by the Parties through the ******will not be ******; provided, that the foregoing will not ******set forth in this Agreement ****** ****** ******in this Agreement;

(e) AstraZeneca's Chief Executive Officer or designee will not, without POZEN's prior written consent, ******.

2.3.4 Extension of Pre−Approval Failure Time Limits. ******, if AstraZeneca proposes to change either the U.S. Development Plan or the ROW Development Plan so as to add Development activities that are reasonably expected to delay the NDA Approval of the Initial POZEN Product in the U.S. or any Major Ex−U.S. Market country (other than in a manner required by a Regulatory Authority to obtain NDA Approval in the U.S. or any Major Ex−U.S. Market country) beyond the dates for NDA Approval set forth in the Initial U.S. Development Plan Timeline and the Initial ROW Development Plan Timeline, then if the plan is so amended, the Parties will determine in good faith negotiations whether to adjust the periods referred to in paragraphs ****** of the definition of Pre−Approval Failure in Section 1.81 (Pre−Approval Failure) to take account of such delay; provided, that in no event will either period be extended longer than ******.

2.3.5 Interim Results of ****.** If the interim results of the ****** ****** described in the Initial U.S. Development Plan lead either Party to reasonably believe that there is a substantial likelihood that the ****** will not ******, then such Party will provide written notice to the other Party of such determination and the Parties will discuss in good faith, through the GPT, whether to postpone commencement of some or all of the future Core Development Activities or Additional Development Activities pending the receipt of ****** (it being understood that ongoing activities will continue).

(a) If, following such GPT discussion, AstraZeneca elects to postpone commencement of some or all new Additional Development Activities, then POZEN shall not commence such new Additional Development Activities. If AstraZeneca elects to postpone commencement of new Additional Development Activities in a way that would be reasonably likely to delay Development of the Initial POZEN Product, POZEN may postpone commencement of some or all of the new Core Development Activities for the same period that AstraZeneca postpones commencement of such new Additional Development Activities, subject to POZEN's using Diligent Efforts to commence such new Core Development Activities as soon as reasonably practicable at the end of such suspension period. Notwithstanding anything to the contrary herein, any delays in obtaining NDA Approval of the Initial POZEN Product resulting from such postponement of Additional Development Activities or Core Development Activities shall not be counted in determining whether the time period in paragraph (******) of Section 1.81 (Pre−Approval Failure) has been exceeded

(b) If, following such GPT discussion, AstraZeneca desires to postpone commencement of new Additional Development Activities and POZEN does not agree to such postponement, then POZEN in its sole discretion may continue performing the applicable Additional Development Activities at its own expense.

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(c) In any event, if ****** ****** indicates that ******, then unless AstraZeneca terminates this Agreement on account of a Pre−Approval Failure described in Section 1.81(c), (i) the Parties will commence the performance of the postponed Additional Development Activities and Core Development Activities in accordance with the applicable development plans, and (ii) with respect to any Additional Development Activities performed by POZEN pursuant to the preceding clause (b) during the interim period, AstraZeneca will reimburse POZEN for all costs of performing such activities under the terms of Section 3.3.3 (Expenses). In any event, AstraZeneca will reimburse POZEN for any reasonable cancellation or suspension fees paid by POZEN in connection with the postponement of Additional Development Activities contemplated by this Section 2.3.5.

2.3.6 Limitation. Notwithstanding this Section 2.3 (Decision−Making), any dispute regarding the interpretation of this Agreement, the performance or alleged nonperformance of a Party's obligations under this Agreement, or any alleged breach of this Agreement will be resolved in accordance with the terms of Section 15.4 (Governing Law; Dispute Resolution).

3. PRODUCT DEVELOPMENT

3.1 Development Plans.

3.1.1 U.S. Development Plan. The Development of Initial POZEN Product under this Agreement for U.S. Marketing Approval will be governed by the U.S. Development Plan and the U.S. Development Plan Timeline. As promptly as practicable following the Effective Date, the GPT will update the U.S. Development Plan in a manner that is consistent with the Initial U.S. Development Plan and the Initial U.S. Development Plan Timeline. Subject to Section 2.3.3 (Dispute Resolution), from time to time during the Term, the GPT will update the U.S. Development Plan as it deems necessary and appropriate. The U.S. Development Plan will be part of this Agreement and incorporated herein by reference.

3.1.2 ROW Development Plan. The Development of Initial POZEN Product under this Agreement for Marketing Approval outside the U.S. will be governed by the ROW Development Plan and the ROW Development Plan Timeline. As promptly as practicable following the Effective Date, the GPT will update the ROW Development Plan in a manner that is consistent with the Initial ROW Development Plan and the Initial ROW Development Plan Timeline. The ROW Development Plan will be part of this Agreement and incorporated herein by reference. Subject to Section 2.3.3 (Dispute Resolution), from time to time during the Term, the GPT will update the ROW Development Plan as it deems necessary and appropriate.

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3.1.3 TPP Endpoints. The Parties acknowledge that a primary goal of Development efforts under this Agreement is to generate data that will enable AstraZeneca to promote the Initial POZEN Product on the basis of the TPP Endpoints. Accordingly, the Parties agree, subject to Section 3.3 (Additional Development Activities), to use Diligent Efforts to conduct Additional Development Activities directed to achievement of the TPP Endpoints, to include the data from the TPP Studies in the NDA (subject to the terms of Section 4.1.1 (In the U.S.)), and to obtain approval of such Product Labeling as may be necessary for the promotion of the Initial POZEN Product in the U.S. on the basis of the TPP Endpoints (subject to the terms of Section 4.3.3 (Label Negotiations and Approval)).

3.2 Core Development Activities.

3.2.1 Performance. POZEN will use Diligent Efforts to perform the Core Development Activities.

3.2.2 Records and Reports. POZEN will retain all records required by Applicable Law to be maintained in connection with its obligations under Section 3.2.1 (Performance) pursuant to the U.S. Development Plan. POZEN will provide written reports to the GPT on its activities in conjunction with regularly scheduled meetings of the GPT, at a level of detail reasonably sufficient to enable AstraZeneca to monitor POZEN's compliance with its obligation pursuant to this Agreement. Moreover, AstraZeneca shall have the right to audit the facility and records of POZEN and each contract research organization and other vendors employed by POZEN to conduct Development of the Initial POZEN Product in accordance with the terms of Section 3.7 (Audits and Inspections).

3.2.3 Expenses. POZEN will bear the expenses for the Core Development Activities.

3.2.4 Diligence. POZEN will use Diligent Efforts to conduct all Development activities under this Section 3.2 (Core Development Activities) in a good scientific manner and in compliance in all material respects with all Applicable Laws (including cGCP, cGLP and cGMP) and to adhere to the Initial Development Plan Timeline. All efforts of POZEN's Affiliates, Third Party contractors and sublicensees will be considered efforts of POZEN for the purpose of determining compliance with its obligations under this Section 3.2.4 (Diligence).

3.3 Additional Development Activities.

3.3.1 Performance. POZEN shall perform all Additional Development Activities that are identified in Exhibit B and Exhibit D as being POZEN's responsibility and all Additional Development Activities required to obtain NDA Approval of the Initial POZEN Product in the U.S. and EU, at AstraZeneca's expense, subject to Section 3.3.3 (Expenses) below. The GPT will allocate between the Parties the responsibility for the performance of other Additional Development Activities; provided, that each Party will have the right to consent to such activities as may be allocated to it. Each Party hereby agrees to perform such Additional Development Activities as may be allocated to such Party by the GPT.

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3.3.2 Records and Reports. Each Party will retain all records required by Applicable Law to be maintained in connection with such Party's performance of Development Activities. Each Party will provide written reports to the GPT on such activities with the Initial POZEN Product, in conjunction with regularly scheduled meetings of the GPT, at a level of detail reasonably sufficient to enable the other Party to determine the reporting Party's compliance with its obligations pursuant to this Agreement, including Section 3.3.1 (Performance) and 3.3.4 (Diligence).

3.3.3 Expenses. Within ****** (******) days after the Effective Date, POZEN shall develop a schedule of expected activities and related costs for Additional Development Activities to be conducted by POZEN. This schedule will describe in reasonable detail the expected activities to be performed and will contain sufficient detail on both Direct Costs to be incurred with Third Parties and FTE Costs to be incurred by POZEN, as well as estimated timings of such costs. The GPT will review this schedule and approve a budget for the Additional Development Activities conducted by POZEN after the Execution Date (the **"ADA Budget"**). By ****** of each calendar year, beginning 2007, POZEN shall provide the GPT with an update of the ADA Budget for the subsequent calendar year for the review and approval of the GPT, such update to take effect once approved, beginning ****** of such subsequent year. The GPT will reasonably consider each such proposed ADA Budget and may withhold its approval of any proposed ADA Budget (including all updates thereof) only if the budget is not reasonable in light of prevalent market conditions for similar work or is not consistent with POZEN's expenditures on Core Development Activities to the extent the activities are comparable. In addition to this annual process, the GPT may also periodically review and amend the ADA Budget as appropriate in light of approved changes to the Additional Development Activities allocated to POZEN (including upon finalization of the scope of the ******) consistent with the above principles. POZEN will calculate and maintain records of all Direct Costs and FTE Costs incurred by POZEN in performing Additional Development Activities, in accordance with POZEN's internal accounting policies. Within ****** (******) days after the end of each calendar month during which POZEN incurs Direct Costs or FTE Costs in performing the Additional Development Activities, POZEN will submit to AstraZeneca a written invoice setting forth in reasonable detail the Direct Costs and FTE Costs it has incurred in performing the Additional Development Activities. AstraZeneca will pay POZEN within ****** (******) days following the receipt of the invoice for Direct Costs and FTE Costs that do not exceed the then−current ADA Budget by more than ****** percent (******%); provided, that the GPT will approve variances above ******% if and to the extent the variances are (a) reasonable in light of prevalent market conditions for similar work and consistent with POZEN's expenditures on Core Development Activities to the extent the activities are comparable, or (b) beyond POZEN's reasonable control. Any payments made pursuant to this Section 3.3.3 (Expenses) will be subject to the general payment procedures set forth in Sections 8.5 through 8.7, inclusive. POZEN will inform the GPT at least ****** (******) days prior to incurring any Direct Costs or FTE Costs that exceed the then−current ADA Budget by more than ****** percent (******%). AstraZeneca shall not be held responsible for any expenditure relating to the Additional Development Activities incurred by POZEN that exceeds the then−current ADA Budget by more than ****** percent (******%), unless such expenditure has been specifically approved by the GPT as an exception to the ADA Budget in accordance with this Section 3.3.3 (Expenses). For clarity, the terms of this Section 3.3.3 will apply with respect to any Additional Development Activities commenced by POZEN after the Execution Date.

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3.3.4 Diligence. Each Party will use Diligent Efforts to conduct the Additional Development Activities allocated to it in a good scientific manner and in compliance in all material respects with all Applicable Laws (including cGCP, cGLP and cGMP) and to adhere to the Initial U.S. Development Plan Timeline. All efforts of a Party's Affiliates and Third Party contractors will be considered efforts of such Party for the purpose of determining compliance with its obligations under this Section 3.3.4 (Diligence). Without limiting the foregoing general obligation, each Party will use Diligent Efforts to perform the Additional Development Activities in accordance with the U.S. Development Plan Timeline and the ROW Development Plan Timeline.

3.4 Development of Products by AstraZeneca.

3.4.1 General Principles. In addition to the Development of the Initial POZEN Product pursuant to Section 3.3 (Additional Development Activities) above, AstraZeneca will have the right to Develop and Commercialize other Products during the Term in each country of the Territory, for so long as AstraZeneca is using Diligent Efforts to Develop and Commercialize at least one POZEN Product in accordance with the terms and conditions of this Agreement, it being understood that the Parties intend for AstraZeneca to focus its initial efforts on the Development and Commercialization of the Initial POZEN Product.

3.4.2 Substitution.

(a) Upon Certain Pre−Approval Failures. If a Pre−Approval Failure of the Initial POZEN Product described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs in the U.S. (it being understood that the failure described in paragraph ****** will not be deemed to have occurred until expiration of the ****** period described in Section ******) and AstraZeneca provides POZEN with a written notice of its election to discontinue the Development of such product and to substitute another POZEN Product, without prejudicing AstraZeneca's right to terminate this Agreement under Section 12.4.1, then AstraZeneca will have the option, in its sole discretion, to identify a POZEN Product as a replacement for the Initial POZEN Product within ****** (******) days of the occurrence of such Pre−Approval Failure. If AstraZeneca elects to make such a replacement, then AstraZeneca will consult in good faith with POZEN regarding the identification of such substitute POZEN Product and shall designate such substitute in writing to POZEN; provided, that as of the time of such election, ****** of such ******must be ****** in the ******and at ******must be ******. Such substitution shall be effective immediately upon AstraZeneca's designation of the replacement POZEN Product.

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(b) Otherwise. If circumstances occur which ****** to ****** the ****** ****** and AstraZeneca wishes to discontinue the Development of the Initial POZEN Product, then AstraZeneca may identify a different POZEN Product to replace the Initial POZEN Product, either throughout the Territory or in one or more countries of the Territory, by written notice to POZEN of such election; provided, that as of the time of such election, ******of such ******must be ******in the ******must be ******. AstraZeneca will consult in good faith with POZEN regarding the identification of such proposed substitute POZEN Product, and POZEN shall either approve or disapprove the identification of such proposed substitute Initial POZEN Product within ****** (******) days of AstraZeneca's providing POZEN with such notice, such approval not to be unreasonably withheld, conditioned or delayed. If POZEN approves the identification of the substitute Initial POZEN Product, then the Parties shall negotiate to agree upon the applicable development plan for such proposed substitute Initial POZEN Product in accordance with Section 3.4.2(c) (Effects of Election), and such substitution shall not become effective until the Parties have agreed upon such revised development plan pursuant to Section 3.4.2(c).

(c) Effects of Election. In the event of any proposed Product substitution pursuant to this Section 3.4.2, AstraZeneca will prepare and submit to POZEN a new U.S. Development Plan and ROW Development Plan, as applicable, for the applicable replacement Initial POZEN Product within ****** (******) days following the election of such replacement, and the Parties will use good faith efforts to agree upon such plan.

(i) If the Parties, despite the use of good faith efforts, fail to agree upon a new U.S. Development Plan and/or ROW Development Plan, as applicable, for a substitute Initial POZEN Product, then (1) if such substitution was made pursuant to Section 3.4.2(a) above, then such failure will be subject to the applicable dispute resolution procedures set forth in this Agreement, or (2) if such substitution was made pursuant to Section 3.4.2(b) above, then, notwithstanding anything to the contrary herein, the proposed substitution shall not be effective and AstraZeneca may not proceed with the Development of the substitute Initial POZEN Product.

(ii) If the Parties agree upon a new U.S. Development Plan and/or ROW Development Plan, as applicable, for a substitute Initial POZEN Product, any such development plan must provide for a proof of concept study with mutually agreed endpoints. Furthermore, any such U.S. Development Plan and/or ROW Development Plan shall provide that if such proof of concept study fails to meet its mutually agreed endpoints, then AstraZeneca shall have the right, at its option, to terminate this Agreement without penalty either in its entirety or with respect to the territory of such substitute Initial POZEN Product; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following the receipt of the final clinical study report for such proof of concept study. For the purposes of this Section 3.4.2(c)(ii), a “proof of concept” study is a study that provides clinical confirmation that the substitute Initial POZEN Product possesses a desired pharmacological effect in patients, and is typically a positive placebo−controlled study or dose−response study using a validated surrogate variable or the final clinical outcome variable.

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(d) Effects of Substitution. Upon the effectiveness of a substitution pursuant to this Section 3.4.2, the applicable replacement POZEN Product shall be deemed the "Initial POZEN Product" in the Territory or such country(ies), as applicable, for all purposes under this Agreement; provided, however if the market opportunity and timing of NDA Approval for the POZEN Product that is substituted for the original Initial POZEN Product is not substantially equivalent, the Parties shall meet and negotiate in good faith to adjust milestone payments that would be due with respect to such replacement Initial POZEN Product under Section 8.2 (Development Milestone Payments) in a manner that reflects the commercial opportunity for such replacement Initial POZEN Product and the Parties' relative contribution to the Development of the replacement POZEN Product.

3.5 Oversight of Proof of Concept Studies. Without limiting the generality of POZEN's obligations with respect to Additional Development Activities generally, POZEN shall conduct the Proof of Concept Studies, including design, execution and analysis to AstraZeneca's reasonable satisfaction. Without limiting the foregoing, POZEN will consult with AstraZeneca with respect to the foregoing activities and will give reasonable consideration to and use Diligent Efforts to give effect to AstraZeneca's comments with respect thereto. POZEN will provide AstraZeneca with copies of all data from the Proof of Concept Studies and all draft reports for such studies as the data and draft reports become available. The clinical study reports for the Proof of Concept Studies are subject to review and comment by AstraZeneca; provided, that ****** such study reports will not affect either Party's rights under this Agreement. AstraZeneca shall be permitted to reasonably participate in POZEN's study team meetings and receive communications from the POZEN study team as reasonably necessary to keep AstraZeneca informed regarding the conduct of the Proof of Concept Studies.

3.6 Exchange of Know−How. In addition to the periodic reports provided to the other Party pursuant to Section 3.2.2 (Records and Reports), each Party will provide to the other Party copies of any Know−How in its possession relating to the Initial POZEN Product, including, without limitation, procedures, formulations, manufacturing reports, pre−clinical and clinical protocols and data, regulatory filings, and toxicology reports with respect to the Initial POZEN Product, including any final versions of any study reports and any drafts then−outstanding of any study reports, all to the extent reasonably required for the requesting Party to perform its obligations under this Agreement.

3.7 Audits and Inspections.

3.7.1 Audits. At all times that POZEN is participating in the Development of the Initial POZEN Product, a delegation consisting of a reasonable number of representatives of AstraZeneca (or its Third Party contractors reasonably acceptable to POZEN) will have the right to inspect and audit any POZEN facility and the facilities of Third Party contractors and Affiliates of POZEN where the Development is being conducted and the documentation generated in connection with the Development of the Initial POZEN Product. Such inspections will take place no more than ****** per site during any calendar year, and will be conducted during regular business hours and after at least ****** (******) days prior notice to POZEN. However, any such inspections that are made for cause in response to a failure or deficiency at the applicable site will not count toward such annual limit. AstraZeneca will discuss the results of any inspection with POZEN. Any inspection by or on behalf of AstraZeneca, if it occurs, does not relieve POZEN of its obligation to comply with all Applicable Laws and does not constitute a waiver of any right otherwise available to AstraZeneca.

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3.7.2 Inspections. POZEN will notify AstraZeneca promptly following notice from the FDA or any Regulatory Authority of a visit to any POZEN facility and the facilities of Third Party contractors and Affiliates of POZEN wherein the Development of the Initial POZEN Product is conducted. A representative of AstraZeneca (or its Third Party contractor reasonably acceptable to POZEN) will have the right to be present as a silent observer at any announced visits to POZEN's facility and the facilities of Third Party contractors (to the extent POZEN is entitled to attend such visits) and Affiliates of POZEN by any Regulatory Authority relating to the Development of the Initial POZEN Product. Furthermore, POZEN will inform AstraZeneca of the results of any inspection by a Regulatory Authority that does or could reasonably be expected to affect the Development of the Initial POZEN Product. POZEN will promptly provide AstraZeneca with copies of notifications from any Regulatory Authority (including, without limitation, any Form No. 483 notification, Enforcement Inspection Reports, Notice of Adverse Finding, etc.). AstraZeneca will treat all information subject to review under this Section 3.7.2 (Inspections) in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party auditor retained by AstraZeneca (and reasonably acceptable to POZEN) to enter into a reasonably acceptable confidentiality agreement with POZEN obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

4. REGULATORY MATTERS

4.1 Responsibilities; Diligence.

4.1.1 In the U.S. Subject to Section 2.3.3 (Dispute Resolution), POZEN will be responsible, at its sole expense, for preparing and filing the NDA and seeking NDA Approval for the Initial POZEN Product as outlined in the U.S. Development Plan, including preparing all reports and other documents necessary as part of any IND or NDA; provided, that each Party will be responsible for preparing reports for studies or activities for which it has responsibility in accordance with Articles 3 and 6. The initial NDA submission for the Initial POZEN Product shall include ******, and POZEN shall not, without AstraZeneca's prior written consent (but subject in any event to Applicable Law), submit the initial NDA for the Initial POZEN Product ******. Such NDA will be filed in the name of POZEN. POZEN will provide all filings (including the NDA) to AstraZeneca for review and comment prior to their submission to the FDA. Each Party will conduct the Development activities in accordance with the agreed U.S. Development Plan. Subject to Section 2.3.3 (Dispute Resolution), each Party will use Diligent Efforts to obtain NDA Approval of the Initial POZEN Product in the U.S. AstraZeneca shall have the right at its own expense to seek any Marketing Approval in the U.S. for claims not obtained in the initial U.S. NDA Approval for POZEN Products. Within ****** (******) days following receipt of NDA Approval for the Initial POZEN Product in the United States and POZEN's receipt of the milestone payment set forth in item 4 of the table in Section 8.2, POZEN will transfer and assign, without additional compensation, corresponding Regulatory Materials (including the relevant NDA) to AstraZeneca. During the period between ******. As owner of the NDA, AstraZeneca will be the sole owner of all data exclusivity protection related to the Initial POZEN Product as provided by Applicable Law. The GPT will allocate responsibility for preparing the “Chemistry and Manufacturing Controls” (“CMC”) section for the NDA for the Initial POZEN Product, as commercially reasonable. POZEN's Direct Costs and FTE Costs of preparing the CMC section of such NDA shall be included in the Formulation Budget established pursuant to Section 6.1.4 (Expenses).

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4.1.2 Outside the U.S. AstraZeneca will be responsible at AstraZeneca's expense, but other than as set forth in this Agreement, shall not be obligated to, prepare and file INDs and NDAs and seek NDA Approvals for the Initial POZEN Product in all countries in the Territory other than the U.S., including preparing all reports necessary as part of any such IND or NDA. All such INDs and NDAs will be filed in the name of AstraZeneca. AstraZeneca will use Diligent Efforts to obtain Marketing Approval of the Initial POZEN Product in each Major Ex−U.S. Market country. However, AstraZeneca shall not be required to Develop or Commercialize a POZEN Product in a particular Major Ex−U.S. Market country if it is not commercially reasonable to do so consistent with the exercise of Diligent Efforts and, upon POZEN's request, will provide POZEN data supporting such determination. AstraZeneca will have the right in its sole discretion, at any time upon ****** (******) Business Days prior written notice to POZEN, to replace any country in the Major Ex−U.S. Market with any other country or group of countries having a market potential of at least ****** percent (******%) of the market potential of the relevant Major Ex−U.S. Market country based on the then−current IMS MAT (Moving Annual Total) Data for sales of ****** drugs in such Major Ex−U.S. Market country as compared to sales of ****** drugs in such other country or group of countries, and AstraZeneca's diligence requirements hereunder shall accordingly transfer from such initial Major Ex−U.S. Market country to the replacement country or countries. Schedule 4.1.2 sets forth IMS MAT Data that is current as of December 2005. Based on such data, by way of example, if AstraZeneca desired to elect one or more countries to replace ****** as a Major Ex−U.S. Market country (having $****** in sales), any of the following countries or combinations of countries would be acceptable substitutes: (i) ******, with $****** in sales (approx. ******% in sales), (ii) ******, with $****** in sales (approx. ******% in sales), or (iii) ****** combined (approx. ******% in sales).

4.1.3 Core Development Activities Failure. Without limiting any right or remedy that AstraZeneca may have under this Agreement or otherwise, if a dispute arises regarding POZEN's cessation of Core Development Activities and pursuant to the dispute resolution procedures described in Section 15.4 a court of competent jurisdiction makes a determination (whether in a preliminary or final order) that POZEN has materially breached its obligation to perform the Core Development Activities and that such material breach has not been cured within ****** (******) days of POZEN receiving notice of such breach, then, if requested by AstraZeneca in writing, POZEN shall do the following:

(a) to the extent permitted by Applicable Law, transfer and assign to AstraZeneca all Regulatory Materials, including any IND or NDA, for any POZEN Product that are Controlled by POZEN;

(b) transfer to AstraZeneca or its designee the management and continued performance of any clinical trials for any POZEN Product ongoing as of the effective date of such request, which clinical trials will be conducted at AstraZeneca's expense after such transfer; and

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(c) for a reasonable period of time, provide such assistance, at AstraZeneca's cost, to transfer or transition to AstraZeneca all then−existing Third Party contracts (to the extent transferable in accordance with the terms and conditions thereof) as may be reasonably necessary or useful for AstraZeneca to conduct the Core Development Activities and Additional Development Activities, to the extent POZEN is then performing or having performed such activities (including without limitation transferring, upon request of AstraZeneca, any relevant agreements with Third Party contractors, to the extent such agreements are transferable in accordance with their terms and conditions). POZEN shall use Diligent Efforts to cause all contracts that it enters into after the Execution Date related to the Development of the Initial POZEN Product to be assignable to AstraZeneca as contemplated by this paragraph.

4.2 Access to Filings. Each Party will permit the other Party access to, and the right to reference and use (including by providing a letter of authorization to the applicable Regulatory Authorities), all data, regulatory filings and regulatory communications associated with any submissions for NDA Approval of the Initial POZEN Product for the purpose of seeking NDA Approval of the Initial POZEN Product, in accordance with Section 4.1 (Responsibilities; Diligence). AstraZeneca and its Affiliates will have the right of cross−reference to all NDAs or other filings made by or on behalf of POZEN for the purpose of prosecuting Marketing Approval applications for Products, and POZEN and its Affiliates will, or will use reasonable efforts to cause their licensees to, take all such reasonable actions to allow such cross−reference.

4.3 Interactions with Regulatory Authorities.

4.3.1 Consultation. Each Party will consult with the other Party regarding (and provide copies of materials prior to any submission to a Regulatory Authority and materials after receipt from a Regulatory Authority), and keep such other Party reasonably and regularly informed of, the status of the preparation of all Regulatory Materials, review of such materials by the relevant Regulatory Authority, and Marketing Approvals received for the Initial POZEN Product.

4.3.2 Communications. Except as may be required by Applicable Law and subject to Section 2.3.3 (Dispute Resolution), only the Party responsible for the preparation of Regulatory Materials in a particular country or territory will communicate regarding the Initial POZEN Product with any Regulatory Authority having jurisdiction in such country or territory; provided, that if POZEN is required by Applicable Law to provide to a Regulatory Authority any communication that relates to ******; provided, that this sentence shall not be construed to obligate POZEN to take any action or make any omission in violation of Applicable Law. If POZEN is required to make such a communication by a Regulatory Authority, then POZEN will ******. During the period which the Regulatory Materials for the Initial POZEN Product are under POZEN's name, AstraZeneca will provide copies of all ex−US correspondence regarding such Initial POZEN Product with Regulatory Authorities to POZEN, and POZEN will provide copies of all U.S. correspondence regarding such Initial POZEN Product to AstraZeneca. In addition, during such period, POZEN shall not submit any substantive correspondence or communication to the FDA that is material to the NDA of the Initial POZEN Product without prior review by and consultation with AstraZeneca, and POZEN shall provide AstraZeneca with copies of all other correspondence.

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4.3.3 Label Negotiations and Approval. Notwithstanding anything in this Agreement to the contrary, POZEN shall not submit to the FDA any draft label, revised draft label, or correspondence regarding the label of the Initial POZEN Product without AstraZeneca's prior written review and consent, which shall not be unreasonably withheld, conditioned or delayed. AstraZeneca will review and provide POZEN with a response on all draft labels and revised draft labels proposed for submission to the FDA, and on draft correspondence with the FDA, as promptly as reasonably practicable and in any event will use Diligent Efforts to approve labeling proposed by the FDA for the Initial POZEN Product within ****** (******) days after the ******. In the event that the U.S. label for the Initial POZEN Product is not approved by AstraZeneca within ****** (******) days after the ******, then any time period after such ****** (******) day period shall not be counted in determining whether the time period in paragraph ****** of Section 1.81 (the definition of Pre−Approval Failure) has been exceeded.

4.3.4 Meetings. Prior to the first NDA Approval, each Party responsible for the preparation of Regulatory Materials for the Initial POZEN Product in a particular country will request the applicable Regulatory Authority in such country to allow a reasonable number of the other Party's representatives to attend and, to the extent permitted under Applicable Law, participate in all meetings and telephone conferences between the responsible Party and such Regulatory Authority in respect of any Regulatory Materials. The responsible Party shall inform the other Party of any such meetings and telephone conferences scheduled with any such Regulatory Authority in respect of any Regulatory Materials as soon as practically possible. Each Party will bear its own expenses in attending or otherwise participating in any meetings and conferences pursuant to this Section.

4.4 Information Sharing. Each Party will provide the other Party, in a timely manner, with copies of, and all information received by it pertaining to, notices, questions, actions and requests from or by Regulatory Authorities with respect to the Initial POZEN Product, or the testing, Manufacture, packaging, distribution or facilities in relation thereto, including any notices of non−compliance with laws in connection with the Initial POZEN Product (*e.g.*, warning letters or other notices of alleged non−compliance), audit notices, notices of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Initial POZEN Product (or its manufacture, distribution, or facilities connected thereto), notice of violation letters (*i.e.*, an untitled letter), warning letters, service of process or other inquiries. Except as otherwise set forth in this Agreement or as reasonably necessary for POZEN to perform its Development obligations hereunder or to comply with Applicable Law, ******.

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4.5 Regulatory Audits. If a Regulatory Authority desires to conduct an inspection or audit of a Party's facility, or a facility under contract with a Party, with regard to a POZEN Product, then such Party will promptly notify the other Party and permit and cooperate with such inspection or audit, and will cause the contract facility to permit and cooperate with such Regulatory Authority and such other Party during such inspection or audit. Such other Party will have the right upon request (which request shall not be unreasonably withheld) to have a representative observe such inspection or audit; provided, that POZEN'S rights of observance under this Section will end upon the transfer of the U.S. NDA for the Initial POZEN Product to AstraZeneca. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the audited Party will immediately provide to the other Party), the audited Party will prepare the response to any such observations, and will provide a copy of such response to the other Party. The audited Party agrees to conform its activities under this Agreement to any commitments made in such a response, except to the extent it believes in good faith that such commitments violate Applicable Laws.

4.6 Adverse Event Reporting. Within ****** (******) days after the Effective Date, the Parties will enter into an Adverse Event Reporting Agreement, which upon such execution will be attached as an exhibit hereto and hereby incorporated into this Agreement by reference (the **"AE Agreement"**), governing the Parties' respective adverse event reporting and global safety database maintenance obligations. Without limiting the generality of the AE Agreement, the Parties hereby agree as follows:

4.6.1 Until POZEN transfers the approved US NDA to AstraZeneca, POZEN will be solely responsible for reporting all Adverse Events (AEs) and Serious Adverse Events (SAEs) associated with the Initial POZEN Product from any source (including AEs and SAEs from AstraZeneca sponsored studies) to the FDA and any other Regulatory Authority outside the U.S. as required by Applicable Laws. In addition, prior to such transfer of the U.S. NDA, POZEN shall report to AstraZeneca all AEs and SAEs of which POZEN becomes aware within the timelines specified in the AE Agreement to the extent necessary to enable AstraZeneca to comply with its reporting obligations outside the U.S., and AstraZeneca shall report to POZEN all AEs and SAEs of which AstraZeneca becomes aware within the timelines specified in the AE Agreement to the extent necessary to enable POZEN to comply with its reporting obligations in the U.S., each as more fully described in the AE Agreement. Notwithstanding the foregoing, if ******to make any ******in an ******and follow ****** ******of such ******as they ****** ******; ******, that this ******to take any ******.

4.6.2 All AE and SAE reports will be exchanged using either approved study forms, electronic, or computer generated reports agreed upon by both parties (*e.g.*, CIOMS I form).

4.6.3 Subject to Section 4.6.1, AstraZeneca will maintain and will be the recognized holder of a global safety database for AE and SAE reports related to POZEN Products received by either Party. Direct access to this database will not be granted to POZEN. Upon request, all reasonable assistance will be provided by either Party in responding to safety inquiries.

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4.6.4 Each Party shall keep the other Party informed of notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority which: (i) raises any material concerns regarding the safety or efficacy of the Initial POZEN Product; (ii) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with the Initial POZEN Product; (iii) is reasonably likely to lead to a "Dear Doctor" letter, recall or market withdrawal of the Initial POZEN Product; (iv) relates to the Initial POZEN Product, Regulatory Materials, Promotional Materials, samples, package inserts, the indications, labeling, expedited and periodic Adverse Event Reports, medical inquiries, Initial POZEN Product complaints, this Agreement, or (v) is otherwise important to the Development and/or Commercialization of the Initial POZEN Product.

5. COMMERCIALIZATION

5.1 Commercialization. As between the Parties, AstraZeneca will be solely responsible for the Commercialization of POZEN Products during the Term.

5.2 Regulatory Obligations during Commercialization. On a country−by−country basis, AstraZeneca will own and maintain all regulatory filings and Marketing Approvals for POZEN Products developed pursuant to this Agreement, including all INDs and NDAs for the Initial POZEN Product following POZEN's transfer of such filings and approvals subsequent to NDA Approval of the Initial POZEN Product in the U.S. As between the Parties, but subject to ******, AstraZeneca will be solely responsible for all activities in connection with maintaining Marketing Approvals required for the Commercialization and manufacture of POZEN Products, including communicating and preparing and filing all reports (including Adverse Event reports) with the applicable Regulatory Authorities.

5.3 Performance; Diligence.

5.3.1 Level of Efforts. Upon the grant of Marketing Approval for a POZEN Product in the U.S. or a country of the Major Ex−U.S. Market, AstraZeneca will use Diligent Efforts to Commercialize a POZEN Product in such country. The foregoing Diligent Efforts requirement will apply only to one POZEN Product in each of the U.S. and the Major Ex−U.S. Market countries, irrespective of the number of POZEN Products AstraZeneca elects to Develop and Commercialize, and AstraZeneca may elect to fulfill its Diligent Efforts obligation in such countries in respect to any POZEN Product of its choice in the exercise of its reasonable and good faith judgment.

5.3.2 Specific Timelines. AstraZeneca will use Diligent Efforts in the U.S. and in each country of the Major Ex−U.S. Market to achieve Commercial Launch within ****** (******) days after the date on which Marketing Approval is granted for such Initial POZEN Product in such country; provided, that for any country in which Marketing Approval is granted by Regulatory Authorities ******, then the obligations set forth in this Section 5.3.2 will apply only to ******; and provided, further, that if AstraZeneca elects to launch the Initial POZEN Product in a particular country or territory following NDA Approval in such country or territory, but before or without obtaining pricing or reimbursement approval therein, then the ****** (******)−day period set forth in this Section 5.3.2 will commence as of the date of such NDA Approval.

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5.4 Commercialization Plan.

5.4.1 AstraZeneca shall prepare and update from time to time an initial commercialization plan summarizing the plan for Commercializing the Initial POZEN Product in the U.S. and the Major Ex−U.S. Markets (the "**Commercialization Plan**") within ****** (******) days after U.S. NDA filing for the Initial POZEN Product and the first filing of a Marketing Approval application for the Initial POZEN Product in a country of the Major Ex−U.S. Markets, respectively. The Commercialization Plan as reviewed by the GPT shall describe the overall plan for Commercializing the Initial POZEN Product during the first three years after First Commercial Sale of the Initial POZEN Product in the U.S. and the Major Ex−U.S. Market.

5.4.2 The Commercialization Plan will be in a format consistent with the format of similar plans prepared by AstraZeneca for its other products.

5.5 Threatened Removal. In the event that any governmental authority threatens or initiates any action to remove any POZEN Product from the market in a country or territory, AstraZeneca will promptly notify POZEN of such communication. Any voluntary recall or withdrawal of any POZEN Product will be at AstraZeneca's sole discretion and expense. Before AstraZeneca initiates a recall or withdrawal, the Parties will promptly and in good faith discuss the reasons therefor; provided, that such discussions do not delay the recall or withdrawal. In the event of any recall or withdrawal for any POZEN Product, AstraZeneca will implement any necessary action, with assistance from POZEN as reasonably requested by AstraZeneca.

5.6 Compliance. Each Party will comply with all Applicable Laws relating to activities performed or to be performed by such Party (or its Affiliates or contractors) under or in relation to the Commercialization of the Initial POZEN Product pursuant to this Agreement. Each Party represents, warrants and covenants to the other Party that, as of the Effective Date and during the Term, such Party and its Affiliates have adequate policies and procedures in place: (i) to ensure their compliance with such laws; (ii) to bring any non−compliance therewith by any of the foregoing entities to its attention; and (iii) to promptly remedy any such non−compliance.

5.7 Branding; Trademarks; Domain Names; Trade Dress; Logos.

5.7.1 Responsibilities. AstraZeneca will select all Product Trademarks for use on or in connection with POZEN Products, will be the sole owner of the Product Trademarks, will be responsible for the filing, prosecution, maintenance and defense of all registrations of the Product Trademarks, and will be responsible for the payment of any costs relating to filing, prosecution, maintenance and defense of the Product Trademarks.

5.7.2 Use. AstraZeneca will use the Product Trademarks in connection with the Commercialization of POZEN Products hereunder. The packaging, Promotional Materials and Product Labeling for POZEN Products will carry the POZEN House Marks only if and to the extent required by Applicable Law in a country or territory.

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5.7.3 AstraZeneca Marks. AstraZeneca reserves all rights in the Product Trademarks and AstraZeneca House Marks. POZEN acknowledges AstraZeneca's exclusive right, title and interest in and to such trademarks and acknowledges that nothing herein will be construed to accord to POZEN any rights in such trademarks. POZEN agrees not to use or file any application to register any trademark or trade name that is confusingly similar to any Product Trademarks or AstraZeneca House Mark.

5.7.4 POZEN Marks. POZEN reserves all rights in the POZEN House Marks not expressly granted to AstraZeneca in this Agreement. AstraZeneca acknowledges POZEN's exclusive right, title and interest in and to the POZEN House Marks and acknowledges that nothing herein will be construed to accord to AstraZeneca any rights in such trademarks except as expressly provided herein. AstraZeneca further acknowledges that its use of the POZEN House Marks will not create in AstraZeneca any right, title or interest in such trademarks, and that all use of such trademarks and the goodwill generated thereby will inure solely to the benefit of POZEN. AstraZeneca agrees not to use or file any application to register any trademark or trade name that is confusingly similar to any POZEN House Mark.

5.7.5 Promotional Materials. AstraZeneca will own all right, title and interest in and to any Promotional Materials created by or on behalf of AstraZeneca (or its Affiliates) relating to POZEN Product, but excluding the POZEN House Marks. The GPT will approve a standard template for use of the POZEN House Marks in Promotional Materials, and AstraZeneca will use the POZEN House Marks in accordance with approved template.

6. MANUFACTURE OF POZEN PRODUCTS

6.1 Manufacturing Development.

6.1.1 Initial POZEN Product. POZEN has developed formulations for ****** and Manufacturing processes for bulk and finished supplies, itself and through one or more Third Party contract manufacturers. ****** (******) days after the Effective Date, AstraZeneca will provide the Esomeprazole Materials (as defined below) to POZEN. POZEN shall, no later than ****** after the date that POZEN receives the Esomeprazole Materials (as defined below), develop (itself and through one or more Third Party contract manufacturers) a formulation and a manufacturing process (and related testing procedures) for the Initial POZEN Product meeting the specifications set forth in Schedule 6.1 (the "**Specifications**") and sufficient quantities of the Initial POZEN Product meeting the Specifications as reasonably necessary to conduct the ****** studies described in the Initial U.S. Development Plan. However, AstraZeneca will be responsible for supplying to POZEN or its designee ****** as a separate component that will be used for the ****** described in the Initial U.S. Development Plan, and POZEN will supply ****** for such study. As used herein, **"Esomeprazole Materials"** means sufficient quantities of Esomeprazole substance for POZEN to perform the activities described in Sections 6.1.1 and 6.1.2 as well as the ****** studies designated as ******, including a certificate of analysis, ID test method for esomeprazole, reference standard for esomeprazole, cleaning method for esomeprazole, current drug product methods for esomeprazole for assay, related substances and dissolution (*i.e.*, chromatographic conditions), and esomeprazole solubility data and associated technical information.

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6.1.2 ROW POZEN Products. POZEN shall develop (itself and through one or more Third Party contract manufacturers) a formulation and a manufacturing process (and related testing procedures) for each Initial POZEN Product contemplated to be developed under the Initial ROW Development Plan meeting the Specifications and shall deliver to AstraZeneca sufficient quantities of such Initial POZEN Products as reasonably necessary to conduct the ****** described in the Initial ROW Development Plan within the timeline for such studies set forth in the Initial ROW Development Plan Timeline.

6.1.3 Manufacturing, Cooperation, and Assistance. The manufacturing processes developed by POZEN shall be designed to be scalable for commercial manufacture of the Initial POZEN Product under the Initial U.S. Development Plan and Initial ROW Development Plan and to enable the manufacture of the Initial POZEN Product routinely and predictably in conformance with the Specification and in compliance with Applicable Law. POZEN will consult with AstraZeneca on a regular basis with respect to the development described in this Section 6.1 (Manufacturing Development) and will give reasonable consideration to AstraZeneca's suggestions. AstraZeneca will provide all reasonable assistance requested by POZEN. AstraZeneca hereby consents to POZEN's using ****** to perform the process development activities described in this Section 6.1 (Manufacturing Development). In furtherance of the forgoing, if POZEN does use ****** to perform such activities, POZEN shall enter into an agreement with ****** that, as between POZEN and ******, requires ****** to transfer to POZEN and gives POZEN ownership of all formulation and Manufacturing Know−How developed by ****** related to the Initial POZEN Product and all intellectual property rights therein.

6.1.4 Expenses. Promptly following the Execution Date and not later than the Effective Date, the Parties will agree on a schedule of expected activities and related costs for activities to be conducted by or on behalf of POZEN pursuant to Sections 6.1 and 6.2 after the Execution Date (including the Direct Costs of any inventory used in connection with such activities whether or not purchased by POZEN prior to the Execution Date) (**"Formulation Development Activities"**) and a budget for the Formulation Development Activities including both Direct Costs to be incurred with Third Parties and FTE Costs to be incurred by POZEN, as well as estimated timings of such costs (the **"Formulation Budget"**), which will be attached to this Agreement as Exhibit A. POZEN will calculate and maintain records of all Direct Costs and FTE Costs incurred by POZEN in performing the Formulation Development Activities, in accordance with POZEN's internal accounting policies. Within ****** (******) days after POZEN incurs Direct Costs or FTE Costs in performing the Formulation Development Activities, POZEN will submit to AstraZeneca a written invoice setting forth in reasonable detail the Direct Costs and FTE Costs it has incurred in performing the Formulation Development Activities. AstraZeneca will pay POZEN within ****** (******) days following the receipt of the invoice for Direct Costs and FTE Costs that do not exceed the then−current Formulation Budget by more than ****** percent (******%). Any payments made pursuant to this Section 6.1.4 (Expenses) will be subject to the general payment procedures set forth in Section 8.5 through 8.7, inclusive. POZEN will inform the GPT at least ****** (******) days prior to incurring any Direct Costs or FTE Costs that exceed the then−current Formulation Budget by more than ****** percent (******%) and the GPT will meet to consider the adjustment of such budget or approval of such variance; provided, that the GPT will approve variances above ******% if and to the extent the variances are (a) reasonable in light of prevalent market conditions for similar work, or (b) beyond POZEN's reasonable control. AstraZeneca shall not be held responsible for any expenditure relating to the Formulation Development Activities incurred by POZEN that exceeds the then−current Formulation Budget by more than ****** percent (******%), unless such expenditure has been specifically approved by the GPT as an exception to the Formulation Budget.

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6.1.5 AstraZeneca Development of Formulation. If POZEN fails to perform its obligations under Section 6.1.1 (Initial POZEN Product) or 6.1.2 (ROW POZEN Products), within the time periods required thereby, without limiting any other rights and remedies available to AstraZeneca, unless AstraZeneca has selected a substitute Initial POZEN Product pursuant to Section 3.4.2 (Substitution) or has terminated the Agreement, then AstraZeneca shall use Diligent Efforts to develop (itself and through one or more Third Party contract manufacturers) a formulation and a manufacturing process for the Initial POZEN Product meeting the Specifications and to deliver to POZEN sufficient quantities of the Initial POZEN Product meeting the Specifications within ****** after AstraZeneca receives from POZEN all formulation Know−How in POZEN's possession. In such event, POZEN will provide all reasonable assistance requested by AstraZeneca in connection with such efforts. POZEN hereby consents to AstraZeneca's using ****** to perform the activities described in this Section 6.1.5 (AstraZeneca Development of Formulation) and consents to AstraZeneca's granting to ****** a sublicense of rights under the Licensed Technology to the extent reasonably necessary for ****** to perform such work.

6.1.6 POZEN Warranties. POZEN hereby warrants that the Initial POZEN Product provided by POZEN (itself or through one or more Third Party contractors) for use in clinical studies pursuant to Sections 6.1.1 or 6.1.2, at the time of delivery will have been manufactured and shipped in accordance with cGMP and cGLP, the IND for the Initial POZEN Product and other Applicable Law; and will not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as amended.

6.2 Process Transfer. Following the completion of the activities described in Section 6.1.1, POZEN will transfer all formulation and Manufacturing Know−How necessary to establish the applicable Manufacturing processes at commercial scale at a site designated by AstraZeneca (including such formulation and Manufacturing Know−How possessed by its Third Party contractors), and will use Diligent Efforts to cause such Third Party manufacturers to allow AstraZeneca employees or agents to reasonably observe the Manufacture of the Initial POZEN Product at POZEN's subcontractor's or agent's premises and subject to any reasonable rules imposed by such Third Party. Thereafter, (i) POZEN will continue to be reasonably available, and will use reasonable efforts to cause its subcontractors and agents to be reasonably available, to AstraZeneca and will provide all reasonable assistance requested by AstraZeneca in connection with the establishment and implementation of such Manufacturing process, and (ii) AstraZeneca will use Diligent Efforts to establish commercial−scale Manufacturing processes for bulk and finished supplies of the Initial POZEN Product.

****** Portion for which confidential treatment requested.

6.3 Terms for Clinical Supply.

6.3.1 Responsibility. AstraZeneca will use Diligent Efforts to conclude a supply agreement for the Initial POZEN Product with a Third Party contract manufacturer ****** within ****** (******) days after the Effective Date, under which such Third Party contract manufacturer will supply AstraZeneca Initial POZEN Product in quantities for all clinical studies ******, Commercial Launch, and post−launch supply until such time as AstraZeneca has, itself or through its designated contract manufacturer, successfully manufactured at commercial scale a product that meets such specifications as may be required by Applicable Law and that is bioequivalent to the Initial POZEN Product Clinical Trial Material used in the Phase III clinical studies for such Initial POZEN Product. Once POZEN has established a qualified source of Initial POZEN Product supply for the ****** studies contemplated by the Initial U.S. Development Plan and transferred the necessary formulation and Manufacturing Know−How pursuant to Section 6.2 (Process Transfer)), AstraZeneca will Manufacture and supply the Parties' entire requirements of Initial POZEN Product for the Development of the Initial POZEN Product under the U.S. Development Plan sufficient for the Parties to conduct the applicable clinical activities in accordance with the time periods set forth in U.S. Development Plan Timeline. Likewise, once POZEN has established a qualified source of the Initial POZEN Product for the ****** study contemplated by the ROW Development Plan and transferred the necessary formulation and manufacturing Know−How pursuant to Section 6.2 (Process Transfer), AstraZeneca will Manufacture and supply (itself or through one or more Third Party contractors) the Parties' entire requirements of Initial POZEN Product for the Development of the Initial POZEN Product under the ROW Development Plan sufficient for the Parties to conduct the applicable clinical activities in accordance with the time periods set forth in ROW Development Plan Timeline. ****** will bear all costs and expenses incurred for any such Manufacture and supply. POZEN hereby consents to AstraZeneca's using ****** to Manufacture clinical supplies and commercial quantities of POZEN Products if AstraZeneca should so desire and consents to AstraZeneca's granting to ****** a sublicense of rights under the Licensed Technology to the extent reasonably necessary for ****** to perform such work.

6.3.2 Clinical Supply. Except as provided in Section 6.1 (Manufacturing Development), AstraZeneca will supply POZEN ****** with Clinical Trial Materials in order for POZEN to perform clinical studies pursuant to Section 3.2 (Core Development Activities) and 3.3 (Additional Development Activities), as applicable, in accordance with a reasonable delivery schedule as the Parties may jointly agree in writing (which such schedule, in any event, will enable the completion of the applicable clinical trials in accordance with the timelines set forth in the applicable development plan).

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6.3.3 Packaging, Shipping and Delivery. AstraZeneca will fill, release, package and label such Clinical Trial Materials to be used in clinical trials conducted by POZEN pursuant to this Agreement in final bottles or blisters (or such other dose per package as agreed by the GPT) using due care and in accordance with Applicable Laws and any specifications as the Parties may agree in writing. POZEN will be responsible for identification testing, randomization and clinical patient labeling of Clinical Trial Materials supplied to POZEN by AstraZeneca in the final packaging. POZEN ****** will complete such identification testing, randomization, and clinical patient labeling of Clinical Trial Materials as soon as practicable following receipt of the Clinical Trial Materials from AstraZeneca. AstraZeneca will ship the Clinical Trial Materials DDU (Incoterms 2000) to the facility in the U.S. as POZEN may designate to AstraZeneca by a common carrier designated by AstraZeneca. Each shipment will be made generally in accordance with an agreed timeline and under the terms and conditions set forth in this Section 6 (Manufacture of POZEN Product) and the U.S. Development Plan or ROW Development Plan, as applicable. Each shipment will include a certificate of analysis and any other release data customarily transferred by AstraZeneca in accordance with its usual practice. There will be a remaining shelf life for Clinical Trial Materials upon delivery that is appropriate in light of the expected schedule and duration of the clinical trial(s) in which such Clinical Trial Materials are to be used. AstraZeneca will notify POZEN of the results of ongoing stability testing of the Clinical Trial Materials by AstraZeneca.

6.3.4 Warranties. AstraZeneca hereby warrants that any Clinical Trial Materials provided by AstraZeneca to POZEN under this Agreement, at the time of delivery pursuant to Section 6.3.3 (Packaging, Shipping and Delivery): (i) will conform to the specifications for such Clinical Trial Materials, within applicable regulatory requirements, as agreed by the Parties in writing; (ii) will have been manufactured and shipped to POZEN (or its designee) in accordance with cGMP, cGLP, the IND for POZEN Product and other Applicable Laws; and (iii) will not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as amended (collectively, the **"CTM Warranties"**).

6.3.5 Remedies for Non−Conforming Clinical Trial Materials. In the event that a shipment of Clinical Trial Materials does not conform with the CTM Warranties, in whole or in part, then AstraZeneca will promptly produce (at its cost) for POZEN sufficient quantities of Clinical Trial Materials to replace the non−conforming portion of such shipment of Clinical Trial Materials, in accordance with the provisions of this Agreement. In the event that the Clinical Trial Materials are rendered non−conforming to the CTM Warranties by the action of POZEN or its agent following delivery as provided in Section 6.3.3 (Packaging, Shipping and Delivery), then AstraZeneca will produce (at POZEN's cost) for POZEN sufficient quantities of Clinical Trial Materials to replace the non−conforming portion of such shipment of Clinical Trial Materials, in accordance with the provisions of this Agreement.

6.4 Commercial Supply. AstraZeneca will be solely responsible****** for the Manufacture and supply of AstraZeneca's entire requirements of supplies of POZEN Product for Commercialization.

****** Portion for which confidential treatment requested.

6.5 Audits and Inspections.

6.5.1 Audits. At all times that AstraZeneca is supplying Clinical Trial Material to POZEN, a delegation consisting of a reasonable number of representatives of POZEN (or its Third Party contractors reasonably acceptable to AstraZeneca), no more than ****** per site per calendar year, will have the right to inspect and audit any AstraZeneca facility where the Clinical Trial Material, including their active pharmaceutical ingredients ******, are Manufactured, and the documentation generated in connection with the Manufacture and testing of Initial POZEN Product. However, any such inspections that are made for cause in response to a failure or deficiency at the applicable site will not count toward such annual limit. Such inspections will take place during regular business hours and after at least ****** (******) days prior notice to AstraZeneca. POZEN will discuss the results of any inspection with AstraZeneca. Any inspection by or on behalf of POZEN, if it occurs, does not relieve AstraZeneca of its obligation to comply with all Applicable Laws and does not constitute a waiver of any right otherwise available to POZEN.

6.5.2 Inspections. AstraZeneca will notify POZEN promptly following notice from the FDA or any other Regulatory Authority of a visit to any AstraZeneca facility where the Clinical Trial Material ****** is Manufactured. A representative of POZEN (or its Third Party contractor reasonably acceptable to AstraZeneca) may request to be present as a silent observer at any announced visits to AstraZeneca by any Regulatory Authority relating to the Manufacture of Clinical Trial Material, such request not to be unreasonably refused. Furthermore, AstraZeneca will inform POZEN of the results of any inspection by a Regulatory Authority that does or could reasonably be expected to affect the Manufacture of Clinical Trial Material ******. AstraZeneca will promptly provide POZEN with copies of notifications from any Regulatory Authority (including, without limitation, any Form No. 483 notification, Enforcement Inspection Reports, Notice of Adverse Finding, etc.). POZEN will treat all information subject to review under this Section 6.5.1 (Audits and Inspections) in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party auditor retained by POZEN (and reasonably acceptable to AstraZeneca) to enter into a reasonably acceptable confidentiality agreement with AstraZeneca obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

6.6 Reference Rights; Support. In connection with any supply or transfer of Clinical Trial Materials under this Section 6 (Manufacture of POZEN Product) and for so long as AstraZeneca supplies any of the foregoing to POZEN, or POZEN is using such Clinical Trial Materials pursuant to this Agreement, AstraZeneca will grant to POZEN rights of reference (including by providing a letter of authorization to the applicable Regulatory Authorities) to any AstraZeneca IND or NDA pertaining to Esomeprazole. Upon the expiration of such right, POZEN will send written notice to such effect to the applicable Regulatory Authority.

****** Portion for which confidential treatment requested.

7. LICENSES

7.1 Licensed Technology. Subject to the terms and conditions of this Agreement, POZEN hereby grants to AstraZeneca an exclusive (including with regard to POZEN and its Affiliates), royalty−bearing license, with the right to grant sublicenses as described in Section 7.3 (Sublicenses), under the Licensed Technology to make, use, have made, sell, offer for sale, import, and export Products in the Field of Use in the Territory. For the avoidance of doubt, AstraZeneca shall have no license or other right under the Licensed Technology to make, use, have made, sell, offer for sale, import, and export any product containing acetyl salicylic acid (including salts and derivatives thereof).

7.2 Trademarks. Subject to the terms and conditions set forth in this Agreement, POZEN hereby grants to AstraZeneca a license to use the POZEN House Marks in connection with the Commercialization of POZEN Products in the Field of Use in the Territory.

7.3 Sublicenses. AstraZeneca may grant a sublicense, option to sublicense, or any other right relating to any Licensed Technology to any of its Affiliates without the right to grant further sublicense rights to any Third Party. AstraZeneca may grant a sublicense, option to sublicense, or any other right relating to any Licensed Technology to any Third Party solely as provided in this Section 7.3 (Sublicenses). AstraZeneca may enter into Sublicense Agreements only with POZEN's prior consent. In order for rights under Licensed Technology to be validly granted to a Sublicensee, the Sublicense Agreement with such Sublicensee must be consistent with the following terms and conditions of this Agreement, and will include provisions for the benefit of POZEN corresponding to Section ******. AstraZeneca will use Diligent Efforts to (i) procure the performance by any Sublicensee of the terms of each such Sublicense Agreement, and (ii) ensure that any Sublicensee will comply with the applicable terms and conditions of this Agreement. AstraZeneca hereby guarantees the performance of its Affiliates and Sublicensees that are sublicensed as permitted herein, and the grant of any such sublicense will not relieve AstraZeneca of its obligations under this Agreement, except to the extent they are satisfactorily performed by such Affiliate or Sublicensee. Notwithstanding the foregoing, AstraZeneca will have the right to sell POZEN Products through any distributors or sub−distributors of its choice, without the need to obtain prior consent from POZEN, in carrying out its Commercialization activities under this Agreement.

7.4 Reservation of Rights; No Implied Licenses. POZEN retains rights under the Licensed Technology to the extent necessary to perform its obligations under this Agreement. Except for the rights specifically granted in this Agreement, POZEN reserves all rights to the Licensed Technology. No implied licenses are granted under this Agreement. In particular POZEN is not by this Agreement, by implication or otherwise, granted any license or other right relating to Esomeprazole, Nexium or the Nexium Business or any Esomeprazole based products or any products containing acetyl salicylic acid (including salts and derivatives thereof) or any right in relation to any patent, trademark or other intellectual property right belonging to AstraZeneca or any of its Affiliates, and likewise AstraZeneca is not by this Agreement, by implication or otherwise, granted any license or other right under the Licensed Technology relating to any products containing acetyl salicylic acid (including salts and derivatives thereof) or any right in relation to any patent, trademark or other intellectual property right belonging to POZEN or any of its Affiliates, in each case, except as expressly set forth in this Agreement.

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7.5 Restrictive Covenant. AstraZeneca hereby covenants and agrees not to use any Licensed Technology, nor grant any Third Party any license or right under any Licensed Technology, other than as expressly permitted in this Agreement. The Parties agree that nothing in this Agreement restricts or prohibits AstraZeneca from by itself or with Third Parties exploiting any products, including without limitation any products containing non−steroidal anti−inflammatory drugs (*e.g.*, acetyl salicylic acid and esters and derivatives thereof); provided, that AstraZeneca shall not use or practice Licensed Technology in connection with the development, manufacture or commercialization of any product that is not a Product, and nothing requires AstraZeneca to compensate POZEN if AstraZeneca so exploits such products.

7.6 Japan Option. POZEN hereby grants AstraZeneca an option for a period of twenty−four (24) months (the **"Japan Option Period"**) after the Effective Date to include Japan in the Territory at no additional cost to AstraZeneca. The option will be exclusive to AstraZeneca during ****** of the Japan Option Period, and during such exclusive period POZEN will not solicit or enter into discussions with any Third Party regarding the availability or exploitation of Licensed Know−How or Licensed Patents in Japan. Thereafter, the option will be non−exclusive, and POZEN may, prior to exercise of the option by AstraZeneca, grant rights in Japan to any Third Party. AstraZeneca may exercise the option at any time prior to the expiration of the Japan Option Period by providing written notice to POZEN and a Development plan for a Product AstraZeneca intends to Commercialize in Japan, whereupon Japan shall immediately be included in the Territory.

8. FINANCIAL TERMS

8.1 Upfront Fee. Within ten (10) Business Days following the Effective Date, AstraZeneca will pay to POZEN a non−creditable, non−refundable upfront fee of $40,000,000.

8.2 Development Milestone Payments. Subject to the terms and conditions of this Agreement, including without limitation the last paragraph of this Section 8.2 (Development Milestone Payments), AstraZeneca will pay to POZEN the following one−time, non−creditable, non−refundable payments with respect to the first achievement of the corresponding events with a POZEN Product.

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Milestone Event	Milestone Payment
1. Receipt by the ******of the final written ****** for the ****** as described in the Initial U.S. Development Plan and the final written ****** for the ******Study as described in the Initial U.S. Development Plan, and either (a) the ****** of ****** for at least ****** of the ******, or (b) ****** does not ****** pursuant to Section 12.4 due to a ******described in ****** within ****** (******from receipt by the ****** of the final written ****** for the ******Study described in the Initial U.S. Development Plan.	$******
2. Notification by the FDA that it has accepted the first U.S. NDA submission for a POZEN Product in accordance with Section 4.1.1 (Regulatory Responsibilities Inside the U.S.).	$******
3. Submission of the first NDA in a Major Ex−U.S. Market country for a POZEN Product.	$******
4. Receipt of the first NDA Approval for a POZEN Product in the U.S.	$******
5. Receipt of the first NDA Approval for a POZEN Product in a Major Ex−U.S. Market country.	$******
6. ****** of the first ****** to ****** a ****** in a ****** that includes ****** and/or ****** (if available) at an ******of the POZEN Product ****** than the ****** (a) the ****** for a ****** in such ******, or (b) ******.	$******

POZEN shall notify AstraZeneca in writing upon the achievement of Milestones Events 2 and 4 above, and shall provide AstraZeneca with reasonable evidence that such Milestone Events have been achieved. The payments due with respect to achievement of each Milestone Event shall be due and payable within ****** (******) days after (i) AstraZeneca receives notification from POZEN of the achievement of Milestone Events #2 and 4, and (ii) the occurrence of the Milestone Events #1, 3, 5, and 6, it being understood that with respect to Milestone Event #1(b) the Milestone Event will not have occurred until the end of the ****** (******) day period referenced therein. The date on which any such milestone payment is due and payable in accordance with the preceding sentence is hereinafter referred to as the **"Milestone Due Date**.**"**

****** Portion for which confidential treatment requested.

Each milestone payment identified in this Section 8.2 (Development Milestone Payments) shall be payable one time only, irrespective of the number of POZEN Products that achieve the applicable Milestone Event. Notwithstanding the foregoing, if a Milestone Event for which a payment would be due under this Section 8.2 (Development Milestone Payments) is achieved, but AstraZeneca provides notice to POZEN that it is exercising its right to terminate this Agreement pursuant to Section 12.3 (Termination for Material Breach), 12.4 (Termination for Cause) or 12.5 (Termination at Will) prior to the applicable Milestone Due Date for such Milestone Event, then such milestone payment will not be payable; provided, that AstraZeneca complies with its obligations under Section 12.6.3(b) (Effect of Termination for Cause or Material Breach) or 12.6.4 (Effect of Termination at Will) if applicable.

8.3 Sales Milestone Payments. Subject to the terms and conditions of this Agreement, AstraZeneca will pay to POZEN the following one−time, non−creditable, non−refundable payments within ****** (******) days following the achievement of the corresponding events described in the table below.

Milestone Event	Milestone Payment
1. End of first calendar year during which aggregate annual Net Sales of Products were at least $******	$******
2. End of first calendar year during which aggregate annual Net Sales of Products were at least $******	$******
3. End of first calendar year during which aggregate annual Net Sales of Products were at least $******	$******

Each milestone payment identified in this Section 8.3 (Sales Milestone Payments) shall be payable one time only, and not for each time that the “annual Net Sales” of Products exceeds a specified amount.

8.4 Royalties.

8.4.1 Royalty Rate. Subject to the terms and conditions of this Agreement, AstraZeneca will pay to POZEN royalties based on the aggregate annual Net Sales of Products sold by AstraZeneca, its Affiliates or Sublicensees, at the rates set forth below:

(a) For Net Sales ******:

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(i) ******% of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than $******;

(ii) ******% of the portion of aggregate Net Sales of Products during a calendar year that is greater than $****** but equal to or less than $******; and

(iii) ******% of the portion of aggregate Net Sales of Products during a calendar year that is greater than $******.

(b) For Net Sales ******:

(i) ******% of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than $******; and

(ii) ******% of the portion of aggregate Net Sales of Products during a calendar year that is greater than $******.

(c) Notwithstanding the foregoing provisions of this Section 8.4.1 (Royalty Rate), if a ****** is sold in one or more countries where ******, the total royalties owed for Products shall be determined on a segregated basis, according to the following calculations:

(i) ****** percent (******%) of the total Net Sales of the ****** ****** sold in any country shall be added to the total Net Sales of the ****** (the resulting amount being the **"Segregated Net Sales"**), and the applicable royalty rates set forth in Section 8.4.1(a) and (b) shall be applied to the Segregated Product Net Sales (the resulting amount being the **"Segregated Royalty Amount"**);

(ii) the applicable royalty rates set forth in Section 8.4.1(a) and (b) shall be applied to the remaining ****** percent (******%) of the total Net Sales of the ****** (the resulting amount being the **"Remaining Royalty Amount"**); and

(iii) the amount owed by AstraZeneca shall be equal to the Segregated Royalty Amount plus the Remaining Royalty Amount.

(iv) If ****** are also sold in a country where there are at least ****** being sold, then the calculations above shall be applied similarly to each such additional Product, such that ****** percent (******%) of the Net Sales of each additional Product shall be added to the Segregated Royalty Amount, and the remaining ****** percent (******%) of each additional Product shall be combined only with the remaining ****** percent (******%) of Net Sales of the other additional Products (*i.e.*, the ******) that are being sold in other countries. The example set forth in Schedule 8.4.1 illustrates the application of this 8.4.1(c).

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8.4.2 Royalty Term. AstraZeneca acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to AstraZeneca of certain elements of, the Licensed Technology pursuant to this Agreement (including the Licensed Know−How and the regulatory data to be provided to AstraZeneca pursuant to this Agreement) as well as from AstraZeneca's own development of technology derived from the practice of such license and AstraZeneca's use of such Licensed Technology, even after expiration of all Valid Claims of the Licensed Patents covering the composition of matter, manufacture, use or sale of POZEN Product in a country. Accordingly, subject to the terms of Section 8.4.3 (Rate Step Down for Competing Product Entrants), AstraZeneca's royalty payment obligations under this Section 8.4 (Royalties) will commence upon First Commercial Sale of a Product in a particular country and will expire on a country−by−country basis upon the later of: (i) expiration of the last−to−expire Valid Claim of the Licensed Patents that, but for the licenses granted in this Agreement, would be infringed by the sale of such Product in such country, and (ii) ten (10) years after the First Commercial Sale of such Product in such country (such period ending at the later of the periods set forth in clause (i) and (ii) above, the **"Royalty Term"**).

8.4.3 Rate Step Down For Competing Product Entrants. With respect to any particular Product and country, if in any Calendar Quarter there is a Market Reduction of such Product (based on prescription market data published by IMS Health, Scott−Levin, or such other industry standard source as the Parties may agree), then the royalty rates which would otherwise apply to Net Sales of such Product in such country during such Calendar Quarter will be reduced to ****** percent (******%) of the rates set forth in Section 8.4.1 (Royalty Rate); provided, that in no event will ****** (resulting in ****** and ****** for ******; and ****** and ******). Such reduced royalty rates will continue in effect, on a Product−by−Product and country−by−country basis, until expiration of the applicable Royalty Term. As used in this Section 8.4.3, the term **"Market Reduction"** of a Product in a Calendar Quarter occurs when (i) ****** by ****** for such ****** by ****** in such ****** of the ****** in such ******of the ****** and ******of the ******in such ******to the ******in which the ******of a ******occurred. The example set forth in Schedule 8.4.3 illustrates the application of this Section 8.4.3.

8.4.4 Third Party Payments. If AstraZeneca determines that a license to certain Third Party technology is reasonably necessary for the successful Development, Manufacture or Commercialization of a Product, then AstraZeneca will notify POZEN in writing of such determination. The Parties will consult in good faith regarding the need for such Third Party technology and, subject to POZEN's consent (not to be unreasonably withheld, conditioned or delayed), AstraZeneca will negotiate the terms on which such a Third Party license would be granted to AstraZeneca and will serve as the primary point of contact with the applicable Third Party licensor following the execution of the license agreement. The royalties required to be paid by AstraZeneca with respect to a Product in a particular country pursuant to Section 8.4 (Royalties) shall be subject to a reduction by AstraZeneca in an amount equal to ******of the amount of ******that are ******under such ******in such ******for the ******of such ******during the ******provided, that (i) ******of the ****** of such ******in such ******for such ******and (ii) if such ******is a****** (*i.e.*, if the ******for such ****** ******). Notwithstanding anything to the contrary in this Agreement, AstraZeneca shall be solely responsible for any Third Party Payment obligations it may have to Merck & Co., Inc. or its affiliates, without any offset or deduction. Any amount of Third Party Royalties that may, pursuant to the preceding paragraph be used to reduce royalties due hereunder, in any Calendar Quarter, but are not so used as a result of the limitation described in clause (i) of this paragraph may be carried over and used for further reduction in any succeeding royalty payment due for such Product.

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8.4.5 ****

8.5 Payments and Sales Reporting.

8.5.1 Sales Reporting. AstraZeneca will provide POZEN, within ****** days (******) of the end of each Calendar Quarter, with a report setting forth, on a country−by−country and Product−by−Product basis, the amount of gross sales of each Product in such country, a calculation of Net Sales, the currency conversion rate used and Dollar−equivalent of such Net Sales, and a calculation of the amount of royalty payment due on such Net Sales, provided that AstraZeneca shall use reasonable efforts to provide such report as soon as practicable to accommodate POZEN's SEC filing requirements and to provide such reports in a shorter time period than the periods specified above if AstraZeneca has such reports available for its own internal purposes. If any payment reduction is claimed by AstraZeneca under this Agreement from the full royalty rates set forth in Section 8.4 (Royalties), then the report will set forth in detail the claimed reduction and the related facts.

8.5.2 Payment Timing. AstraZeneca will make royalty payments to POZEN within ****** (******) days of the last day of each Calendar Quarter for which such payments are due under Section 8.4 (Royalties).

8.5.3 Payment Method. All amounts due hereunder will be paid in United States Dollars by wire transfer in immediately available funds to the following account, or such other account as may be designated in writing by POZEN:

Receiving bank name:	******	
Receiving bank address:	******	******
ABA routing number (1):	******	(1) − required for domestic transfers
SWIFT BIC address (2):	******	(2) − required for international transfers
For credit to the account of:	POZEN Inc.	
For credit to account number:	******	

8.5.4 Currency Conversion. All payments required under this Article 8 shall be made in U.S. Dollars. For the purpose of computing the Net Sales of Licensed Products sold in a currency other than U.S. Dollars, such currency shall be converted from local currency to U.S. Dollars by AstraZeneca in accordance with the rates of exchange for the relevant month for converting such other currency into U.S. Dollars used by AstraZeneca's internal accounting systems, which are independently audited on an annual basis.

8.5.5 Late Payments. If a Party does not receive payment of any sum due to it on or before the due date, simple interest will thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of ****** percent (******%) over the then−current ****** quoted by Citibank in New York City, or the maximum rate allowable by Applicable Law, whichever is lower.

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8.6 Records; Audit. AstraZeneca will maintain complete and accurate records in sufficient detail to permit POZEN to confirm the accuracy of the calculation of payments under this Agreement. Upon reasonable prior notice, such records will be available during regular business hours of AstraZeneca for a period of ****** (******) calendar years following the year in which such records were created, for examination at POZEN's expense, and not more often than once each calendar year, by an independent certified public accountant selected by POZEN and reasonably acceptable to AstraZeneca, for the sole purpose of verifying the accuracy of the financial reports furnished by AstraZeneca pursuant to this Agreement. Any such auditor will not disclose AstraZeneca's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by AstraZeneca or the amount of payments due by AstraZeneca under this Agreement. Any amounts shown to be owed but unpaid will be paid within ****** (******) days from the accountant's report, plus interest (as set forth in Section 8.5.5 (Late Payments)) from the original due date. Any amounts determined to be overpaid will be refunded within ****** (******) days from the accountant's report. POZEN will bear the full cost of such audit unless such audit discloses an underpayment of the amount actually owed during the applicable calendar year of more than ****** percent (******%), in which case AstraZeneca will bear the full cost of such audit.

8.7 Taxes.

8.7.1 General. The royalties, milestones and other amounts payable by one Party to the other Party pursuant to this Agreement ("**Payments**") shall not be reduced on account of any taxes unless required by Applicable Law. The Party receiving any Payment shall be responsible for paying any and all taxes (other than withholding taxes or deduction of tax at source required by Applicable Law to be paid by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The paying Party shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if the Party receiving payment is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to the paying Party or the appropriate governmental authority (with the assistance of the paying Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding tax or to relieve the paying Party of its obligation to withhold tax, and the paying Party shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be, provided that the paying Party has received evidence, in a form satisfactory to the paying Party, of the other Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least ****** (******) days prior to the time that the Payments are due. If, in accordance with the foregoing, the paying Party withholds any amount, it shall pay to the other Party the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to the other Party proof of such payment within ****** (******) days following that payment.

****** Portion for which confidential treatment requested.

8.7.2 Indirect Taxes. Notwithstanding anything contained in Section 8.7.1 (General), this Section 8.7.2 (Indirect Taxes) shall apply with respect to Indirect Taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, the paying Party shall pay the Indirect Taxes at the applicable rate in respect of any such Payments following the receipt of an Indirect Taxes invoice in the appropriate form issued by Party receiving Payments in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate.

9. INTELLECTUAL PROPERTY

9.1 Prosecution and Maintenance of Licensed Patents. POZEN will be responsible for the preparation, filing, prosecution and maintenance of the Licensed Patents (other than Joint Patents), at its own expense. Notwithstanding the foregoing, ******. POZEN will provide a copy of all proposed filings at least ****** (******) days in advance of the filing date and will consider in good faith the requests and suggestions of AstraZeneca with respect to filing and prosecuting the Licensed Patents and will keep AstraZeneca promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of Licensed Patents. In the event that POZEN desires to abandon any Licensed Patent, POZEN will provide reasonable prior written notice to AstraZeneca of such intention to abandon (which notice will, in any event, be given no later than ****** (******) days prior to the next deadline for any action that may be taken with respect to such Licensed Patent with the U.S. Patent & Trademark Office or any foreign patent office), and AstraZeneca will have the right to assume responsibility for such Licensed Patent.

9.2 Prosecution and Maintenance of Joint Patents. AstraZeneca will be responsible for the preparation, filing, prosecution and maintenance of Joint Patents, at its own expense. AstraZeneca will provide to POZEN a copy of all proposed filings at least ****** (******) days in advance of the filing date and will consider in good faith the requests and suggestions of POZEN with respect to filing and prosecuting the Joint Patents and will keep POZEN promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of Joint Patents. In the event that AstraZeneca desires to abandon any Joint Patent, AstraZeneca will provide reasonable prior written notice to POZEN of such intention to abandon (which notice will, in any event, be given no later than ****** (******) days prior to the next deadline for any action that may be taken with respect to such Joint Patent with the U.S. Patent & Trademark Office or any foreign patent office), and POZEN will have the right to assume responsibility for such Joint Patent.

****** Portion for which confidential treatment requested.

9.3 Ownership of Inventions. Inventorship of Inventions will be determined in accordance with the rules of inventorship under United States patent laws. Subject to the licenses granted under this Agreement, as between the Parties, AstraZeneca will own all AstraZeneca Inventions, POZEN will own all POZEN Inventions, and Joint Inventions will be owned jointly by AstraZeneca and POZEN; provided, however, that during the Term of this Agreement: (i) neither POZEN nor AstraZeneca shall ****** other than as expressly provided in this Agreement, including Section 7.1 (Licensed Technology), without the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, and (ii) neither Party shall assign, pledge, encumber, license or otherwise transfer any of its rights in any Joint Invention or Joint Patent without the other Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Upon any expiration or termination of this Agreement, each Party will have the right to exploit, license and grant rights to sublicense each such Joint Invention and Joint Patent, without any duty of accounting to the other Party, and each Party hereby consents, and agrees to consent, without payment of any further consideration or royalty, to the Joint Party's exploitation and licensing of said Joint Party's interest in such Joint Invention or Joint Patent to Third Parties; provided, that nothing in this Section 9.3 gives either Party any right or license under any intellectual property rights Controlled by the other Party other than Joint Inventions and Joint Patents, regardless of whether such rights are necessary in order to exploit the Joint Inventions and Joint Patents pursuant to this Section 9.3.

9.4 Disclosure. Each Party will promptly disclose to the other Party in writing, and will cause its Affiliates, agents, and independent contractors to so disclose to the other Party, the conception and reduction to practice of any Invention.

9.5 Cooperation. Each Party acknowledges the importance of securing and maintaining effective patent protection for the Licensed Technology and Joint Patents throughout the Territory. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of the Licensed Patents and Joint Patents and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect to the Licensed Patents and Joint Patents. Such cooperation includes, but is not limited to: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to effectuate the ownership of Inventions set forth in Section 9.3 (Ownership of Inventions), and Patents claiming or disclosing such Inventions, and to enable the other Party to apply for and to prosecute patent applications in any country; and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

****** Portion for which confidential treatment requested.

9.6 Enforcement of Licensed Patents.

9.6.1 Infringement by Third Parties. AstraZeneca and POZEN will each, within ****** (******) Business Days of learning of any alleged or threatened infringement of the Licensed Patents or Joint Patents, notify the other Party in writing. ****** will have the first right, but not the obligation, to prosecute any such infringement. If ****** does not commence an infringement action against the alleged or threatened infringement (i) within ****** (******) days following the detection of the of alleged infringement, or (ii) ****** (******) Business Days before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then ****** will so notify ****** promptly, and ****** may commence litigation with respect to the alleged or threatened infringement at its own expense.

9.6.2 Challenge by Third Parties. AstraZeneca and POZEN will each notify the other Party in writing within ****** (******) Business Days of learning of any alleged or threatened opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability of the Licensed Patents or Joint Patents by a Third Party. ****** will have the first right, but not the obligation, to defend any such challenge. If ****** does not commence Diligent Efforts to defend against the alleged or threatened challenge (i) within ****** (******) days following the detection of the alleged challenge, or (ii) ****** (******) Business Days before the time limit, if any, set forth in appropriate laws and regulations for making a filing in defense of such a challenge, whichever comes first, then ****** will so notify ****** promptly, and ****** may take action with respect to the alleged or threatened challenge at its own expense.

9.6.3 Cooperation. In the event a Party brings an infringement action pursuant to Section 9.6.1 (Infringement by Third Parties), the other Party will cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or to join such action as a necessary party, executing all papers and instruments, or requiring its employees or contractor, to execute such papers and instruments, so as to successfully prosecute any such actions. Neither Party will have the right to settle any patent infringement litigation under this Section 9.6.3 (Cooperation) in a manner that could be reasonably expected to diminish the rights or interest of the other Party, or adversely effect the validity or enforceability of such other Party's Patents, without the express written consent of such other Party. The Party commencing the litigation will provide the other Party with copies of all pleadings and other documents filed with the court and will consider reasonable input from the other Party during the course of the proceedings.

9.6.4 Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in Section 9.6.1 (Infringement by Third Parties) (whether by way of settlement or otherwise) will be first allocated to reimbursement of unreimbursed legal fees and all litigation expenses incurred by the Party initiating the proceeding, then toward reimbursement of any of unreimbursed legal fees and all litigation expenses of the other Party, and then the remainder will be divided between the Parties as follows: (a) settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought by ****** will be ****** and subject to the ****** set forth in Section ******; and (b) settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought by ****** will be ******.

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9.7 Defense of Infringement Claims. If the manufacture, sale or use of a POZEN Product pursuant to this Agreement results in any claim, suit, or proceeding by a Third Party alleging that such activities infringe a Third Party patent, or if a Third Party threatens such a claim, suit or proceeding, each Party will promptly notify the other Party thereof. ****** (or its ******) will have the exclusive right to defend and control the defense of any such claim, suit or proceeding at its own expense, using counsel of its own choice; provided, that if any such proceedings involve matters relating to the validity or enforceability of the Licensed Patents or Joint Patents, then the provisions of Section 9.6.3 (Cooperation) above shall apply. In any claim, suit or proceeding under this Section 9.7, ****** will keep ****** reasonably informed of all material developments in connection with any such claim, suit, or proceeding; provided, that if ****** is named as a defendant in any such claim, suit or proceeding, that ****** shall have the right to participate in the defense using counsel of its choice at its own expense. In any claim, suit or proceeding under this Section 9.7, ****** agrees to provide ****** with copies of all pleadings filed in such action and to allow ****** reasonable opportunity to participate in the defense of the claims.

9.8 Patent Term Extension and Supplementary Protection Certificate. Upon receiving Marketing Approval for a POZEN Product, the Parties agree to coordinate the application for any patent term extension or supplementary protection certificates that may be available. The primary responsibility of applying for any extension or supplementary protection certificate will be the Party having the right to make the application under the Applicable Law. The Party responsible for filing the application will keep the other Party fully informed of its efforts to obtain such extension or supplementary protection certificate. Each Party will provide prompt and reasonable assistance, without additional compensation, to obtain such patent extension or supplementary protection certificate. The Party filing such request will pay all expenses in regard to obtaining the extension or supplementary protection certificate.

9.9 Consequence of Patent Challenge. If AstraZeneca or its Affiliates challenge the validity or enforceability of any of the Licensed Patents by any opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof before any governmental agency, court or other similar adjudicative forum (any such proceeding, a **"Patent Challenge"**), such Patent Challenge shall give POZEN the right to terminate this Agreement as provided in Section 12.3. (Termination for Material Breach) or to terminate all licenses granted under any of the Licensed Patents subject to such Patent Challenge; provided, that the foregoing provisions of this Section 9.9 (Consequence of Patent Challenge) will not apply in the event that, prior to such Patent Challenge, POZEN or any of its licensees or assignees initiates or threatens litigation against, or makes claims or assertions against, AstraZeneca or its Affiliates, Sublicensees or Third Party contractors, that allege that any of such parties infringe a Licensed Patent.

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9.10 Patent Certifications.

9.10.1 Orange Book Listings. To the extent required or permitted by Applicable Law, after the completion of the assignment and transfer of the U.S. Regulatory Materials (including the NDA) for the Initial POZEN Product to AstraZeneca as required by Section 4.1.1 (Regulatory Matters in the U.S.), AstraZeneca will use Diligent Efforts to promptly list and maintain with the applicable Regulatory Authorities during the Term correct and complete listings of applicable Licensed Patents for such POZEN Product, including all so called "Orange Book" listings required under the Hatch−Waxman Act. Prior to such assignment and transfer, to the extent required or permitted by Applicable Law, POZEN will use Diligent Efforts to promptly list and maintain with the applicable U.S. Regulatory Authorities correct and complete listings of the applicable Licensed Patents for such POZEN Product, including so−called Orange Book listings. Promptly after the Effective Date, POZEN and AstraZeneca will meet to discuss the Parties' efforts under this Section 9.10.1 (Patent Certification). ******

9.10.2 Hatch−Waxman Act. Notwithstanding Section 9.6.1 (Infringement by Third Parties) above, each Party will immediately give notice to the other Party of any notice it receives of certification filed under the Hatch−Waxman Act claiming that any of the Licensed Patents is invalid, unenforceable or that any infringement will not arise from the manufacture, use or sale of the POZEN Product by a Third Party. If ****** decides not to bring infringement proceedings against the entity making such a certification with respect to any such Licensed Patents, ****** will give notice to ****** of its decision not to bring suit within ****** (******) Business Days after receipt of notice of such certification (or, if the time period permitted by law is less than ****** (******) Business Days, within ****** of the time period permitted by law for ****** to commence such action). ****** may then, but is not required to, bring suit against the Third Party that filed the certification. Any suit by either Party may be in the name of either or both Parties, as may be required by law. For this purpose, the Party not bringing suit will execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.

9.11 Patent Marking. Any POZEN Product marketed and sold by AstraZeneca under this Agreement will be marked with appropriate patent numbers or indicia as permitted or required by law. The Parties agree to cooperate to reach a decision on the marking requirements.

10. REPRESENTATIONS, WARRANTIES; COVENANTS

10.1 POZEN Representations and Warranties. POZEN hereby warrants and represents to AstraZeneca as of the Execution Date and the Effective Date that, except as set forth on Schedule 10.1 to this Agreement (as such schedule may be updated by POZEN pursuant to Section 10.2 (Notice of Developments)):

10.1.1 POZEN is the sole and exclusive owner of the Licensed Patents and has the right to perform its obligations hereunder and to grant to AstraZeneca the rights and licenses set forth in this Agreement in and to the Licensed Technology;

****** Portion for which confidential treatment requested.

10.1.2 Each person who has contributed to the conception of an invention claimed in the Licensed Patents has been identified to the United States Patent & Trademark Office and the applicable patent offices in all other countries where such Licensed Patent is filed, registered, nationalized or validated and is named on such Licensed Patent. ****** is the sole inventor of U.S. Patent ******. Each inventor of any invention claimed in any Licensed Patent has assigned all of that inventor's right, title and interest in and to the Licensed Patent to POZEN, and such assignment has been recorded at the United States Patent & Trademark Office and at the applicable patent offices in all other countries where such Licensed Patent is nationalized or validated;

10.1.3 To the knowledge of POZEN, each person associated with the invention, filing or prosecution of any Licensed Patent has complied with the obligation under Applicable Law to disclose to the relevant patent authority, during the pendency of any patent application included in the Licensed Patents, information known by any such person to be material to the patentability of the pending claims in such application;

10.1.4 To the knowledge of POZEN, none of the Licensed Patents existing on the Execution Date is involved in any action for declaratory judgment, nullity action, reexamination, interference proceeding, or other attack upon its validity, title or enforceability, and POZEN has not received any written request, demand or notice from any Third Party or governmental authority threatening or disclosing any such action, proceeding or attack with respect to any of the Licensed Patents;

10.1.5 There is no action or proceeding pending or, to the knowledge of POZEN, threatened that relates to, affects or arises in connection with any Licensed Technology or POZEN Product; and POZEN is not subject to any order, ruling or judgment of any governmental or Regulatory Authority that could reasonably be expected to impair or delay the ability of POZEN to perform its obligations under this Agreement;

10.1.6 The Licensed Patents are not subject to any encumbrance, lien, license rights (including any covenant not to sue in respect thereto) or claim of ownership by any Third Party;

10.1.7 To the knowledge of POZEN, there are no activities by Third Parties that would constitute infringement of any Licensed Patents or misappropriation of Licensed Know−How existing on the Execution Date;

10.1.8 To the knowledge of POZEN, there are no Patents or trade secret rights owned or controlled by a Third Party, that would be infringed or misappropriated by the Development, Manufacture or Commercialization of POZEN Product(s), and POZEN has received no written claims relating to any such infringement or misappropriation. To the knowledge of POZEN, AstraZeneca's use and exploitation of the Regulatory Materials as contemplated by this Agreement will not misappropriate any confidential information or trade secret of any Third Party;

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10.1.9 POZEN has made available to AstraZeneca all clinical study reports, formulation development study reports and Regulatory Materials in its possession or Control regarding or related to POZEN Products. All such clinical study reports, formulation development study reports and Regulatory Materials are true and complete as of the Execution Date;

10.1.10 As of the Execution Date, POZEN has prepared, maintained and retained all Regulatory Materials required to be maintained or reported pursuant to and in accordance with cGCP, cGLP, and cGMP to the extent required, and all Applicable Law and, to POZEN's knowledge, the Regulatory Materials do not contain any materially false and misleading statements; POZEN has conducted, and has caused its contractors and consultants to conduct, any and all formulation development and clinical studies related to the POZEN Product in accordance with cGCP, cGMP, and cGLP, to the extent required, and all other Applicable Law;

10.1.11 The Licensed Patents listed on Schedule 1.58 are all of the Patents Controlled by POZEN that are necessary for the Development, Manufacture, Commercialization, use, sale, offer for sale or importation of the POZEN Product in the Field of Use.

10.1.12 POZEN has disclosed to AstraZeneca all information in its possession relating to any interaction with the FDA and other Regulatory Authorities regarding the Initial POZEN Product. POZEN has not received any communication from the FDA that leads it to believe that the studies set forth in Exhibit B may be insufficient to obtain NDA Approval of the Initial POZEN Product from the FDA;

10.1.13 POZEN has obtained all necessary licenses, consents, approvals, permits and authorizations to enable it to carry on its research and business related to the Licensed Technology and POZEN Products and all such licenses, consents, approvals, permits and authorizations are in effect;

10.1.14 True and complete copies of all of POZEN's agreements relating to the Licensed Technology or to the Development or Commercialization (excluding marketing research) of POZEN Products have been made available to AstraZeneca and such agreements will be listed on an updated Schedule 10.1 to be agreed by the Parties before the Effective Date. Except as identified on such Schedule 10.1, each such agreement is in full force and effect. POZEN is not, and to its knowledge no other party to any such agreement is, in breach of or in default, in any material respect, under any such agreement; and to POZEN's knowledge, no event or circumstance has occurred which constitutes, or after notice or lapse of time or both, would constitute a material breach or default thereunder on the part of POZEN or any other party thereto, or which would result in a right to accelerate or a loss of material rights under any such agreement that has not been cured or waived;

10.1.15 Neither POZEN nor any Third Party engaged by it, in any capacity, has been debarred or is subject to debarment or has otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the FDA or any other governmental or regulatory authority or professional body with respect to the performance of scientific or clinical investigations;

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10.1.16 True, complete and correct copies of all licenses and other agreements under which any Third Party has or grants to POZEN any right or license to the Licensed Patents, including any amendments to such agreements, have been made available to AstraZeneca;

10.1.17 All applicable fees have been timely paid to file, prosecute and maintain the Licensed Patents. To the knowledge of POZEN without inquiry, (i) the Licensed Patents are subsisting, or pending, and are not invalid or unenforceable, and (ii) the conception, development and reduction to practice of the Licensed Patents have not constituted or involved the misappropriation of trade secrets or other rights or property of any Third Party;

10.1.18 The development of the Licensed Technology has not been funded, in whole or in part, by the United States Government.

10.1.19 The execution and delivery of this Agreement, the performance contemplated hereby, and the grant of rights and licenses hereunder will not (i) result in a breach of any judgment, decree, order or approval of any court of law or authority applicable to the Licensed Technology or POZEN Product; (ii) cause any acceleration or maturity of any contract or of any obligation relating to the Licensed Technology or POZEN Product; (iii) result in the creation or imposition of any encumbrance upon or give to any other person or entity any interest or right (including any right of termination or cancellation or change) in or with respect to the Licensed Technology or POZEN Product except as expressly permitted herein; or result in any termination of, or change in the terms of, or conditions of, or rights or obligations under, any permit or approval of any authority applicable to the Licensed Technology or POZEN Product; or (iv) result in a violation of, or be in material conflict with, or constitute a material default, under any agreement in existence as of the Execution Date between POZEN and Third Parties and that it is not party to any other agreements that limits AstraZeneca's rights under this Agreement.

10.2 Notice of Developments. From the Execution Date until the Effective Date of this Agreement, POZEN will give AstraZeneca prompt written notice upon becoming aware of any development, event or circumstance that could reasonably be expected to result in a breach of or inaccuracy in any of POZEN's representations and warranties in Section 10.1 (POZEN Representations and Warranties). On the Effective Date, POZEN shall deliver to AstraZeneca an updated Schedule 10.1 reflecting all exceptions to the representations and warranties made by POZEN as of the Effective Date.

10.3 AstraZeneca Warranties. AstraZeneca hereby warrants and represents to POZEN as of the Execution Date and the Effective Date that AstraZeneca is not subject to any order, ruling or judgment of any governmental or Regulatory Authority that could reasonably be expected to impair or delay the ability of AstraZeneca to perform its obligations under this Agreement.

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10.4 Reciprocal Representations and Warranties. Each Party represents and warrants to the other Party that: (a) this Agreement is a legal and valid obligation binding upon its execution and enforceable against it in accordance with its terms and conditions; and (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary corporate action, and the person executing this Agreement on behalf of such Party has been duly authorized to do so by all requisite corporate actions.

10.5 DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTIONS 10.1 (POZEN WARRANTIES) AND 10.3 (ASTRAZENECA WARRANTIES) AND 10.4 (RECIPROCAL REPRESENTATIONS AND WARRANTIES), EACH PARTY MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND POZEN AND LICENSEE EACH SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY OR MERCHANTABILITY, OR ANY WARRANTY AS TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENTS OR THE NON−INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

10.6 POZEN Non−Compete. POZEN covenants that it will not at any time prior to the expiration of the Royalty Term, and will ensure that its Affiliates do not, directly or indirectly, develop or commercialize or license any Third Party to develop or commercialize any product having a ******; provided, that after ****** (******) years following the Commercial Launch of a POZEN Product in the European Union, POZEN and its Affiliates shall be free, in the European Union only, to Develop, Commercialize or license a Third Party to Develop or Commercialize a product having a ****** in ****** with an ******. Without limiting AstraZeneca's rights under this Agreement or otherwise, in case of any breach of this Section 10.6 (POZEN Non−Compete), AstraZeneca will notify POZEN and, if such breach is not cured by POZEN within ****** (******) days after receipt of such notice, ******.

10.7 POZEN Subcontractors. POZEN will not, without AstraZeneca's prior written consent (not to be unreasonably withheld), engage or use any Third Party contract research organizations or other contractors (other than individuals hired as consultants) involved in the conduct of Development activities under this Agreement. All subcontractors identified in Schedule 10.7 (which such schedule will be agreed upon by the Parties before the Effective Date) are hereby approved by AstraZeneca. Any subcontract between POZEN and a Third Party to perform POZEN's responsibilities under this Agreement will be in writing and include provisions requiring the Third Party (i) to assign to POZEN all rights in any inventions relating to a Product and conceived by such Third Party in the course of performing such activities, along with all intellectual property rights therein, and (ii) to comply with confidentiality provisions at least as restrictive as those set forth in Section 11 (Confidentiality) with respect to all materials and information received by such Third Party in connection with such activities.

10.8 ****.

****** Portion for which confidential treatment requested.

10.9 Other Covenants.

10.9.1 POZEN will not enter into any agreement, whether written or oral with respect to, or otherwise assign, transfer, license, convey or otherwise encumber its rights, title or interest in the Licensed Technology (including by granting any covenant not to sue with respect thereto) to any Person in a manner that is inconsistent with the rights and licenses granted to AstraZeneca under this Agreement.

10.9.2 Each Party will obtain from each of its Affiliates, sublicensees, employees and agents and from the employees and agents of its Affiliates, sublicensees and agents who are or will be involved in the Development of the POZEN Products or of the Licensed Technology, rights to any and all inventions, information, and intellectual property rights conceived in the course of performance of this Agreement, necessary to enable such Party to grant the licenses and other rights granted to the other Party under this Agreement.

11. CONFIDENTIALITY.

11.1 Definition. During the Term and subject to the terms and conditions of this Agreement, a Party (a **"Disclosing Party"**) may communicate to the other Party (a **"Receiving Party"**) information in connection with this Agreement or the performance of its obligations hereunder, including scientific and manufacturing information and plans, marketing and business plans, and financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business (collectively, **"Confidential Information"**). Without limiting the foregoing, "Confidential Information" is hereby deemed to include any information disclosed by one Party to the other Party pursuant to that certain confidentiality agreement between the Parties dated as of March 27, 2006 or that certain confidentiality agreement between the Parties dated as of June 15, 2006. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, during the Term, the Licensed Know−How will be deemed to be the Confidential Information of both Parties.

11.2 Exclusions. Notwithstanding the foregoing, information of a Disclosing Party will not be deemed Confidential Information with respect to a Receiving Party for purposes of this Agreement to the extent the Receiving Party can demonstrate by competent evidence that such information:

11.2.1 was already known to the Receiving Party or its Affiliates, as evidenced by their written records, other than under an obligation of confidentiality or non−use, at the time of disclosure to the Receiving Party;

11.2.2 was generally available or was otherwise part of the public domain at the time of its disclosure to the Receiving Party;

11.2.3 became generally available or otherwise became part of the public domain after its disclosure to the Receiving Party, through no fault of or breach of its obligations under this Section 11 (Confidentiality) by the Receiving Party;

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11.2.4 was disclosed to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality or non−use, by a Third Party who had no obligation to the Party that controls such information and know−how not to disclose such information or know−how to others; or

11.2.5 was independently discovered or developed by the Receiving Party or its Affiliates, as evidenced by their written records, without the use of, and by personnel who had no access to, Confidential Information belonging to the Party that controls such information and know−how.

11.3 Disclosure and Use Restriction. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term and for ****** (******) years thereafter, the Receiving Party will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the Disclosing Party. The Receiving Party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement or in connection with the exercise of its rights hereunder. The Receiving Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information.

11.4 Authorized Disclosure. A Receiving Party may disclose Confidential Information of a Disclosing Party to the extent that such disclosure is:

11.4.1 made in response to a valid order of a court of competent jurisdiction or other governmental or regulatory body of competent jurisdiction; provided, however, that such Receiving Party will have given notice to the Disclosing Party within ****** (******) Business Days of receipt of such order and given the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;

11.4.2 otherwise required by law; provided, that the Disclosing Party will provide the Receiving Party with notice of such disclosure at least ****** (******) days in advance thereof to the extent practicable and take reasonable steps as requested by the Disclosing Party to protect the Disclosing Party's rights;

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11.4.3 made by a Receiving Party, in connection with the performance of this Agreement, (a) to Affiliates, employees, consultants, representatives or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non−use at least equivalent in scope to those set forth in this Section 11 (Confidentiality) or (b) to Regulatory Authorities (provided, that in the case of disclosures to Regulatory Authorities, the Receiving Party will, to the extent practicable, provide the Disclosing Party with notice of such disclosure at least ****** (******) days in advance thereof and will reasonably consider any comments received from the Disclosing Party);

11.4.4 made by a Receiving Party to existing or potential acquirers or merger candidates; potential sublicensees or collaborators (to the extent contemplated hereunder); investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; or Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non−use at least equivalent in scope to those set forth in this Section 11 (Confidentiality); or

11.4.5 made by the Receiving Party with the prior written consent of the Disclosing Party.

11.4.6 In addition to the foregoing, within ****** (******) days after the Effective Date, the Parties shall mutually agree in good faith on a written document specifying the statements regarding ****** are permitted to make in response to appropriate questions from ****** relating to POZEN Products, and the Parties shall update such document by mutual agreement as appropriate from time to time, such agreement not to be unreasonably withheld, conditioned or delayed. ****** shall not make any public statement ****** that is not consistent with such agreed written document.

11.5 Use of Name. Neither Party may make public use of the other Party's name except (a) in connection with announcements and other disclosures relating to this Agreement and the activities contemplated hereby as permitted in Section 11.6 (Press Releases), (b) as required by Applicable Law, and (c) otherwise as agreed in writing by such other Party.

11.6 Press Releases.

11.6.1 On or after the Execution Date of this Agreement at a mutually agreed time, each Party will issue a mutually agreed press release announcing the existence of this Agreement each in the form and substance to be mutually agreed upon in advance. For subsequent press releases and other written public disclosures relating to this Agreement or the Parties' relationship hereunder (each, a **"Public Disclosure"**), each Party will use reasonable efforts to submit to the other Party a draft of such Public Disclosures for review and comment by the other Party at least ****** (******) Business Days prior to the date on which such Party plans to release such Public Disclosure, and in any event will submit such drafts at least ****** prior to the release of such Public Disclosure, and will review and consider in good faith any comments provided in response. Notwithstanding the foregoing, subject to Section ******.

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11.6.2 If a Party is unable to comply with the foregoing ****** notice requirement because of a legal obligation or stock exchange requirement to make more rapid disclosure, such Party will not be in breach of this Agreement but will in that case provide notice as promptly as practicable under the circumstances.

11.6.3 A Party may publicly disclose, without regard to the preceding requirements of this Section 11.6 (Press Releases), information that was previously disclosed in a Public Disclosure that was in compliance with such requirements.

11.7 Terms of Agreement to be Maintained in Confidence. The Parties agree that the terms of this Agreement are confidential and will not be disclosed by either Party to any Third Party (except to a Party's professional advisors, including without limitation accountants, financial advisors, and attorneys) without prior written permission of the other Party; provided, however, that (a) either Party may make any filings of this Agreement required by law or regulation in any country so long as such Party uses its reasonable efforts to obtain confidential treatment for portions of this Agreement as available, consults with the other Party, and permits the other Party to participate, to the greatest extent practicable, in seeking a protective order or other confidential treatment; (b) either Party may disclose this Agreement on a confidential basis to potential Third Party investors or acquirors or, in the case of AstraZeneca, to potential Sublicensees, in each case in connection with due diligence or similar investigations; and (c) a Party may publicly disclose, without regard to the preceding requirements of this Section 11.7, information that was previously disclosed in compliance with such requirements.

12. TERM AND TERMINATION

12.1 HSR Act. To the extent required by the Hart−Scott−Rodino Antitrust Improvements Act of 1976, as amended (**"HSR Act"**), each Party will (i) file or cause to be filed, as promptly as practicable after the date hereof, with the United States Federal Trade Commission (**"FTC"**) and the United States Department of Justice (**"DOJ"**), all reports and other documents required to be filed by such Party under the HSR Act concerning the transactions contemplated hereby and (ii) promptly comply with or cause to be complied with any requests by the FTC or DOJ for additional information concerning such transactions, in each case so that the waiting period applicable to this Agreement and the transactions contemplated hereby under the HSR Act will expire as soon as practicable after the date hereof. Each Party agrees to request, and to cooperate with the other Party in requesting, early termination of any applicable waiting period under the HSR Act. The filing fees payable in connection with the filings will be borne by AstraZeneca as the acquiring party under this Agreement. This Agreement is effective on the date after which the waiting period pursuant to the HSR Act has expired, or the date on which the transaction contemplated in this Agreement has been approved by the FTC and DOJ or, if the Parties agree that no filing is required under the HSR Act, the date first written above (**"Effective Date"**).

12.2 Term. The term of this Agreement will commence as of the Effective Date and, unless earlier terminated in accordance with this Section 12 (Term and Termination), will expire upon the expiration of the Royalty Term for all POZEN Products in all countries (the **"Term"**).

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12.3 Termination for Material Breach. In the event that either Party (the **"Breaching Party"**) shall be in material default of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the **"Non−Breaching Party"**) may have, the Non−Breaching Party may terminate this Agreement in its entirety or with respect to the country or countries to which such material default applies by ****** (******) days prior written notice (the **"Notice Period"**) to the Breaching Party, specifying the breach and its claim of right to terminate; provided, that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach complained about during the Notice Period (or, if such default cannot be cured within such Notice Period, if the Breaching Party commences actions to cure such default within the Notice Period and thereafter diligently continues such actions); provided, further, that in the event that AstraZeneca is the Party in material default and the default is with respect to AstraZeneca's failure to use Diligent Efforts as required under this Agreement with respect to the Initial POZEN Products in the United States or in a particular Major Ex−U.S. Market Country, POZEN shall have the right to terminate this Agreement only with respect to such country and not in its entirety. It is understood that termination pursuant to this Section 12.3. (Termination for Material Breach) shall be a remedy of last resort and may be invoked only in the case where the breach cannot be reasonably remedied by the payment of money damages or other remedy under applicable law. If either Party initiates a dispute resolution procedure as permitted under this Agreement prior to the end of the Notice Period to resolve the dispute for which termination is being sought and is diligently pursuing such procedure, including any litigation following therefrom, the termination shall become effective only if and when such dispute is finally resolved through such dispute resolution procedure. This Section 12.3. (Termination for Material Breach) defines exclusively the Parties' right to terminate in case of any material breach of this Agreement.

12.4 Termination for Cause.

12.4.1 AstraZeneca Termination for Cause. AstraZeneca may terminate this Agreement to the extent set forth below without penalty upon written notice to POZEN, as follows:

(a) Subject to Section 12.4.1(n), if a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs with respect to ******, AstraZeneca may, at its option, terminate the Agreement either ******, or with respect to ******, or ****** with respect to any ****** where obtaining ****** is, according to common practice, ******or the ****** provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Pre−Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2 (a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2 (b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2 (b), within ****** (******) days following the election of such product pursuant to such Section).

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(b) Subject to Section 12.4.1(n), if a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs with respect to ******, AstraZeneca may, at its option, terminate this Agreement either with respect to ******, or ****** with respect to any ****** where obtaining ****** is, according to common practice, ****** for the ****** in which the ******; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Pre−Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2 (a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2 (b), within ****** (******) days following the election of such product pursuant to such Section).

(c) Subject to Section 12.4.1(n), if a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs with respect to a ******, AstraZeneca may, at its option, terminate this Agreement either with respect to ******, or ****** with respect to any ****** where obtaining ****** is, according to common practice, ****** for the ****** in which the ******; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Pre−Approval Failure(or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2 (a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2 (b) and AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2 (b), within ****** (******) days following the election of such product pursuant to such Section)..

(d) If a Pre−Approval Failure described in paragraph ****** of Section 1.82 (Pre−Approval Failure) occurs with respect to the ****** of the ****** and ****** for the ******, AstraZeneca may, at its option, terminate this Agreement either ****** or ******; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Pre−Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2 (a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2 (b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2 (b), within ****** (******) days following the election of such product pursuant to such Section)..

(e) If a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs with respect to the ****** of the ****** and ****** for the ****** AstraZeneca may, at its option, terminate this Agreement ****** with respect to ******; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Pre−Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2 (a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2 (b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2 (b), within ****** (******) days following the election of such product pursuant to such Section)..

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(f) If, following a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure), AstraZeneca fails to ****** and a ****** for the applicable ****** within the ****** described in ******, despite using ******, then AstraZeneca may, at its option, terminate this Agreement as follows: (i) if such Pre−Approval Failure related to the ****** and ****** as described in ******, then AstraZeneca may terminate this Agreement either ****** or ****** with respect to ******, and (ii) if such Pre−Approval Failure related to the ****** and ****** as described in ******, then AstraZeneca may terminate this Agreement ****** with respect to ******; provided, in each case, that written notice of termination must be delivered to POZEN within ****** (******) days following the expiration of such ****** period.

(g) If the Regulatory Authority in a particular country or territory requires the development of a particular formulation of a POZEN Product (whether for use in clinical testing or otherwise) and the Parties fail to develop a formulation and a manufacturing process for the applicable POZEN Product despite using Diligent Efforts to do so, then AstraZeneca may, at its option, terminate this Agreement solely with respect to such country; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following the permanent abandonment of the applicable formulation development program.

(h) If a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs, AstraZeneca may, at its option, terminate this Agreement either ******, or ****** with respect to ******; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Pre−Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2 (a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2 (b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2 (b), within ****** (******) days following the election of such product pursuant to such Section).

(i) If a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs, AstraZeneca may, at its option, terminate this Agreement either ******, or ****** with respect to ******; provided, that written notice of termination must be delivered to POZEN not later than the date of NDA Approval of the Initial POZEN Product in the U.S.

(j) If a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs, AstraZeneca may, at its option, terminate this Agreement ****** if the Pre−Approval Failure occurs ******, or ****** with respect to ****** if the Pre−Approval Failure occurs ******.; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Pre−Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2 (a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2 (b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2 (b), within ****** (******) days following the election of such product pursuant to such Section).

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(k) If a Post−Approval Failure occurs anywhere in the Territory, AstraZeneca may, at its option, terminate the Agreement either ******, or ******, or ****** with respect to ******; provided, that written notice of termination must be delivered to POZEN within ****** (******) days following such Post−Approval Failure.

(l) If, after AstraZeneca receives POZEN's updated Schedule 10.1 pursuant to Section 10.1, AstraZeneca determines in its reasonable discretion that a change to Schedule 10.1 either (i) materially adversely affects the value of rights granted to AstraZeneca under this Agreement, or (ii) materially adversely affects POZEN's ability to perform its obligations under this Agreement, AstraZeneca may, at its option, terminate this Agreement in its entirety; provided, that written notice of termination must be delivered to POZEN within ****** (******) Business Days following AstraZeneca's receipt of POZEN's updated Schedule 10.1.

(m) AstraZeneca may, at its option, terminate this Agreement in its entirety to the extent provided in Section 3.4.2 (Substitution).

(n) If a Pre−Approval Failure described in paragraph ****** of Section 1.81 (Pre−Approval Failure) occurs because ****** that would be reasonably expected, in the aggregate, to require AstraZeneca to ****** Section 1.81(b) (Pre−Approval Failure), but (A) the ****** required for NDA Approval in the ****** (without aggregation with activities required in the ****** or in ******) would not be reasonably expected to require AstraZeneca to ******, and (B) the ****** required for NDA Approval outside the ****** (without aggregation with activities required in the ******) would not be reasonably expected to require AstraZeneca to ******, then POZEN may elect, at its option, to deem the Pre−Approval Failure described in paragraph (******) of Section 1.81 (Pre−Approval Failure) to have occurred ******, as applicable, for the purposes of this Section 12.4.1.

12.4.2 POZEN Termination for Cause. Subject to Section 12.6.3 (Effect of Termination for Cause or for Material Breach), POZEN may terminate this Agreement to the extent set forth below without penalty upon written notice to AstraZeneca, which notice must be delivered to AstraZeneca within ****** (******) days following the occurrence of the relevant event described in paragraphs (a), (b), (c) and (d) below:

(a) with respect to ****** if despite using ******has not ****** or to ****** within ****** from the ****** for ****** set forth in the ******;

(b) ****** if a Pre−Approval Failure described in paragraph ****** of Section 1.81 occurs in ******of the ******because the ******has not: ******for the ******pursuant to ******within ****** (******from the date on which the Pre−Approval Failure of the ******occurred in ******for the ******within ******following such ******;

(c) ****** if despite using ****** ****** of the ****** in accordance with ****** and ****** has failed to ****** of the ****** pursuant to ****** that the Parties agree is ******with the ******by this Agreement (including, without limitation, ****** as may be required by ******within ****** (******) ****** ******contemplated by ******; and

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(d) ****** if despite using ****** of the ****** in accordance with ****** of the ****** pursuant to ****** that the ******with the ******of the ******as contemplated by this Agreement (including, without limitation, ****** as may be ****** within ****** (******) ****** contemplated by ******.

12.5 Termination at Will. AstraZeneca may terminate this Agreement in its entirety or with respect to all countries outside of the United States at any time at will upon ****** ****** prior written notice to POZEN.

12.6 Consequences of Expiration and Termination.

12.6.1 Effect of Expiration. Upon expiration (but not earlier termination) of the Term pursuant to Section 12.2 (Term), AstraZeneca will have a non exclusive, irrevocable, perpetual, worldwide, fully−paid license, with the right to sublicense, under the Licensed Technology to research, develop, make, use, sell, offer for sale, and import the POZEN Product in the Field of Use.

12.6.2 Effect of Termination Generally. The use by either party hereto of a termination right provided for under this Agreement and in accordance with this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party with respect thereto. Subject to the preceding sentence, termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief that it may be entitled to upon such termination or for any breach of this Agreement.

12.6.3 Effect of Termination for Cause or for Material Breach.

(a) If either Party terminates this Agreement pursuant to Section 12.3 (Termination for Material Breach) in its entirety or with respect to a particular country, or if either Party terminates this Agreement pursuant to Section 12.4 (Termination for Cause) in its entirety or with respect to a particular country or group of countries, all rights and licenses granted by POZEN to AstraZeneca and all obligations of AstraZeneca and POZEN under this Agreement will terminate immediately with respect to all countries in which this Agreement has been terminated.

(b) If AstraZeneca terminates this Agreement pursuant to Section 12.4.1 (Termination for Cause) as a result of a TPP Failure but the ****** have ****** (as described on Exhibit B) ******, then AstraZeneca will pay POZEN a termination fee of ****** (which termination fee shall be the sole and exclusive consideration owed to POZEN on account of such termination).

12.6.4 Effect of Termination At Will. Upon termination of this Agreement pursuant to Section 12.5 (Termination at Will), all rights and licenses granted by POZEN to AstraZeneca under this Agreement will terminate immediately. In addition, the following provisions will apply:

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(a) If the termination notice is given ****** of the ****** in the ******, AstraZeneca will pay POZEN a termination fee in an amount determined, as follows (which termination fee shall be the sole and exclusive consideration owed to POZEN on account of such termination):

(i) If the termination notice is given ******.

(ii) If the termination notice is given ******.

(iii) If the termination notice is given ******.

(iv) If the termination notice is given ******.

(b) If such termination becomes effective after ******, AstraZeneca shall, at its sole option, do one of the following (which, in either case, shall be the sole and exclusive consideration owed to POZEN on account of such termination):

(i) pay POZEN an amount equal to (x) ****** if the Agreement is terminated ******, or (y) ****** if the Agreement is terminated ******; or

(ii) only if AstraZeneca is able to convey to POZEN materially the same freedom to operate with respect to the Manufacture and Commercialization of any POZEN Product Commercialized by AstraZeneca at the time of such termination (the **"Commercialized POZEN Product"**) as AstraZeneca enjoyed immediately prior to such termination (x) worldwide (if the Agreement is terminated in its entirety), or (y) in all countries outside the United States (if the Agreement is terminated with respect to all countries outside the United States), perform the actions described in paragraphs (1) through (10) below:

(1) To the extent permitted by Applicable Law, AstraZeneca shall transfer and assign to POZEN all Regulatory Materials and Marketing Approvals that are Controlled by AstraZeneca for Commercialized POZEN Product either (x) worldwide (if the Agreement is terminated in its entirety), or (y) in all countries outside the United States (if the Agreement is terminated with respect to all countries outside the United States).

(2) In the case of termination of this Agreement in its entirety, AstraZeneca shall transfer to POZEN or its designee the management and continued performance of any clinical trials for the Commercialized POZEN Product ongoing as of the effective date of such termination, which clinical trials will be conducted at POZEN's expense after such transfer.

(3) Upon POZEN's request, AstraZeneca shall transfer to POZEN at AstraZeneca's full manufacturing cost any stock of finished Commercialized POZEN Product held by AstraZeneca or its Affiliates for either (x) the entire Territory (if the Agreement is terminated in its entirety), or (y) in all countries outside the United States (if the Agreement is terminated with respect to all countries outside the United States).

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(4) AstraZeneca shall for a reasonable period of time, provide such assistance, at no cost to POZEN, to transfer or transition to POZEN all other technology or know−how Controlled by AstraZeneca, or then−existing commercial arrangements (to the extent transferable in accordance with the terms and conditions of such arrangements) as may be reasonably necessary or useful for POZEN to commence or continue developing, manufacturing, or Commercializing the Commercialized POZEN Products, to the extent AstraZeneca is then performing or having performed such activities (including without limitation transferring, upon request of POZEN, any agreements or arrangements with Third Party suppliers or vendors to supply or sell the Commercialized POZEN Product, to the extent such agreements or arrangements are transferable in accordance with their terms and conditions).

(5) AstraZeneca shall transfer to POZEN or its designee any then−current manufacturing processes for the Commercialized POZEN Product. In addition, to the extent that AstraZeneca or its Affiliate is then manufacturing Commercialized POZEN Product, AstraZeneca will negotiate in good faith a supply agreement for the Commercialized POZEN Product on commercially reasonable terms under which AstraZeneca will continue to manufacture, and will supply to POZEN, at a cost that equals ****** percent (*******%) of AstraZeneca's actual manufacturing costs (calculated in accordance with AstraZeneca's standard cost and accounting policies), POZEN's requirements of POZEN Product, for a period of up to ******, in order to permit POZEN to establish sufficient manufacturing capacity for Commercialized POZEN Product; provided, however, that POZEN shall use commercially reasonable efforts to transition manufacture of the Commercialized POZEN Product to a Third Party as soon as reasonably practicable.

(6) The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that at all times that AstraZeneca is supplying POZEN Product under such agreement, allow a delegation consisting of a reasonable number of representatives of POZEN, no more than once per calendar year, to inspect and audit any AstraZeneca facility where such Commercialized POZEN Product, including its active pharmaceutical ingredients ******, is Manufactured, and the documentation generated in connection with the Manufacture and testing of such Commercialized POZEN Product for the purpose of verifying that the POZEN Product is being manufactured in accordance with applicable Laws. The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that such inspections will take place during regular business hours and after at least thirty (30) days prior notice to AstraZeneca. POZEN will discuss the results of any inspection with AstraZeneca. Any inspection by or on behalf of POZEN, if it occurs, does not relieve AstraZeneca of its obligation to comply with all Applicable Laws and does not constitute a waiver of any right otherwise available to POZEN. POZEN will treat all information subject to review under this paragraph in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party representative retained by POZEN (and reasonably acceptable to AstraZeneca) to enter into a reasonably acceptable confidentiality agreement with AstraZeneca obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

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(7) The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that, during any period when AstraZeneca is supplying Commercialized POZEN Product under such agreement, AstraZeneca shall notify POZEN promptly following notice from the FDA or any Regulatory Authority of a visit to any AstraZeneca facility where such Commercialized POZEN Product is Manufactured. The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that AstraZeneca will inform POZEN of the results of any inspection by a Regulatory Authority that does or could reasonably be expected to affect the Manufacture of such Commercialized POZEN Product. AstraZeneca will promptly provide POZEN with copies of notifications from any Regulatory Authority (including, without limitation, any Form No. 483 notification, Enforcement Inspection Reports, Notice of Adverse Finding, etc.). POZEN will treat all information subject to review under this paragraph in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party auditor retained by POZEN (and reasonably acceptable to AstraZeneca) to enter into a reasonably acceptable confidentiality agreement with AstraZeneca obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

(8) During any period when AstraZeneca is supplying POZEN Product under the supply agreement between POZEN and AstraZeneca contemplated by paragraph (5) above, or POZEN is using such Commercialized POZEN Product, AstraZeneca shall grant to POZEN rights of reference (including by providing a letter of authorization to the applicable Regulatory Authorities) to any AstraZeneca IND or NDA pertaining to Esomeprazole. Upon the expiration of such right, POZEN will send written notice to such effect to the applicable Regulatory Authority.

(9) AstraZeneca shall grant to POZEN an exclusive, royalty−bearing license, with the right upon prior written notice to AstraZeneca to sublicense through multiple tiers, under any Patents Controlled by AstraZeneca that would be infringed by the manufacture, use or sale of Commercialized POZEN Products, solely to make, have made, use, sell, offer for sale, have sold, import, and export such Commercialized POZEN Products in the Field of Use in the Territory (if the Agreement is terminated in the entirety) or outside the United States (if the Agreement is terminated with respect to all countries outside the United States). In consideration of the foregoing license, POZEN shall pay to AstraZeneca royalties on net sales of Commercialized POZEN Products at the rates specified in Section 8.4 (Royalties). For purposes of the foregoing royalty obligations, the references to “AstraZeneca” in Section 8.3 through 8.7 inclusive, and in the related definitions shall be deemed to be, and shall be, references to “POZEN” for purposes of this paragraph. The royalties provided for under this paragraph shall be the sole payments due by POZEN to AstraZeneca in connection with the practice of such license, and AstraZeneca shall be solely responsible for any payment obligations it may have to Merck & Co., Inc. or its affiliates in connection therewith.

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(10) AstraZeneca shall grant to POZEN a worldwide, non−exclusive, perpetual, irrevocable license under the Product Trademarks to use such marks for the promotion and sale of Commercialized POZEN Products, including the Initial POZEN Product, in the Field of Use in the Territory (if the Agreement is terminated in the entirety) or outside the United States (if the Agreement is terminated with respect to all countries outside the United States).

For the avoidance of doubt, in the event that, upon termination pursuant to Section 12.5 (Termination at Will) after First Commercial Sale of the Initial POZEN Product in the U.S., AstraZeneca is not able to convey to POZEN the same freedom to operate with respect to the Manufacture and Commercialization of Commercialized POZEN Products as AstraZeneca enjoyed immediately prior to such termination in all material respects, then AstraZeneca shall be obligated to make the applicable payment to POZEN specified in Section 12.6.4(b)(i) (Effect of Termination at Will).

(c) Any termination fee due pursuant to Section 12.6.4 (a) or Section 12.6.4(b) (Effect of Termination at Will) above shall be due and payable as follows:

(i) if AstraZeneca exercises its termination right under Section 12.5 (Termination At Will) after achievement of a Milestone Event for which a payment would be due under Section 8.2 (Development Milestone Payments) but before the applicable Milestone Due Date for such Milestone Event, such termination fee shall be due on such Milestone Due Date in lieu of the milestone payment; and

(ii) in all cases other than those described in Section 12.6.4(c)(i) (Effect of Termination at Will) above, such termination fee shall be due within ****** (******) days after AstraZeneca's exercise of is termination right under Section 12.5 (Termination at Will).

12.7 Termination for Insolvency. This Agreement may be terminated by written notice by either Party at any time during the Term upon the declaration by a court of competent jurisdiction that the other Party is bankrupt and, pursuant to the U.S. Bankruptcy Code such other Party's assets are to be liquidated; upon the filing or institution of bankruptcy, liquidation or receivership proceedings (other than reorganization proceedings under Chapter 11 of the U.S. Bankruptcy Code); or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; or in the event a receiver or custodian is appointed for such Party's business; provided, however, that in the case of any involuntary proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within 60 days after the filing thereof (each of the foregoing, a **"Bankruptcy Event"**).

****** Portion for which confidential treatment requested.

12.8 Effect of Bankruptcy. All rights and licenses with respect to Patents and Know−How granted under or pursuant to this Agreement by one Party to the other Party are, for all purposes of Section 365(n) of Title 11 of the United States Code (**"Title 11"**), licenses of rights to "intellectual property" as defined in Title 11. Each Party agrees that the other Party, as licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under Title 11. POZEN******AstraZeneca******POZEN ******POZEN ******POZEN ******(i) ******(ii) ******(iii) ******(iv) ******(v) ******(vi) ******(vii) ******POZEN ******(viii) ******. POZEN agrees not to interfere with AstraZeneca and its Affiliates' exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use commercially reasonable efforts to assist AstraZeneca and its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary or desirable for AstraZeneca or its Affiliates to exercise such rights and licenses in accordance with this Agreement. Each party agrees and acknowledges that all payments by AstraZeneca to POZEN payable under this Agreement other than royalty payments pursuant to Section 8.4 (Royalties) and commercialization milestone payments under Section 8.3 (Sales Milestone Payments) do not constitute "royalties" within the meaning of Section 365(n) of Title 11 or relate to licenses of intellectual property hereunder.

12.9 Post Termination Royalties. Upon any termination of this Agreement pursuant to (i) Section 12.4.1 (Termination for Cause) and ****** for the failure of the ****** described in the ****** to ******, or (ii) Sections 12.4.1 and 1.82 (h), then, for a period of ****** (******) years following any such termination, AstraZeneca shall pay POZEN a royalty on Net Sales of Products sold by AstraZeneca, its Affiliates or Sublicensees in an amount equal to ****** percent (******%) of the royalty amount calculated according to Section 8.4.1 (Royalty Rate), in accordance with the terms and conditions of Sections 8.4 (Royalties) through 8.7 (Taxes) of this Agreement.

12.10 Formulation Technology. If AstraZeneca terminates this Agreement for any reason other than for material breach by POZEN under Section 12.3 or as a result of POZEN's insolvency under Section 12.7, then, subject to the terms and conditions of this Agreement, AstraZeneca agrees to grant to POZEN, and does hereby grant effective automatically upon such termination, a worldwide, perpetual, irrevocable, non−exclusive license under the Formulation Technology, with the right to grant sublicenses and authorize the grant of sublicenses to the extent provided in this Section 12.10, to make, have made, use, sell, offer for sale, and import POZEN Products; provided, that nothing herein gives POZEN any right or license under any other intellectual property rights Controlled by AstraZeneca, regardless of whether such rights are necessary in order to exploit the Formulation Technology pursuant to this Section 12.10. POZEN may grant sublicenses and the right to grant further sublicenses under the foregoing license only as follows: (i) for any sublicense relating to the development or commercialization of a Commercialized POZEN Product, POZEN may grant such sublicense upon notice to AstraZeneca, but without obtaining AstraZeneca's consent, and (ii) for any sublicense relating to POZEN Products other than Commercialized POZEN Products, POZEN may grant such sublicense with AstraZeneca's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed).

****** Portion for which confidential treatment requested.

12.11 Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of Sections 8.4 (Royalties), 8.5 (Payments and Sales Reporting), 8.6 (Records; Audits), 9.2 (Prosecution and Maintenance of Joint Patents), 9.3 (Ownership of Inventions), 10.5(Disclaimer of Warranty), 11 (Confidentiality), 12.6 (Consequences of Expiration and Termination), 12.8 (Effect of Bankruptcy), 12.9 (Post Termination Royalties), 12.10 (Formulation Technology), 12.11 (Survival), 13 (Indemnification and Insurance), 14 (Limitation of Liability), and 15 (Miscellaneous) will survive any termination or expiration of this Agreement.

13. INDEMNIFICATION AND INSURANCE

13.1 Indemnification by POZEN. POZEN hereby agrees to save, defend and hold AstraZeneca and its Affiliates and their respective directors, officers, employees and agents (each, a **"AstraZeneca Indemnitee"**) harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, **"Losses"**), to which any AstraZeneca Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (i) the gross negligence or willful misconduct of any POZEN Indemnitee or (ii) the breach by POZEN of any warranty, representation, covenant or agreement made by POZEN in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any AstraZeneca Indemnitee or the breach by AstraZeneca of any warranty, representation, covenant or agreement made by AstraZeneca in this Agreement.

13.2 Indemnification by AstraZeneca. AstraZeneca hereby agrees to save, defend and hold POZEN and its Affiliates and their respective directors, officers, employees and agents (each, an **"POZEN Indemnitee"**) harmless from and against any and all Losses to which any POZEN Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (i) the development, manufacture, use, handling, storage, sale or other disposition of any Product by AstraZeneca, its Affiliates or any of their respective Sublicensees, (ii) the gross negligence or willful misconduct of any AstraZeneca Indemnitee, or (iii) the breach by AstraZeneca of any warranty, representation, covenant or agreement made by AstraZeneca in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any POZEN Indemnitee or the breach by POZEN of any warranty, representation, covenant or agreement made by POZEN in this Agreement.

****** Portion for which confidential treatment requested.

13.3 Indemnification Procedure.

13.3.1 Notice of Claim. The indemnified Party will give the indemnifying Party (the **"Indemnifying Party"**) prompt written notice (an **"Indemnification Claim Notice"**) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 13.1 (Indemnification by POZEN) or Section 13.2 (Indemnification by AstraZeneca); provided, however, that the failure to give such prompt written notice will not relieve Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. In no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents (collectively, the **"Indemnitees"** and each an **"Indemnitee"**) will be made solely by such Party to this Agreement (the **"Indemnified Party"**).

13.3.2 Control of Defense. At its option, the Indemnifying Party may assume the defense of any claim for which indemnification is sought (a **"Third Party Claim"**) by giving written notice to the Indemnified Party within ****** (******) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim.

13.3.3 Right to Participate in Defense. Without limiting Section 13.3.2 (Control of Defense) above, any Indemnitee will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnitee's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.3.2 (Control of Defense) (in which case the Indemnified Party will control the defense).

****** Portion for which confidential treatment requested.

13.3.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnitee's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnitee in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, will deem appropriate, and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the time prior to the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.3.2 (Control of Defense), the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party's sole and absolute discretion). The Indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnitee will admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party.

13.3.5 Cooperation. The Indemnified Party will, and will cause each other Indemnitee to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with the defense or prosecution of any Third Party Claim. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out−of−pocket expenses in connection therewith.

13.4 Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim will be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

13.5 Insurance. Each Party will have and maintain such types and amounts of liability insurance as is normal and customary in the industry generally for parties similarly situated, and will upon request provide the other Party with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.

****** Portion for which confidential treatment requested.

14. LIMITATION OF LIABILITY

IN NO EVENT WILL EITHER PARTY BE LIABLE FOR LOST PROFITS, LOSS OF DATA, OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION AND ARISING IN ANY WAY OUT OF THIS AGREEMENT. THE FOREGOING LIMITATIONS WILL NOT APPLY TO AN AWARD OF ENHANCED DAMAGES AVAILABLE UNDER THE PATENT LAWS FOR WILLFUL PATENT INFRINGEMENT AND WILL NOT LIMIT EITHER PARTY'S LIABILITY TO THE OTHER PARTY UNDER SECTIONS 7.5 (RESTRICTIVE COVENANT), 10.6 (POZEN NON−COMPETE), 11 (CONFIDENTIALITY), AND 13 (INDEMNIFICATION AND INSURANCE) OF THIS AGREEMENT.

15. MISCELLANEOUS

15.1 Assignment. Without the prior written consent of the other Party hereto (which may be granted at the other Party's discretion), neither Party will sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either Party hereto may assign or transfer this Agreement or any of its rights or obligations hereunder without the consent of the other Party (a) to any Affiliate of such Party; or (b) in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise. The assigning Party (except if it is not the surviving entity) will remain jointly and severally liable with the relevant Affiliate or Third Party assignee under this Agreement, and the relevant Affiliate assignee, Third Party assignee or surviving entity will assume in writing all of the assigning Party's obligations under this Agreement. Any purported assignment or transfer in violation of this Section 15.1 (Assignment) will be void ab initio and of no force or effect.

****** Portion for which confidential treatment requested.

15.2 Termination of Certain Rights Upon POZEN Change of Corporate Control. POZEN shall promptly notify AstraZeneca in writing following consummation of a Change of Corporate Control of POZEN. Notwithstanding anything else in this Agreement to the contrary, in the event of a Change of Corporate Control of POZEN, then AstraZeneca will have the right, exercisable by written notice to POZEN or its successor in interest given within ****** (******) days after AstraZeneca receives written notice from POZEN of the completion of such Change of Corporate Control: (a) to terminate ****** established pursuant to this Agreement; (b) to make all decisions under Section 2.3.3 (Dispute Resolution), (c) to conduct ****** regarding POZEN Products, (d) to cause POZEN to****** pertaining to POZEN Products; and (e) to terminate its obligation to make ****** to POZEN pursuant to this Agreement other than ****** and as reasonably required to ******, except in the event of subsequent termination of this Agreement by AstraZeneca pursuant to Section 12.5 (Termination at Will) and election by AstraZeneca of the option specified in Section 12.6.4(b)(ii) (Effect of Termination at Will); subject, in each case, to AstraZeneca's continued compliance with all applicable provisions of this Agreement (including, without limitation, Articles 8, 9 and 11). POZEN shall cooperate in providing to AstraZeneca all information, assistance, assignments and other support reasonably requested to assist AstraZeneca in assuming such control. In addition, if POZEN has not completed the Development activities that are its responsibility under this Agreement, then AstraZeneca may assume all responsibility for, at its expense, all such Development activities, and POZEN shall provide to AstraZeneca all information, assistance, assignments and other support reasonably requested to assist AstraZeneca in assuming such responsibility in an efficient and orderly manner. For purposes of clarification, all Confidential Information of AstraZeneca in POZEN's or its successor's possession following AstraZeneca's exercise of its rights under this Section 15.2 shall continue to be subject to all applicable provisions of this Agreement (including, without limitation, Articles 7 and 11).

15.3 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision prohibited or unenforceable in any respect.

****** Portion for which confidential treatment requested.

15.4 Governing Law; Dispute Resolution.

15.4.1 This Agreement, and any disputes between the Parties related to or arising out of this Agreement, including the Parties' relationship created hereby, the negotiations for and entry into this Agreement, its conclusion, binding effect, amendment, coverage, termination, or the performance or alleged non−performance of a Party of its obligations under this Agreement (each a **"Dispute"**), will be governed by the laws of the State of New York without reference to any choice of law principles thereof that would cause the application of the laws of a different jurisdiction.

15.4.2 In the event of any Dispute, a Party may notify the other Party in writing of such Dispute, and the Parties will try to settle such Dispute amicably between themselves. If the Parties are unable to resolve the Dispute within ****** Business Days of receipt of the written notice by the other Party, such Dispute will be referred to the Chief Executive Officers of each of the Parties (or their respective designees) who will use their good faith efforts to resolve the Dispute within ****** Business Days after it was referred to the Chief Executive Officers.

15.4.3 Any Dispute that is not resolved as provided in Section 15.4.2, whether before or after termination of this Agreement, will be resolved by litigation in the courts of competent jurisdiction located in New York, New York; provided, that, at its election, POZEN may submit a Dispute to arbitration in lieu of litigation as provided in Section 15.4.5 by providing written notice to AstraZeneca within the time period specified in Section 15.4.5, in which event the procedures of Section 15.4.5 shall govern resolution of the Dispute. Each Party hereby agrees to the exclusive jurisdiction of such courts and waives any objections as to the personal jurisdiction or venue of such courts.

15.4.4 Notwithstanding the foregoing, nothing in this Section 15.4 (Governing Law; Dispute Resolution) will limit either Party's right to seek immediate temporary injunctive or other temporary equitable relief whenever the facts or circumstances would permit a Party to seek such relief in a court of competent jurisdiction.

****** Portion for which confidential treatment requested.

15.4.5 In the event AstraZeneca terminates this Agreement for TPP Failure pursuant to Section 12.4.1(i) (Termination for Cause) and POZEN disputes whether such a TPP Failure has occurred, then POZEN shall have the right, at its election, to submit such Dispute to binding arbitration in lieu of litigation by providing written notice of such election to AstraZeneca within ****** (******) days of receiving notice from AstraZeneca that it has terminated the Agreement for TPP Failure pursuant to Section 12.4.1. If POZEN wishes to submit such Dispute to arbitration, POZEN shall so notify AstraZeneca, and the arbitration shall be conducted before a single arbitrator (**"Arbitrator"**) selected from and administered by the New York, New York office of the American Arbitration Association (the **"Administrator"**) in accordance with its then existing comprehensive arbitration rules and procedures; however, upon the written demand of either Party, the arbitration shall be conducted by and submitted to three Arbitrators selected from and administered by the Administrator's Rules & Procedures. The Arbitrator(s), whether selected by agreement or the Administrator, shall have knowledge of and experience with the process and standards used by the FDA to approve NDA applications for pharmaceutical products and DDMAC's approval of promotion materials for pharmaceutical products. The arbitration hearing shall be held in New York, New York. The Arbitrator shall be authorized solely to determine whether there has been a TPP Failure as defined in Section 1.103 (TPP Failure). Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the Administrator and the Arbitrator. The Arbitrator shall, within ****** (******) calendar days after the conclusion of the arbitration hearing, issue a written statement of decision describing the material factual findings and conclusions on which the decision is based. Such decision shall be final and binding upon the Parties. If such decision finds that a TPP Failure did not occur, then AstraZeneca's termination of this Agreement shall be deemed to have been made at will pursuant to Section 12.5, and accordingly, AstraZeneca shall pay POZEN the difference between the termination fee provided for in Section 12.6.4(a) and the amount paid by AstraZeneca to POZEN pursuant to Section 12.6.3(b), which payment shall be the sole and exclusive consideration owed to POZEN on account of such termination and such decision. If such decision provides that a TPP Failure did occur, then AstraZeneca's termination of this Agreement shall be deemed to have been made pursuant to Section 12.4.1(i).

15.5 Notices. All notices or other communications that are required or permitted hereunder will be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier as provided herein), or sent by internationally−recognized overnight courier addressed as follows:

****** Portion for which confidential treatment requested.

If to POZEN, to:	
	POZEN Inc. 1414 Raleigh Road, Suite 400 Chapel Hill, NC 27517 USA Attention: President and CEO Facsimile: (919) 913−1039
With a copy to:	
	Cooley Godward LLP One Freedom Square 11951 Freedom Square Reston, Virginia 20190 USA Attention: Kenneth J. Krisko Facsimile: (703) 456−8000
If to AstraZeneca, to:	
	AstraZeneca AB SE−431 83 Mölndal Sweden Attention: Manager Legal Department Mölndal Facsimile: +46 31 776 38 15

****** Portion for which confidential treatment requested.

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed to have been given (i) when delivered, if personally delivered or sent by facsimile on a Business Day, and (ii) on the second Business Day after dispatch, if sent by nationally−recognized overnight courier. It is understood and agreed that this Section 15.5 (Governing Law; Dispute Resolution) is not intended to govern the day−to−day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

15.6 Entire Agreement; Modifications. This Agreement including the Exhibits attached hereto, each of which is hereby incorporated and made part of in this Agreement by reference, together with the AE Agreement (as such term is defined in Section 4.6 (Adverse Event Reporting)), sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment or modification of this Agreement will be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties. Subject to Section 11.1 (Confidentiality) hereof, the Parties hereby confirm that the Confidentiality Agreement by and between the Parties, dated as of June 15, 2006 is hereby terminated.

15.7 Relationship of the Parties. It is expressly agreed that the Parties' relationship under this Agreement is strictly one of licensor−licensee, and that this Agreement does not create or constitute a partnership, joint venture, or agency. Neither Party will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding (or purport to be binding) on the other.

15.8 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of claims based on the failure to perform or a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

15.9 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

15.10 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any Third Party.

****** Portion for which confidential treatment requested.

15.11 Further Assurance. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.12 No Drafting Party. This Agreement has been submitted to the scrutiny of, and has been negotiated by, both Parties and their counsel, and will be given a fair and reasonable interpretation in accordance with its terms, without consideration or weight being given to any such terms having been drafted by any Party or its counsel. No rule of strict construction will be applied against either Party.

15.13 Construction. Except where the context otherwise requires, wherever used, the use of any gender will be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description preceding such term. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document refer to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws refer to such laws as from time to time enacted, repealed or amended, (c) the words "herein", "hereof" and "hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, and (d) all references herein to Sections and Exhibits, unless otherwise specifically provided, refer to the Sections and Exhibits of this Agreement.

[Remainder of page intentionally left blank. Signature page follows.]

****** Portion for which confidential treatment requested.

IN WITNESS WHEREOF, the Parties have executed this Collaboration and License Agreement by their respective authorized representatives as of the date first written above.

POZEN INC.

By: _____

Name: _____

Title: _____

ASTRAZENECA AB (publ)

By: _____

Name: _____

Title: _____

****** Portion for which confidential treatment requested.

EXHIBIT A

FORMULATION BUDGET

****** Portion for which confidential treatment requested.

EXHIBIT B

INITIAL U.S. DEVELOPMENT PLAN

Study Number	Title/Design	Endpoints	Comment	Responsibility to Conduct	Responsibility to Pay
NONCLINICAL					
******	******	******	******	******	******
******	******	******	******	******	******
PHASE 1					
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
PHASE 2					
******	******	******	******	******	******
PHASE 3					
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******

****** Portion for which confidential treatment requested.

Study Number	Title/Design	Endpoints	Comment	Responsibility to Conduct	Responsibility to Pay
PHASE 3					
******	******	******	******	******	******

****** Portion for which confidential treatment requested.

EXHIBITS C AND E
U.S AND ROW DEVELOPMENT PLAN TIMELINES

U.S. DEVELOPMENT PLAN TIMELINE

******

ROW DEVELOPMENT PLAN TIMELINE

******

****** Portion for which confidential treatment requested.

EXHIBIT D

INITIAL ROW DEVELOPMENT PLAN

Study Number	Title/Design	Endpoints	Comment	Responsibility to Conduct	Responsibility to Pay
NONCLINICAL					
******	******	******	******	******	******
******	******		******	******	******
PHASE 1					
******	******	******	******	******	******
******	******	******	******	******	******
PHASE 2					
******					
PHASE 3					
******	******	******	******	******	******

****** Portion for which confidential treatment requested.

EXHIBIT E

ROW DEVELOPMENT PLAN TIMELINE

(See Exhibit C)

****** Portion for which confidential treatment requested.

EXHIBIT F

TPP STUDIES

******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
******	******	******	******	******	******
******					

****** Portion for which confidential treatment requested.

SCHEDULE 1.58

LICENSED PATENTS

S E R I A L NUMBER/FILING DATE	PUBLICATION NUMBER/ DATE	TITLE	TERRITORY
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******
******	******	******	******

****** Portion for which confidential treatment requested.

SCHEDULE 4.1.2

IMS MAT DATA

******** markets (******) Combined**	MAT Q4/05 Sales USD Thousands
Total	******
US TOTAL	******
JAPAN COMBINED	******
FRANCE COMBINED	******
TURKEY RETAIL	******
ITALY COMBINED	******
U.K. COMBINED	******
MEXICO RETAIL	******
BRAZIL RETAIL	******
G E R M A N Y COMBINED	******
CANADA COMBINED	******
SPAIN COMBINED	******
KOREA COMBINED	******
PORTUGAL RETAIL	******
INDIA RETAIL	******
VENEZUELA RETAIL	******
POLAND COMBINED	******
A U S T R A L I A COMBINED	******
GREECE RETAIL	******
ARGENTINA RETAIL	******
N E T H E R L A N D S COMBINED	******
Total Others	******

****** Portion for which confidential treatment requested.

SCHEDULE 6.1

INITIAL POZEN PRODUCT SPECIFICATIONS

PN Drug Product Release Specifications

******	******
******	******
******	******
******	******
******	******
******	******
******	******
******	******
******	******
******	******
******	******
******	******
******	******
******	******

******

****** Portion for which confidential treatment requested.

SCHEDULE 8.4.1

In ******, AZ has Net Sales for ****** in country Y in the amounts of $****** for the first Product and $****** for the ******. In ****** in all other countries of the Territory the total Net Sales of Products are $******, and Net Sales do not occur in any other country for more than ******.

The calculation of the Segregated Royalty Amount would be:

******	******	******	******	******	******	******
******	******	******	******	******	******	******
				******	******	******
				**********		**********

The calculation of the Remaining Royalty Amount would be:

******	******	******	******	******
******	******	******	******	******

The total royalty payable for all Net Sales in the Territory would be $******.

****** Portion for which confidential treatment requested.

SCHEDULE 8.4.3

Assume that in the ****** the total world−wide Net Sales of Products are ******. In that example the following royalties would be payable prior to application of any Market Reduction:

******	******	******	******	******
******	******	******	******	******
******	******	******	******	******
******	******	******	******	******
****	****	****	****	****

Assume that in country X during Q1 of ****** a Competing Product had commenced sales in country X, and in Q1 of this year, ******, achieved the criteria to trigger a Market Reduction under Section 8.4.3 (Rate Step Down for Competing Product Entrants). Assume that Net Sales of Products in Country X were $****** in ******.

****

******	******	******	******		******	******
******	******	******	******		******	******
******	******	******	******		******	******
******	******	******	******		******	******
****	****		****			****

The Market reduction in Country X would result in a reduction to royalties payable of an amount equal to ****** Therefore the total royalty payable for Product Net Sales would be ******

****** Portion for which confidential treatment requested.

SCHEDULE 10.1

Part 10.1.14 − Agreements

[To be agreed by the Parties prior to the Effective Date]

****** Portion for which confidential treatment requested.

SCHEDULE 10.7

POZEN Subcontractors

[To be agreed by the Parties prior to the Effective Date]

****** Portion for which confidential treatment requested.

EXHIBIT 10.2

September 19, 2006

Re: Collaboration and License Agreement dated as of August 1, 2006 by and between POZEN INC. and Astrazeneca AB (the "Collaboration Agreement")

Dear Denise:

This letter sets forth the understanding between POZEN INC. (“POZEN”) and Astrazeneca AB (“Astrazeneca”) with regard to the matters set forth below and in connection with the Collaboration Agreement. Any capitalized terms not otherwise defined herein shall have the meaning given such term in the Collaboration Agreement. POZEN and Astrazeneca herein are collectively referred to as the Parties.

1. In accordance with Section 12.1 of the Collaboration Agreement, the Effective Date of the Collaboration Agreement is September 7, 2006.

2. The Parties have attached hereto final versions of Schedule 10.1 and Schedule 10.7, which shall be incorporated by this reference and made part of the Collaboration Agreement.

3. The Parties agree that a final schedule of Formulation Development Activities and a Formulation Budget pursuant to Section 6.1.4 of the Collaboration Agreement shall be agreed by the Parties as soon as reasonably practicable but not later than *****.

4. This letter is being executed pursuant to the terms of Section 15.6 of the Collaboration Agreement and shall be governed by the general terms of Article 15 of the Collaboration Agreement. Except as otherwise expressly provided in this letter, the terms of the Collaboration Agreement shall remain in full force and effect. This letter may be executed in counterparts, each of which when so executed and delivered shall be an original, and all of which together shall constitute one instrument.

***** Portion for which confidential treatment requested.

If this letter reflects your understanding, please countersign in the space provided below and return one original copy to POZEN by facsimile at (919) 913−1039.

Regards,

_____
John R. Plachetka
Chairman, President and CEO

AGREED:

ASTRAZENECA AB (publ)

By: _____
Name: Denise Goode
Title: Licensing Director

***** Portion for which confidential treatment requested.

SCHEDULE 10.1

Part 10.1.14 − Agreements

Consultant/Vendor	Form of Contract	Service Description
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****
*****	*****	*****

***** Portion for which confidential treatment requested.

SCHEDULE 10.7
POZEN SUBCONTRACTORS

*****

If AstraZeneca provides POZEN with written notice describing in reasonable detail information that has reasonably and in good faith caused AstraZeneca to believe that it would not be in the best interest of the Product for POZEN to enter into any new subcontract with any of the subcontractors listed above, then POZEN will not, without AstraZeneca's prior written consent (not to be unreasonably withheld) engage such subcontractor in the conduct of Development activities under the Agreement.

301264 v2/RE

***** Portion for which confidential treatment requested.

EXHIBIT 31.1

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: November 3, 2006

/s/ John R. Plachetka

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

EXHIBIT 31.2

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: November 3, 2006

/s/ William L. Hodges

William L. Hodges
Senior Vice President, Finance and Administration
and
Chief Financial Officer

EXHIBIT 32.1

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: November 3, 2006

/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.

EXHIBIT 32.2

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: November 3, 2006

/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.