# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

X	QUARTERLY REPORT PURSUANT TO SECENCHANGE ACT OF 1934	CTION 13 OR 15(d) OF THE SECURITIES
	For the quarterly period e	nded September 30, 2007
	Ol	R
	TRANSITION REPORT PURSUANT TO SEC EXCHANGE ACT OF 1934	CTION 13 OR 15(d) OF THE SECURITIES
	For the transition period	from to
	Commission File N	umber 000-31719
	POZE	
	Delaware (State or other jurisdiction of incorporation or organization)	62-1657552 (I.R.S. Employer Identification No.)
	1414 Rale	
	Suite Chapel Hill, Nortl (Address of principal executiv	n Carolina 27517
	(919) 91 (Registrant's telephone num	
Excha	ate by check mark whether the registrant (1) has filed all reporting ange Act of 1934 during the preceding 12 months (or for such s2) has been subject to such filing requirements for the past 90 c	shorter period that the registrant was required to file such reports),
of "ac	ate by check mark whether the registrant is a large accelerated ecclerated filer" and "large accelerated filer" in Rule 12b-2 of targe Accelerated Filer    Accelerated Filer    Non-Accelerated Fil	
Indica	ate by check mark whether the registrant is a shell company (as	s defined in Rule 12b-2 of the Exchange Act): ☐ Yes ☒ No
The n	umber of shares outstanding of the registrant's common stock	as of October 31, 2007 was 29,704,760.

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

## **INDEX**

		Page
PART I.	FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)	
	Balance Sheets as of September 30, 2007 and December 31, 2006	1
	Statements of Operations for the Three and Nine Months Ended September 30, 2007 and 2006 and Period From Inception (September 26, 1996) Through September 30, 2007	2
	Statements of Cash Flows for the Nine Months Ended September 30, 2007 and 2006 and Period From Inception (September 26, 1996) Through September 30, 2007	3
	Notes to Financial Statements	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	23
Item 4.	Controls and Procedures	23
PART II.	OTHER INFORMATION	
Item 1.	Legal Proceedings	24
Item 1A.	Risk Factors	24
Item 6.	Exhibits	38
Signature	and Certifications	39
Exhibit Pa	age	40

## PART I. FINANCIAL INFORMATION

### **Item 1. Financial Statements**

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

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 47,560,632	\$ 26,296,884
Short-term investments	31,199,522	36,285,102
Accounts receivable	4,339,607	3,267,153
Prepaid expenses and other current assets	419,024	1,108,506
Total current assets	83,518,785	66,957,645
Property and equipment, net of accumulated depreciation	139,349	183,468
Total assets	\$ 83,658,134	\$ 67,141,113
LIABILITIES AND STOCKHOLDERS' EQUITY		<u> </u>
Current liabilities:		
Accounts payable	\$ 1,957,069	\$ 965,563
Accrued compensation	1,223,231	1,434,591
Accrued expenses	4,121,605	1,756,300
Deferred revenue	16,092,191	14,870,200
Total current liabilities	23,394,096	19,026,654
Long-term liabilities:		
Deferred revenue	22,170,089	24,000,000
Total liabilities	45,564,185	43,026,654
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; 29,703,529, and 29,447,913 shares		
issued and outstanding at September 30, 2007 and December 31, 2006, respectively	29,704	29,448
Additional paid-in capital	160,995,115	155,920,068
Accumulated other comprehensive loss	(313)	(4,092)
Deficit accumulated during the development stage	(122,930,557)	(131,830,965)
Total stockholders' equity	38,093,949	24,114,459
Total liabilities and stockholders' equity	\$ 83,658,134	\$ 67,141,113

See accompanying Notes to Financial Statements.

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

**Period From** 

	Three Months End	led September 30,	Nine Months Ende	ed September 30,	Inception (September 26, 1996) Through September 30,
	2007	2006	2007	2006	2007
Revenue Operating expenses:	\$ 27,629,476	\$ 3,424,819	\$ 47,219,863	\$ 6,548,619	\$ 116,188,917
General and administrative	2,248,897	3,662,984	8,404,001	10,393,998	71,299,002
Research and development	, -,	4,275,168	30,587,889	16,422,811	178,955,804
Total operating expenses Other income:		7,938,152	38,991,890	26,816,809	250,254,806
Interest and other income Income (loss) before provision	781,516	447,127	2,317,536	1,336,420	13,714,910
for income tax	16,482,223	(4,066,206)	10,545,509	(18,931,770)	(120,350,979)
Provision for income tax	(1,645,099)	_	(1,645,099)		(1,645,099)
Income/(loss)		(4,066,206)	8,900,410	(18,931,770)	(121,996,078)
Non-cash preferred stock charge					27,617,105
Preferred stock dividends	_	_	_	_	934,478
Net income/(loss) attributable to common stockholders	\$ 14,837,124	\$ (4,066,206)	\$ 8,900,410	\$(18,931,770)	\$ (150,547,661)
Basic net income/(loss) per common share	\$ 0.50	\$ (0.14)	\$ 0.30	\$ (0.65)	
Shares used in computing basic net income/(loss) per common share	29,695,596	29.240.696	29,555,787	29,173,200	
per common situation	23,030,030	2>,2:0,0>0	25,000,707	27,170,200	
Diluted net income/(loss) per common share	\$ 0.48	\$ (0.14)	\$ 0.29	\$ (0.65)	
Shares used in computing diluted net income/(loss)					
per common share	30,598,807	29,240,696	30,627,282	29,173,200	

See accompanying Notes to Financial Statements.

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

Operating activities         50         (micropile prepared south)           Net income/(loss)         \$ 8,900,40         \$ (8,931,70)         \$ (120,763,478)           Adjustments to reconcile net income/(loss) to net cash used adjustments to reconcile net income/(loss) to net cash used a preparing activities         \$ 70,282         1,005,612           Operating activities         667,814         670,825         1,005,612           Bond amortization income         2,937,873         4,742,155         20,753,732           Noncash financing charge         2,937,873         4,742,155         20,753,232           Noncash financing charge         1(1,072,454)         (1,057,819)         4,330,007           Prepaid expenses and other current assets         689,481         495,455         4,019,009           Prepaid expenses and other current assets         689,481         495,455         4,019,009           Prepaid expenses and other current assets         689,481         495,455         4,019,009           Accounts payable and accrud expenses         12,017,21         18,149,12         16,019,309           Prepaid expenses and other current assets         689,481         495,455         4,149,209           Prepaid expenses and other current assets         61,241,415         1,149,219         1,150,005,309           Purchase of invest		Nine Months Er	Period from September 26, 1996	
Not cash provided by (used in) operating activities   Purchase of equipment   Purchase equivalents at end of period   Purchase hand cash equivalents at end of period   Purchase shedule of noncash investing and financing activities   Purchase of equipment   Purchase of equipment   Purchase of equipment   Purchase of expansion expense   Purchase of equipment   Purchase of expansion expense   Purchase of equipment   Purchase of expansion expense   Purchase of expansion expansion expansion expense   Purchase of equipment   Purchase of expansion expansion expansion expansion expansion expansion expansion expansion expansion   Purchase of equipment   Purchase of equ		2007	2006	
Adjustments to reconcile net income/(loss)to net cash used in operating activities:  Depreciation 67,814 70,282 1,005,612 Write-down of impaired assets 6.7,814 (636,165) 1,55,576 Bond amortization income (1,443,534) (636,165) 20,675,329 Noncash compensation expense 2,937,873 4,742,155 20,675,329 Noncash financing charge 2,937,873 4,742,155 20,675,329 Noncash financing charge (1,072,454) (1,567,819) 450,000 Changes in operating assets and liabilities: Accounts receivable (1,072,454) (1,567,819) 6,0693,0607 Prepaid expenses and other current assets 689,481 495,455 (419,025) Accounts payable and accrued expenses (6607,920) 35,019,200 38,262,280  Net cash provided by (used in) operating activities 12,617,121 18,149,127 (60,546,785)  Investment activities Purchase of equipment (23,695) (41,181) (1,300,536) Purchase of equipment (23,695) (44,181) (1,300,536) Sale of investments (45,193,716) (46,735,365) (146,339,682) Sale of investments (45,193,716) (46,735,365) (146,339,682) Sale of investments (45,193,716) (46,735,365) (146,339,682) Sale of investments (23,695) (41,181) (1,300,536) Proceeds from issuance of preferred stock (21,37,429) 2,023,219 (30,887,594) Praceads from issuance of preferred stock (21,37,429) 2,023,219 (30,4310) Proceeds from issuance of common stock (21,37,429) 2,023,219 (30,4310) Proceeds from collections of stockholders' receivables (21,37,429) 2,023,219 (30,000) Payment of dividend (21,300,300) Payment of dividend (21,300,300) (30,300,300) Payment of dividend (21,300,300) (30,300,300) Payment of dividend (31,300,300) (31,300,300) (31,300,300) Payment of dividend (31,300,300) (3				
operating activities:         67,814         70,282         1,005,612           Write-down of impaired assets         —         —         —         155,576           Bond amortization income         (1,443,534)         (636,165)         (1,642,778)           Noncash compensation expense         2,937,873         4,742,155         20,675,329           Noncash financing charge         —         450,000           Changes in operating assets and liabilities:         689,481         495,455         (4,339,607)           Prepaid expenses and other current assets         689,481         495,455         (419,025)           Accounts payable and accrued expenses         3,145,451         (1,042,211)         6,069,306           Deferred revenue         (607,920)         35,019,200         38,262,280           Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         (45,193,716)         (46,735,365)         (41,811)         (1,300,536)           Purchase of equipment         (23,695)         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         5,1726,600         32,300,000         116,78		\$ 8,900,410	\$(18,931,770)	\$ (120,763,478)
Depreciation	· · ·			
Write-down of impaired assets         —         —         155,576           Bond amortization income         (1,443,54)         (636,165)         (1,642,778)           Noncash compensation expense         2,937,873         4,742,155         20,675,329           Noncash financing charge         —         —         450,000           Changes in operating assets and liabilities:         —         —         (43,39,607)           Prepaid expenses and other current assets         689,481         495,455         (419,025)           Accounts payable and accrued expenses         3,145,451         (1,042,211)         6,069,306           Deferred revenue         (607,920)         35,019,200         38,262,280           Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         —         (23,695)         (41,181)         (1,300,536)           Purchase of equipment         (23,695)         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         —         —         —		<i>C</i> 7 014	70.202	1.005.610
Bond amortization income         (1,443,534)         (636,165)         (1,642,778)           Noncash compensation expense         2,937,873         4,742,155         20,675,329           Noncash financing charge         450,000           Changes in operating assets and liabilities:         (1,072,454)         (1,567,819)         (4,339,607)           Prepaid expenses and other current assets         689,481         495,455         (419,025)           Accounts payable and accrued expenses         3,145,451         (1,042,211)         6,069,306           Deferred revenue         (607,920)         35,019,200         38,262,280           Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         2,369,5         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         (51,726,609)         32,300,000         116,782,624           Net cash provided by (used in) investing activities         7         7         48,651,850           Proceeds from issuance of preferred stock         2,137,429         2,023,219         86,471,146           Proceeds from collections of stockholders' receivables         7         2,023,219		67,814	70,282	
Noncash compensation expense         2,937,873         4,742,155         20,675,329           Noncash financing charge         —         —         450,000           Changes in operating assets and liabilities:         —         —         450,000           Prepaid expenses and other current assets         689,481         495,455         (419,025)           Accounts payable and accrued expenses         3,145,451         (1,042,211)         6,069,306           Deferred revenue         (607,920)         35,019,200         38,262,280           Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         —         (23,695)         (41,181)         (1,300,536)           Purchase of equipment         (23,695)         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         (45,193,716)         (46,735,365)         (146,239,682)           Sale of investments         (45,193,716)         (44,765,546)		(1.442.524)	(626 165)	
Noncash financing charge         —         450,000           Changes in operating assets and libilities:         (1,072,454)         (1,567,819)         (4,339,607)           Prepaid expenses and other current assets         689,481         495,455         (419,025)           Accounts payable and accrued expenses         3,145,451         (1,042,211)         6,069,306           Deferred revenue         (607,920)         35,019,200         38,262,280           Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         12,617,121         18,149,127         (60,546,785)           Purchase of equipment         (23,695)         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         30,857,594           Financing activities         2,137,429         2,023,219         86,471,146           Proceeds from issuance of preferred stock         2,137,429         2,023,219         86,471,146           Proceeds from notes payable         2,2137,429         2,023,219				
Changes in operating assets and liabilities:         Accounts receivable         (1,072,454)         (1,567,819)         (4,339,607)           Prepaid expenses and other current assets         689,481         495,455         (419,025)           Accounts payable and accrued expenses         3,145,451         (1,042,211)         6,069,306           Deferred revenue         (607,920)         35,019,200         38,262,280           Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         12,617,121         18,149,127         (60,546,785)           Purchase of equipment         (23,695)         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         (30,857,594)           Financing activities         -         -         -         48,651,850           Proceeds from issuance of preferred stock         -         -         -         48,651,850           Proceeds from collections of stockholders' receivables         -         -         3,000,000 <t< td=""><td></td><td>2,931,013</td><td>4,742,133</td><td></td></t<>		2,931,013	4,742,133	
Accounts receivable		_	_	450,000
Prepaid expenses and other current assets Accounts payable and accrued expenses Deferred revenue         689,481 (1,042,211) (1,042,211) (1,0609,306 (607,920) (35,019,200) (38,262,280)           Net cash provided by (used in) operating activities Investment activities         12,617,121 (18,149,127) (60,546,785)           Purchase of equipment Activities         (23,695) (41,181) (1,300,536) (146,339,682) (146,339,682)           Purchase of investments         (45,193,716) (46,735,365) (146,339,682) (146,339,682)           Sale of investments         51,726,609 (32,300,000) (116,782,624)           Net cash provided by (used in) investing activities         6,509,198 (14,476,546) (30,857,594)           Financing activities         6,509,198 (14,476,546) (30,857,594)           Financing activities         2 (3,3742) (3,232		(1.072.454)	(1.567.819)	(4 339 607)
Accounts payable and accrued expenses Deferred revenue         3,145,451 (1,042,211) (600,306) (607,920) (35,019,200) (38,262,280)           Net cash provided by (used in) operating activities         12,617,121 18,149,127 (60,546,785)           Investment activities         12,617,121 (41,181) (1,300,536)           Purchase of equipment         (23,695) (41,181) (46,735,365) (146,339,682)           Purchase of investments         (45,193,716) (46,735,365) (146,339,682)           Sale of investments         51,726,609 (32,300,000) (116,782,624)           Net cash provided by (used in) investing activities         6,509,198 (14,476,546) (30,857,594)           Financing activities         (48,651,850)           Proceeds from issuance of preferred stock         (48,651,850)           Proceeds from collections of stockholders' receivables         (48,651,850)           Proceeds from notes payable         (48,651,850)           Proceeds from notes payable         (48,651,850)           Net cash provided by financing activities         2,137,429 (2,023,219) (162,295)           Net cash provided by financing activities         2,137,429 (2,023,219) (162,295)           Net increase in cash and cash equivalents         21,263,748 (5,695,800) (47,560,632) (162,295)           Cash and cash equivalents at end of period         347,560,632 (33,3163,589) (37,600,632) (37,607,789) (37,607,789) (37,607,789) (37,607,789) (37,607,789) (37,607,78				
Deferred revenue         (607,920)         35,019,200         38,262,280           Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         (23,695)         (41,181)         (1,300,536)           Purchase of equipment         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         (30,857,594)           Financing activities         -         -         48,651,850           Proceeds from issuance of preferred stock         2,137,429         2,023,219         86,471,146           Proceeds from collections of stockholders' receivables         -         -         1,004,310           Proceeds from notes payable         -         -         3,000,000           Payment of dividend         -         -         162,295           Net cash provided by financing activities         21,37,429         2,023,219         138,965,011           Net increase in cash and cash equivalents         21,263,748         5,695,800         47,560,632           Cash and cash equivalents at end of period         \$47,560,632         \$3,163,589<				
Net cash provided by (used in) operating activities         12,617,121         18,149,127         (60,546,785)           Investment activities         Purchase of equipment         (23,695)         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         (30,857,594)           Financing activities         —         —         48,651,850           Proceeds from issuance of preferred stock         2,137,429         2,023,219         86,471,146           Proceeds from issuance of common stock         2,137,429         2,023,219         86,471,146           Proceeds from notes payable         —         —         —         1,004,310           Proceeds from notes payable         —         —         —         3,000,000           Payment of dividend         —         —         —         (162,295)           Net cash provided by financing activities         21,263,748         5,695,800         47,560,632           Cash and cash equivalents at beginning of period         26,296,884         27,467,789         —				
Purchase of equipment         (23,695)         (41,181)         (1,300,536)           Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         (30,857,594)           Financing activities         -         -         48,651,850           Proceeds from issuance of preferred stock         2,137,429         2,023,219         86,471,146           Proceeds from collections of stockholders' receivables         -         -         -         1,004,310           Proceeds from notes payable         -         -         1,004,310           Proceeds from notes payable         -         -         1,004,310           Proceeds provided by financing activities         2,137,429         2,023,219         138,965,011           Net cash provided by financing activities         21,263,748         5,695,800         47,560,632           Cash and cash equivalents at beginning of period         26,296,884         27,467,789         -           Cash and cash equivalents at end of period         \$47,560,632         \$33,163,589         47,560,632           Supplemental schedule of cash flow information activit				
Purchase of investments         (45,193,716)         (46,735,365)         (146,339,682)           Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         (30,857,594)           Financing activities         —         —         —         48,651,850           Proceeds from issuance of preferred stock         2,137,429         2,023,219         86,471,146           Proceeds from collections of stockholders' receivables         —         —         1,004,310           Proceeds from notes payable         —         —         3,000,000           Payment of dividend         —         —         13,000,000           Payment of dividend         —         —         —         162,295)           Net cash provided by financing activities         2,137,429         2,023,219         138,965,011           Net increase in cash and cash equivalents         21,263,748         5,695,800         47,560,632           Cash and cash equivalents at beginning of period         26,296,884         27,467,789         —           Cash paid for interest         \$         \$         \$         191,328           Supplemental schedule of cash flow information		(23.695)	(41 181)	(1 300 536)
Sale of investments         51,726,609         32,300,000         116,782,624           Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         (30,857,594)           Financing activities           Proceeds from issuance of preferred stock         —         —         48,651,850           Proceeds from issuance of common stock         2,137,429         2,023,219         86,471,146           Proceeds from collections of stockholders' receivables         —         —         —         1,004,310           Proceeds from notes payable         —         —         —         3,000,000           Payment of dividend         —         —         —         (162,295)           Net cash provided by financing activities         2,137,429         2,023,219         138,965,011           Net increase in cash and cash equivalents         21,263,748         5,695,800         47,560,632           Cash and cash equivalents at beginning of period         26,296,884         27,467,789         —           Cash and cash equivalents at end of period         \$47,560,632         \$33,163,589         47,560,632           Supplemental schedule of cash flow information         \$         —         \$         —         \$         191,328           Supplemental schedule of		, , ,		
Net cash provided by (used in) investing activities         6,509,198         (14,476,546)         (30,857,594)           Financing activities         Proceeds from issuance of preferred stock         ———————————————————————————————————				
Proceeds from issuance of common stock         2,137,429         2,023,219         86,471,146           Proceeds from collections of stockholders' receivables         —         —         1,004,310           Proceeds from notes payable         —         —         3,000,000           Payment of dividend         —         —         (162,295)           Net cash provided by financing activities         2,137,429         2,023,219         138,965,011           Net increase in cash and cash equivalents         21,263,748         5,695,800         47,560,632           Cash and cash equivalents at beginning of period         26,296,884         27,467,789         —           Cash and cash equivalents at end of period         \$ 47,560,632         \$ 33,163,589         \$ 47,560,632           Supplemental schedule of cash flow information         \$ —         \$ —         \$ 191,328           Supplemental schedule of noncash investing and financing activities         \$ —         \$ —         \$ 3,000,000           Preferred stock dividend         \$ —         \$ —         \$ 3,000,000           Preferred stock dividend         \$ —         \$ —         \$ 3,000,000           Profeiture of common stock options and warrants         \$ —         \$ —         \$ 314,179				
Proceeds from collections of stockholders' receivables Proceeds from notes payable Proceeds from notes payable Payment of dividend Net cash provided by financing activities Net increase in cash and cash equivalents Cash and cash equivalents at beginning of period Cash and cash equivalents at end of period Paymental schedule of cash flow information Cash paid for interest  Supplemental schedule of noncash investing and financing activities Conversion of notes payable to preferred stock Preferred stock dividend  Profeiture of common stock options and warrants  - 1,004,310 3,000,000  (162,295) 138,965,011  Paymental schedule of cash equivalents Paymental schedule of period Paymental schedule of period Paymental schedule of cash flow information Cash paid for interest Paymental schedule of noncash investing and financing activities Profeiture of common stock options and warrants  Profeiture of common stock options and warrants Profeiture of common stock options and warrants  Profeiture of common stock options and warrants Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants  Profeiture of common stock options and warrants	Proceeds from issuance of preferred stock	_	_	48,651,850
Proceeds from notes payable         —         —         3,000,000           Payment of dividend         —         —         (162,295)           Net cash provided by financing activities         2,137,429         2,023,219         138,965,011           Net increase in cash and cash equivalents         21,263,748         5,695,800         47,560,632           Cash and cash equivalents at beginning of period         26,296,884         27,467,789         —           Cash and cash equivalents at end of period         \$47,560,632         \$33,163,589         \$47,560,632           Supplemental schedule of cash flow information         \$         —         \$         191,328           Supplemental schedule of noncash investing and financing activities         \$         —         \$         3,000,000           Preferred stock dividend         \$         —         \$         3,000,000           Prefeiture of common stock options and warrants         \$         —         \$         314,179		2,137,429	2,023,219	86,471,146
Payment of dividend — — — — — — — — — — — — — — — — — — —	Proceeds from collections of stockholders' receivables	_	_	1,004,310
Net cash provided by financing activities  2,137,429 2,023,219 138,965,011  Net increase in cash and cash equivalents Cash and cash equivalents at beginning of period 26,296,884 27,467,789 —  Cash and cash equivalents at end of period \$47,560,632 \$33,163,589 \$47,560,632  Supplemental schedule of cash flow information Cash paid for interest \$	Proceeds from notes payable	_	_	3,000,000
Net increase in cash and cash equivalents Cash and cash equivalents at beginning of period Cash and cash equivalents at beginning of period Cash and cash equivalents at end of period  \$47,560,632 \$27,467,789 \$47,560,632  Supplemental schedule of cash flow information Cash paid for interest  \$ \$ \$191,328  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  \$ \$ \$314,179	Payment of dividend			(162,295)
Cash and cash equivalents at beginning of period  Cash and cash equivalents at end of period  \$47,560,632 \$33,163,589 \$47,560,632  Supplemental schedule of cash flow information Cash paid for interest  Supplemental schedule of noncash investing and financing activities  Conversion of notes payable to preferred stock  Preferred stock dividend  Forfeiture of common stock options and warrants  Cash paid for interest  \$	Net cash provided by financing activities	2,137,429	2,023,219	138,965,011
Cash and cash equivalents at end of period \$47,560,632 \$33,163,589 \$47,560,632  Supplemental schedule of cash flow information Cash paid for interest \$ \$ \$191,328  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 \$ \$ \$314,179			5,695,800	47,560,632
Supplemental schedule of cash flow information Cash paid for interest \$ - \$ - \$ 191,328  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 \$ - \$ - \$ 314,179	Cash and cash equivalents at beginning of period	26,296,884	27,467,789	
Cash paid for interest \$ - \$ - \$ 191,328  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 \$ - \$ - \$ 314,179	Cash and cash equivalents at end of period	\$ 47,560,632	\$ 33,163,589	\$ 47,560,632
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 \$ - \$ - \$ 314,179	Supplemental schedule of cash flow information			
activitiesConversion of notes payable to preferred stock\$ - \$ - \$ 3,000,000Preferred stock dividend\$ - \$ - \$ 772,183Forfeiture of common stock options and warrants\$ - \$ - \$ 314,179	Cash paid for interest	<u> </u>	<u>\$</u>	\$ 191,328
Preferred stock dividend \$ - \$ - \$ 772,183  Forfeiture of common stock options and warrants \$ - \$ - \$ 314,179				
Forfeiture of common stock options and warrants \$ \$ \$ 314,179	Conversion of notes payable to preferred stock	<u>\$</u>	\$	\$ 3,000,000
	Preferred stock dividend	\$	\$	\$ 772,183
Conversion of common stock warrants to common stock \$ — \$ — \$ 1,080,001	Forfeiture of common stock options and warrants	\$	\$	\$ 314,179
	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. ("we" or "POZEN" or the "Company") was incorporated in the State of Delaware on September 25, 1996 and is operating in a single reportable segment. The Company is a pharmaceutical company focused primarily on products for the treatment of acute and chronic pain and other pain-related conditions. 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 and 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.).

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, 2007, the Company had \$47.6 million in cash and cash equivalents and \$31.2 million in short-term investments. Our operating expenses for the remainder of 2007 and 2008 are expected to parallel or increase from the level of our operating expenses in the first nine months of 2007. However, we believe that we will have sufficient cash reserves to maintain our current level of business activities through 2008 provided that certain development expenses are paid by AstraZeneca AB (AstraZeneca), as outlined in the collaboration and license agreement dated August 1, 2006 between the Company and AstraZeneca, as amended by an amendment effective as of September 6, 2007. The Company's expenses might increase additionally in the remainder of 2007 and 2008 if any regulatory agency requires the Company to conduct additional clinical trials, studies or investigations in connection with such agency's 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 this period. However, regulatory delays, such as the delay the Company is experiencing related to the approvable letters the Company received from the U.S. Food and Drug Administration (FDA) in June 2006 and in August 2007 in connection with to the Company's New Drug Application (NDA) for Trexima<sup>TM</sup>, or unforeseen situations or unforeseen developments in the progress 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, 2007. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2007.

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 104"), and Emerging Issues Task Force 00-21 ("EITF 00-21"), "Revenue Arrangements with Multiple Deliverables." The non-refundable portion of upfront payments received under the Company's existing agreements is deferred by the Company upon receipt and recognized on a 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 related to the August 2006 Collaboration and License Agreement with AstraZeneca has been deferred and was being amortized over 40 months. As a result of the revised development timeline agreed upon in the September 2007 amendment, we have extended the amortization period to 43 months. This is a change in accounting estimate and will be a prospective adjustment beginning in July 2007. 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. We recognized \$2.7 million and \$8.7 million of revenue from the amortization of the AstraZeneca licensing fee for the three and nine month period ended September 30, 2007, respectively. The September 2007 amendment to the AstraZeneca agreement included a \$10 million payment in connection with execution of the amendment. This payment has been deferred and will be amortized over 31 months. We recognized \$0.3 million of revenue from this amortization in September 2007.
- 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. Although the amortization rate in the first quarter of 2005 would have resulted in 2005 revenue recognition of \$7.2 million, the third quarter change in the amortization period resulted in a \$0.7 million increase in the full-year amortization and 2005 revenue recognition of \$7.9 million. 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 represented what the Company believed to be the conclusion of any obligation on its part under the agreement. During the fourth quarter of 2006 the remaining amortization period of 9 months was increased to 11 months based upon the December 2006 receipt of a notice from the FDA that it had completed its initial review of POZEN's response to the approvable letter related to the Trexima NDA and had requested additional analyses and supporting information relating to submitted data. Although the amortization rate in the first quarter of 2006 would have resulted in 2006 revenue recognition of \$6.4 million, the second and fourth quarter changes in the amortization period resulted in 2006 revenue recognition of \$4.5 million. As a result of the 2006 changes in the estimated amortization period, \$1.9 million of the \$25 million initial licensing and patent-issuance milestone payments was deferred to 2007 and, with the receipt of a second approvable letter in August 2007, unamortized deferred revenue of \$0.3 million will be amortized through March 2008. We recognized \$0.2 million and \$1.6 million of revenue from the amortization of GSK milestone payments for the three and nine month period ended September 30, 2007, respectively.
- The September 2003 \$1.0 million 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.

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 EITF 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent", under the collaboration agreement with AstraZeneca, the Company recognizes as revenue the billings for the direct costs and certain personnel-related time incurred in performing additional development activities described within the AstraZeneca agreement. We recognized \$4.3 million and \$16.5 million of revenue for development activities performed pursuant to the AstraZeneca agreement for the three and nine month periods ended September 30, 2007, respectively.

Royalty revenue will be recognized if and when earned in future periods 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 three and nine month periods ended September 30, 2007, the Company had \$0.2 million and \$0.9 million, respectively, of interest income included in other income for the period. For the three and nine month periods ended September 30, 2007, the Company had \$0.6 million and \$1.4 million, respectively, of bond amortization income included in other income for the period.

Accumulated Other Comprehensive Income—The Company follows the provisions of SFAS 130, "Comprehensive Income." SFAS 130 establishes standards for the reporting and display of comprehensive income and its components for general purpose financial statements. Accumulated other comprehensive income is comprised of unrealized gains and losses on marketable securities and is disclosed as a component of stockholders' equity. The Company had \$313 of unrealized losses on its investments that are classified on the balance sheet as accumulated other comprehensive income (loss) at September 30, 2007 and \$566 gain for the same period of 2006.

	Three Months Ended September 30,				Nine Months Ended September 30,		
		2007		2006	-	2007	2006
Income (loss) before taxes	\$	16,482,223	\$	(4,066,206)	\$	10,545,509	\$ (18,931,770)
Unrealized gain (loss) on marketable securities		(3,948)		10,856		(313)	566
Total comprehensive income (loss) before taxes	\$	16,478,275	\$	(4,055,350)	\$	(10,545,196)	\$ (18,931,204)

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. 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. Additionally, performance condition accounting is based on a probability assessment of achieving the performance condition.

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, 2007 and September 30, 2006 includes the following stock-based compensation expense:

	Three Months Ended September 30,			mber 30,	Nine Months Ended September 30,			
	2007			2006		2007		2006
Research and development	\$	9,295	\$	468,700	\$	798,922	\$	1,582,400
General and administrative		378,733		1,005,300		2,138,951		3,159,800
Operating expense		388,028		1,474,000		2,937,873		4,742,200
Tax benefit		-				-		-
Net expense	\$	388,028	\$	1,474,000	\$	2,937,873	\$	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 1.8 years was \$9.1 million at September 30, 2007 and, over an estimated weighted-average amortization period of 2.0 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, 2007 was \$1.3 million at September 30, 2007 and was \$1.6 million at September 30, 2006 for the remaining period ending December 31, 2006. The stock-based compensation expense for the nine months ended September 30, 2006 included a one-time adjustment of \$308,000 resulting from the performance-based option expensing method conversion to SFAS No. 123(R) for the options granted under the Trexima incentive program.

Based on the receipt of the second approvable letter for Trexima, we have determined that it is no longer probable (defined as >70% probability) that Trexima will be approved by the FDA by December 31, 2007. Accordingly, we have reversed all previously

expensed stock-based compensation related to the Trexima approval-date incentives in the third quarter of 2007. The reversals reduce research and development expenses by \$0.4 million and general and administrative expenses by \$0.6 million in this quarter.

#### Stock Plans

On November 20, 1996, the Company established a Stock Option Plan (the "Option Plan") and authorized the issuance of options for the purchase of up to 1,605,310 shares of common stock to attract and retain quality employees and to allow such employees to participate in the growth of the Company. In 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. At adoption, the Plan authorized up to 3,000,000 shares of common stock for issuance under the terms of 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. On June 13, 2007, the stockholders approved the amendment and restatement of the Plan to, among other things, increase the number of shares authorized for issuance under the 2000 Plan from 5,500,000 to 6,500,000 shares and continue the various performance criteria for use in establishing specific vesting targets for certain awards under the Plan so as to qualify the compensation attributable to any such awards as performance-based compensation under Section 162(m) of the Internal Revenue Code.

In May 2004 and February 2007 awards of 98,135 and 6,200 restricted stock units, respectively, were made to the Company's chief executive officer under the Plan. The May 2004 award of 98,135 restricted stock units were fully vested at March 31, 2007. The February 2007 award of 6,200 restricted stock units vest in four equal amounts on January 1st of the four calendar years subsequent to the respective grant date of the awards. Both the May 2004 and February 2007 awards are 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. The vesting of 25% of the 6,200 restricted stock unit awarded in February 2007 is contingent upon the Company's receiving approval of the Trexima NDA from the FDA on or before December 31, 2007. Based upon receipt of the second approvable letter for Trexima, we have determined that it is no longer probable (defined as >70% probability) that Trexima will be approved by the FDA by December 31, 2007. Therefore we have reversed, in the third quarter of 2007, previously expensed stockbased compensation expense for 1,550 restricted stock units. On June 13, 2007 awards of 14,000 restricted stock units were made to the Company's independent directors. These June 2007 awards vest on the earlier of June 13, 2008 or the date of the Company's next annual stockholders meeting.

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. 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 NASDAO reported market closing price of the common stock on January 3, 2005, the date of grant. Each performance-based option vests 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 was previously forfeited because receipt of the FDA approval letter for the Trexima NDA did 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. Based upon receipt of the second approvable letter for Trexima, we have determined that it is no longer probable (defined as >70% probability) that Trexima will be approved by the FDA by December 31, 2007. Therefore we have reversed all previously expensed stock-based compensation expense for the Trexima incentive program in the third quarter of 2007. As of September 30, 2007, due to the June 30, 2007 forfeiture of 25% of the outstanding options, as described under the terms of the initial grant, and forfeitures resulting from employee terminations, options to purchase an aggregate of 239,541 shares of common stock remain outstanding under the Trexima incentive program, the expense for which has been reversed, but which will not be forfeited until December 31, 2007 if Trexima is not approved by the FDA by that date.

#### 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 three and nine month periods ended September 30, 2007 and 2006 are shown in the following tables:

	Three Months Ended	September 30,	Nine Months Ended September 30,			
(In thousands)	2007	2006	2007	2006		
Expected volatility	78.4 %	83.0 %	76.0 – 79.2 %	76.0 – 83.0 %		
Expected dividends	0 %	0 %	0 %	0 %		
Expected terms	6.25 Years	6.25 Years	6.25 Years	6.25 Years		
Risk-free interest rate	4.4 %	4.9 %	4.4 - 5.1 %	4.3 – 5.1 %		

The expected volatility rates were estimated based on an equal weighting of the historical volatility of POZEN common stock over the preceding six-year period. The expected terms were 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 rates for periods within the contractual life of the option were based on seven year U.S. Treasury securities. The pre-vesting forfeiture rates used for the nine months ended September 30, 2007 and 2006 were based on historical rates. As required under SFAS No. 123(R), we will adjust the estimated forfeiture rate to our actual experience.

A summary of the time-based stock awards as of September 30, 2007, and changes during the three and nine months ended September 30, 2007, is as follows:

	Underlying Shares (000s)	Weighted- Average Exercise Price		Weighted- Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
Stock Awards					
Outstanding at January 1, 2007	3,416	\$	8.50		
Granted	572		16.86		
Exercised	37		3.33		
Forfeited or expired			-		
Outstanding at March 31, 2007	3,951	\$	9.76	7.2	\$ 20,973
Exercisable at March 31, 2007	2,145	\$	7.91	5.9	\$ 14,696
Granted	45		16.77		
Exercised	198		9.58		
Forfeited or expired	273		12.97		
Outstanding at June 30, 2007	3,525	\$	9.61	6.9	\$ 29,841
Exercisable at June 30, 2007	1,956	\$	7.78	5.6	\$ 20,212
Granted	2		10.20		
Exercised	20		5.70		
Forfeited or expired	73		12.24		
Outstanding at September 30, 2007	3,434	\$	9.57	6.6	\$ 8,567
Exercisable at September 30, 2007	1,944	\$	7.66	5.4	\$ 6,837

The vesting of 46,135 time-based stock awards granted in the nine months ended September 30, 2007 are contingent upon the Company's receiving approval of the Trexima NDA from the FDA on or before December 31, 2007. Based upon receipt of the second approvable letter for Trexima, we have determined that it is no longer probable (defined as >70% probability) that Trexima will be approved by the FDA by December 31, 2007. Therefore we have reversed, in the third quarter of 2007, previously expensed stockbased compensation expense for these time-based stock awards.

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:

	Underlying Shares (000s)	Weighted- Average Exercise Price		Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
Stock Awards					
Outstanding at January 1, 2006	3,317	\$	7.67		
Granted	826	1	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	1	12.81		
Exercised	18		2.10		
Forfeited or expired	288	1	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	1	10.31		
Exercised	154		7.46		
Forfeited or expired	69	1	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 nine months ended September 30, 2007 and 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 months ended September 30, 2007 was \$0.2 million and \$2.3 million, respectively. The total intrinsic value of stock options exercised during the three and nine months ended September 30, 2006 was \$0.4 million and \$1.2 million, respectively.

#### Restricted Stock and Restricted Stock Units

As of September 30, 2007, there was \$0.3 million of unrecognized compensation expense related to unvested restricted stock units under the 2007 award of 20,200 restricted stock units and no unrecognized compensation expense related to the May 2004 award of 98,135 restricted stock units. The grant-date per-share fair value of the February 2007 and June 2007 restricted stock units were \$16.89 and \$16.19, respectively. The grant-date per-share fair value of the May 2004 restricted stock units were \$12.24. There were 20,200 unvested restricted stock units outstanding at September 30, 2007. A total of 6,200 time-based restricted stock units were granted of which 1,550 were contingent upon the Company's receiving FDA approval of the Trexima NDA on or before December 31, 2007. Based upon receipt of the second approvable letter for Trexima, we have determined that it is no longer probable (defined as >70% probability) that Trexima will be approved by the FDA by December 31, 2007. Therefore we have reversed all previously expensed stock-based compensation expense for the 1,550 time-based restricted stock units, although the units will not be forfeited until December 31, 2007.

#### Performance-Based Awards

The fair value of each performance-based option granted under the Plan, including those 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 for the nine months ended September 30, 2007, were 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. Under the Trexima incentive program, 25% of

each option grant has been forfeited because receipt of the FDA approval letter for the Trexima NDA did not occur prior to June 30, 2007 (the "25% portion"). Since the Company believed it was unlikely that this performance goal would be met at the end of 2006, no compensation cost was recognized for the 25% portion of the Trexima incentive program and previously recognized compensation cost, related to this portion of the awards, was reversed in the fourth quarter of 2006.

Based on the receipt of the second approvable letter for Trexima, we have determined that it is no longer probable (defined as >70% probability) that Trexima will be approved by the FDA by December 31, 2007. Accordingly, we have reversed all previously expensed stock-based compensation for the Trexima incentive option in the third quarter of 2007, although the shares will not be forfeited until December 31, 2007. The reversal reduces research and development expenses by \$0.3 million and general and administrative expenses by \$0.6 million in this quarter. The grant-date fair value of these performance-based options was \$3.77 per share. There were 239,541 and 375,251 unvested performance-based options outstanding at September 30, 2007 and 2006, respectively. There were 6,019 and 135,710 awards forfeited during the three and nine months ended September 30, 2007. During the three and nine months ended September 30, 2006, 13,342 and 68,160 awards were forfeited. At September 30, 2007, the performance-based options had an intrinsic value of \$0.9 million and a remaining contractual life of 7.2 years, while at September 30, 2006 the performance-based options had no intrinsic value and a remaining contractual life of 8.2 years.

Net Income and Net Loss Per Share—Basic and diluted net income and net loss per common share amounts are presented in conformity with SFAS 128, "Earnings per Share," for all periods presented. In accordance with SFAS 128, basic and diluted net income or loss per common share amounts have been computed using the weighted-average number of shares of common stock outstanding for the nine months ended September 30, 2006. During the nine months ended September 30, 2006 and 2007, 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 because the effect would have been antidilutive. Accordingly, basic and diluted net loss per share is the same for the nine months ended September 30, 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.

The following table reconciles the numerator and denominator used to calculate diluted net income per share (in thousands):

	Thro Sep	Nine months ended September 30, 2007		
Numerator:				
Net income	\$	14,837,124	\$ 8,900,410	
Denominator:				
Weighted average common shares, basic		29,695,596	29,555,787	
Dilutive effect of stock options		903,211	1,071,495	
Weighted average common shares, diluted		30,598,807	30,627,282	

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 the Company'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 July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). FIN 48 is an interpretation of FASB Statement No. 109, "Accounting for Income Taxes," and seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, and accounting in interim periods and requires expanded disclosure with respect to the uncertainty in income taxes. FIN 48 is effective as of the beginning of the Company's 2007 fiscal year. The cumulative effect, if any, of applying FIN 48 is to be reported as an adjustment to the opening balance of retained earnings in the year of adoption. The January 1, 2007 adoption of FIN 48 did not have a material effect on the Company's financial statements.

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. Lead plaintiffs were appointed by the court and a consolidated amended complaint was filed on December 20, 2004. The amended complaint alleged, 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 July 10, 2007 the Company announced that is has reached an agreement to amicably settle the consolidated class action lawsuit. All claims against the Company and Dr. Plachetka will be dismissed in their entirety without admission of liability or wrongdoing by any party. The settlement agreement, which was granted preliminary approval by the court on October 2, 2007, will be funded entirely with proceeds from the Company's directors and officers' liability insurance and it is the current judgment of management that it is unlikely that this settlement will have a material adverse effect on the Company's results of operations, financial condition or cash flows.

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of our securities against us, our chairman and chief executive officer and one of our directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Trexima, during the purported class period, July 31, 2006 through August 1, 2007. The Company and the individual defendants believe that the plaintiff's allegations are without merit, and intend to defend these claims vigorously.

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.

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 required.

#### 3. Subsequent Events

On October 15, 2007 we announced that we had submitted a response to the August 1, 2007 approvable letter for Trexima after meeting with the FDA to discuss the proposed plan for responding to the letter. This response includes, in addition to a required safety update and revised labeling, the results of three non-clinical (*in vitro*) studies that provide clarifying information about the Chinese Hamster Ovary (CHO) assay. The FDA has notified us that it considers the response to be a complete, Class II response (six months) which could result in a new decision date of April 15, 2008.

In addition, POZEN is conducting a seven day clinical evaluation of the genotoxic potential of *Trexima* in human volunteers in the event the FDA requires this information. Results from this evaluation are expected to be available during the first quarter of 2008. If these data are submitted to the FDA, the review period, and the time to approval, may be extended.

#### 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, 2006, as filed on March 8, 2007.

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

- obtaining patents for innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas through proof of concept by working with strategic outsource partners; and
- licensing the resulting product or technology to a strong pharmaceutical partner to commercialize.

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

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

We have developed Trexima<sup>TM</sup> in collaboration with GlaxoSmithKline (GSK). GSK's Trexima was the proposed brand name for the product candidate combining sumatriptan 85 mg, as the succinate salt, formulated with RT Technology<sup>TM</sup> and naproxen sodium 500 mg in a single tablet designed for the acute treatment of migraine. Several new names are under consideration at the U.S. Food and Drug Administration (FDA), but pending a final decision on a new name, the product will still be referred to as Trexima. Trexima incorporates our MT 400 technology, which refers to our proprietary combinations of a triptan (5-HT<sub>IB/ID</sub> agonist) and a nonsteroidal anti-inflammatory drug (NSAID). Under our MT 400 technology, we sought to develop product candidates that provide acute migraine therapy by combining the activity of two drugs that act by different mechanisms to reduce the pain and associated symptoms of migraine. We filed a New Drug Application (NDA) for Trexima with the FDA in August 2005 and in June 2006, we received an approvable letter requiring us to provide certain additional safety information relating to Trexima, some of which required new studies. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. We, along with GSK, met with the FDA in July 2006 to discuss the approvable letter and we submitted a response to the FDA's approvable letter in November 2006. In December 2006, the FDA told us that our response was not a complete submission and requested that we provide additional analyses and supporting information relating to the data we submitted

in our November response. The FDA also indicated that it was necessary to provide a complete and accurate presentation of these data, which had to sufficiently address their safety concerns, including cardiovascular safety. We worked with GSK to compile and format the additional data requested by the FDA and delivered a revised full response to the FDA in early February 2007. On August 1, 2007, we received a second approvable letter from the FDA for Trexima. In that letter, the FDA requested that POZEN further address the FDA's concern about the product's potential for genotoxicity. Together with GSK, we met with the FDA in September and filed a response to the second approvable letter in October 2007. The submission includes, in addition to a required routine Safety Update and revised product labeling, the results of three non-clinical (*in vitro*) studies that provide clarifying information about the Chinese Hamster Ovary (CHO) assay. has notified us that it considers the response to be a complete, Class II response (six months) which could result in a new decision date of April 15, 2008. In addition, POZEN is conducting a seven day clinical evaluation of the genotoxic potential of *Trexima* in human volunteers in the event the FDA requires this information. Results from this evaluation are expected to be available during the first quarter of 2008. If these data are submitted to the FDA, the review period, and the time to approval, may be extended.

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 which was amended in September 2007. We began the phase 3 program in September 2007. As part of the program, we are conducting two Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers. In addition, we are conducting a long-term, open label safety study and a smaller study in patients at high risk of gastrointestinal related events from NSAIDs.

Another product candidate program (our PA program), a combination of a PPI and aspirin, is currently in formulation and clinical development testing. Our PA product candidates are excluded under our agreement with AstraZeneca. We have met with the FDA and confirmed that the development program for PA325 will be similar to our PN product development program. The objective of the program will be to establish that patients taking our PA325 product have fewer gastric ulcers than patients taking enteric coated (EC) 325mg aspirin over the study treatment period. An IND is expected to be filed in the fourth quarter of 2007 and Phase 3 studies could begin as early as the first quarter of 2008.

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) to treat pain or other pain-related indications. These product candidates, which are being developed under an exclusive license agreement with Nycomed Danmark ApS (Nycomed), grant us certain rights to develop and commercialize products containing lornoxicam. We have filed Investigational New Drug Applications (INDs) with the FDA for an oral and an injectable lornoxicam formulation.

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

We have incurred significant losses since our inception and have not generated any revenue from product sales. As of September 30, 2007, our accumulated deficit was approximately \$122.9 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 72% of our total operating expenses. For the nine month period ended September 30, 2007, our research and development expenses represented approximately 78% 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 there from. 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, our PN and PA product candidates and our other product candidates in the clinical and regulatory process;
- The ability of GSK to successfully launch and market Trexima in the United States;
- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates; and
- The acquisition and/or in-licensing, and development, of other therapeutic product candidates.

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. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included elsewhere in this Quarterly Report on Form 10-Q. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

#### **Status 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, 2007 were \$4.3 million. Other research and development department costs for the nine month period ended September 30, 2007 were \$0.3 million.

#### Trexima

In June 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 requested additional safety information on Trexima, some of which required new studies. After meeting with the FDA in July 2006, we and GSK submitted a response to the approvable letter in November 2006 using additional data from GSK sponsored clinical trials. In December 2006, we received notification that the response was not yet considered complete. Specifically, the FDA requested that we provide additional analyses and supporting information relating to the data we submitted in our November response. The FDA also indicated that it was necessary to provide a complete and accurate presentation of these data, which had to sufficiently address their safety concerns, including cardiovascular safety. We worked with GSK to compile and format the additional data requested by the FDA and delivered a revised full response to the FDA in early February 2007. On August 1, 2007, we received a second approvable letter from the FDA for Trexima. In that letter, the FDA requested that we further address the FDA's concern about the product's potential for genotoxicity. The companies met with the FDA in September and submitted a response in October to the approvable letter. The submission includes, in addition to a required routine Safety Update and revised product labeling, the results of three non-clinical (in vitro) studies that provide clarifying information about the Chinese Hamster Ovary (CHO) assay. The FDA has notified us that it considers the response to be a complete, Class II response (six months) which could result in a new decision date of April 15, 2008.

In addition, POZEN is conducting a seven day clinical evaluation of the genotoxic potential of *Trexima* in human volunteers in the event the FDA requires this information. Results from this evaluation are expected to be available during the first quarter of 2008. If these data are submitted to the FDA, the review period, and the time to approval, may be extended.

As part of our NDA program for Trexima, we conducted five Phase 1 trials, two Phase 3 pivotal trials, and one 12-month open label safety trial 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. 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 was sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine. Further, GSK continues to conduct 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 obtain regulatory approval of Trexima. In the second approvable letter from FDA for Trexima which we received on August 1, 2007, the FDA requested that POZEN further address its concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan. We and GSK met with the FDA to discuss the proposed plan for addressing their concerns and we filed a response to the approvable letter in October which contains new non-clinical information. However, it is unknown whether the non-clinical data submitted will adequately address their concerns. Even if the FDA requires and we submit data from a short-term clinical study of the genotoxic potential of Trexima in human volunteers in addition to such non-clinical data, there are no guarantees that the FDA will find our response to the second approvable letter to be sufficient, that additional testing will not be needed to address the FDA's concerns described in the second approvable letter or to address other issues the FDA may raise in the future, that additional warnings will not be required on the product labeling, or that the FDA will approve the NDA. In the event that additional clinical trials or other research and development activities are required, under our agreement, GSK will be responsible for the costs of such additional trials or activities, except for our personnel-related costs. Further, we have no assurance that GSK will continue with the development of the product in the event of additional delays in obtaining marketing approval.

We incurred \$0.8 million in direct development costs associated with the development of MT 400/Trexima for the nine month period ended September 30, 2007 and we have incurred \$25.3 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 several combinations of a 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. We initially conducted studies with two PN product formulations in this program - PN 100, a combination of the PPI lansoprazole and the NSAID naproxen, and PN 200, a combination of the PPI omeprazole and naproxen. Our present development and commercialization efforts under the PN program are covered under our exclusive collaboration agreement with AstraZeneca, which we entered into on August 1, 2006 and was amended in September 2007. Under our agreement with AstraZeneca, we and AstraZeneca are co-developing and AstraZeneca will commercialize proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet. The initial product to be developed under the agreement, PN 400, is being studied for the 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. On March 2, 2007, we filed an IND with the FDA for PN 400 and in April 2007, the initial Phase 1 study was initiated.

In discussions with the FDA during 2005 regarding our development plans for studies to pursue FDA approval of PN 100 and PN 200, the FDA agreed that by including naproxen as the NSAID within the PN formulation, we could expect that all indications for 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 have met with the FDA and confirmed the core development program and the SPA already agreed upon do apply to the new product consisting of proprietary fixed dose combinations of esomeprazole magnesium with naproxen.

In the third quarter of 2006, we began recruiting subjects for a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy. The primary endpoint for the trial is the cumulative incidence of gastric ulcers over six months of treatment. Because we will not have final results until the fourth quarter of 2007, we, together with AstraZeneca

reviewed the interim results of this trial prior to commencing Phase 3 studies of PN 400 in September 2007. We are currently conducting two Phase 3 pivotal trials in patients who are at risk for developing NSAID-associated gastric ulcers. In addition, we are conducting a long-term, open label safety study and a smaller study in patients at high risk of gastrointestinal related events from NSAIDs.

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 likely 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. Under our agreement with AstraZeneca, AstraZeneca has responsibility for the development program for PN outside the United States, including interactions with regulatory agencies.

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

We incurred direct development costs associated with the development of our PN program of \$19.4 million for the nine month period ended September 30, 2007 and we have incurred \$37.2 million from inception to date, \$21.4 million of which was funded by development revenue from AstraZeneca. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

#### **PA Program**

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

Our initial PA product candidate, PA325, is currently in formulation and early-stage clinical development. We completed a Phase I proof of concept study of PA325 in the first quarter of 2007. The primary endpoint was gastrointestinal damage as measured by the Lanza scoring system used in our previous PN studies. The results were highly significant with 10 percent of the PA group having Lanza 3 or 4 gastrointestinal damage, whereas 57.5% of the EC aspirin group had this level of gastrointestinal damage during the 28 day study. We recently completed a second proof of concept study with PA325 as compared to 81 mg of EC aspirin. These results confirmed the earlier levels of gastric damage as measured by Lanza scoring at about 10% for PA325. While these results were numerically different, they did not achieve statistical significance from the results obtained with 81mg EC aspirin (21%). After reviewing these data, we decided to increase the dose of omeprazole to 40mg per tablet and conduct an additional 28 day phase I study using the new PA325 (40 mg of immediate release of omeprazole and 325 mg of aspirin) tablet compared to 325 mg EC aspirin. Topline results from this study indicate a highly significant (P=0.003) reduction in GI damage with the higher strength PA325 tablet as compared with 325mg EC aspirin (2.5% vs 27.5% grade 3 or 4 Lanza scores, respectively). In this last study, 75% of subjects treated with the new PA325 tablet showed no GI damage at all as compared to < 50% with eth 20mg version of PA325. We met with the FDA in July 2007 and confirmed that the development program for PA will be similar to our PN product development program. The objective of the program will be to provide a safer cardioprotective form of aspirin. To achieve that goal, we must prove bioequivalence to EC aspirin to allow Pozen to receive all the cardio- and cerebrovascular secondary prevention claims of aspirin and to establish that patients taking our PA product have fewer gastric ulcers than patients taking EC 325mg aspirin over the study treatment period. An IND is expected to be filed in 4Q07 and Phase 3 studies could commence as early as the first quarter of 2008.

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 \$4.9 million during the nine month period September 30, 2007, and we have incurred \$6.7 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**

We have conducted development work and 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 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.

<u>Injectable Formulation</u> - 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 indication.

We continue to evaluate the strategic direction of our lornoxicam product candidates and the lornoxicam program 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 no direct development costs associated with the development of our lornoxicam program for the nine month period ended September 30, 2007, 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.

#### MT 100

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. 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. 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.

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 direct development costs associated with the development of MT 100 of \$103,200 for the nine month period ended September 30, 2007, and we have incurred \$39.9 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. 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, nor do we believe that we will receive any future cash inflows from MT 300. We incurred direct

development costs associated with the development of MT 300 of \$56,300 for the nine month period ended September 30, 2007, 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 of our overhead expenses.

In July 2005, we received a letter from our partner, 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 the not-approvable letter from the FDA. The agreement requires that unresolved disputes by the parties be referred to the respective chief executive officers for resolution. If still unresolved, the agreement provides for binding arbitration. Valeant NA has disputed our conclusion that the withdrawal fee is not payable and has indicated its intention to pursue the dispute resolution provisions provided for under the agreement. 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.

#### **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<sub>1B/ID</sub> agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. We were responsible for development of the first combination product, while GSK provided formulation development and manufacturing. GSK had proposed Trexima as the brand name of the combination of sumatriptan succinate, formulated with GSK's RT Technology<sup>TM</sup>, and naproxen sodium in a single tablet, but this brand name was not acceptable to the FDA. The Company and GSK have submitted alternative trade names to FDA, which are currently under consideration. Pending a final decision on a new name, the product will still be referred to as Trexima. 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 a total amount of \$20.0 million upon FDA approval of the Trexima NDA and GSK's 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 combination product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop or to launch the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

#### AstraZeneca AB (AstraZeneca)

In August 2006, we entered into a collaboration and license agreement dated as of August 1, 2006 and effective September 7, 2006 with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose

combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers. Under the terms of the agreement, we granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under our patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). AstraZeneca 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 September 2007, we agreed with AstraZeneca to amend our collaboration and license agreement effective as of September 6, 2007. Under the terms of the amendment, AstraZeneca has agreed to pay us up to \$345 million, in the aggregate, in milestone payments upon the achievement of certain development, regulatory and sales events. We received an immediate \$30 million payment in September 2007, which included a \$10 million payment upon execution of the Amendment and a \$20 million payment in recognition of the achievement of successful proof of concept. An additional \$55 million will be paid upon achievement of certain development and regulatory milestones, and \$260 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved. Under the original agreement, we were to have received development and regulatory milestones totaling \$160 million, of which \$20 million was to be paid upon the successful completion of the proof of concept studies, and sales performance milestones totaling \$175 million.

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

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

The agreement, unless earlier terminated, will expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement at 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.

#### 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<sup>®</sup> (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.

### **Results of Operations**

#### Three months ended September 30, 2007 compared to the three months ended September 30, 2006

Net profit/( loss) per share: Net profit attributable to common stockholders for the three months ended September 30, 2007 was \$14.8 million or \$0.48 per share, on a diluted basis, as compared to a net loss of \$(4.1) million, or \$(0.14) per share, on a diluted basis, for the three months ended September 30, 2006. The net profit for the three month period ended September 30, 2007 included a \$0.4 million or \$0.01 per share charge for non-cash stock-based compensation expense as compared to \$1.5 million, or \$(0.05) per share for the same period of 2006. The Company reversed \$1.0 million of previously expensed stock-based compensation in September 2007 for which the vesting is contingent on the FDA approval of Trexima by December 31, 2007.

Revenue: We recognized \$27.6 million of revenue for the three months ended September 30, 2007 as compared to \$3.4 million for the three months ended September 30, 2006. The increase in revenue was primarily due to a \$30.0 million payment received from AstraZeneca for the PN 400 program, of which \$20.0 million was recognized as a milestone payment and \$10.0 million was deferred in accordance with our development and commercialization agreement. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in product development or related activities 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 \$38.3 million remains in deferred revenue at September 30, 2007. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses increased by \$5.4 million to \$9.7 million for the three months ended September 30, 2007, as compared to the same period of 2006. The increase was due primarily to an increase in direct development costs for PN and PA program activities, as compared to the same period of 2006. Direct development costs for the PN program increased by \$3.7 million to \$5.8 million, primarily due to Phase 3 clinical trial activities and other PN product development

activities pursuant to the AstraZeneca agreement during the third quarter of 2007, as compared to the same period of 2006. Direct development costs for the PA program increased by \$2.1 million to \$2.2 million during the third quarter of 2007, as compared to the same period of 2006. Other direct development costs and departmental expenses decreased by \$0.6 million primarily due to lower personnel costs, including reduced non-cash stock based compensation expense, as compared to the same period of 2006. 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 decreased by \$1.5 million to \$2.2 million for the three months ended September 30, 2007, as compared to the same period of 2006. The decrease was due primarily to a reduction in personnel related expenses, including the reversal of previously expensed stock-based compensation expense related to the Trexima incentive program, as compared to the same period of 2006. 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 \$0.2 million for the three months ended September 30, 2007 and \$0.3 million for the three months ended September 30, 2006. Investment income from bond amortization for the three month period ended September 30, 2007 totaled \$0.6 million as compared to \$0.1 million during the same period of 2006.

## Nine months ended September 30, 2007 compared to the nine months ended September 30, 2006

Net profit/( loss) per share: Net profit attributable to common stockholders for the nine months ended September 30, 2007 was \$8.9 million or \$0.29 per share, on a diluted basis, as compared to a net loss of \$(18.9) million, or \$(0.65) per share, on a diluted basis, for the nine months ended September 30, 2006. The net profit for the nine months ended September 30, 2007 included a \$2.9 million or (\$0.09) per share charge for non-cash stock-based compensation expense as compared to \$4.7 million, or \$(0.15) per share for the same period of 2006.

Revenue: We recognized \$47.2 million of revenue for the nine months ended September 30, 2007 as compared to \$6.5 million for the nine months ended September 30, 2006. The increase in revenue was primarily due to a \$30.0 million payment received from AstraZeneca for the PN 400 program, of which \$20.0 million was recognized as a milestone payment, and a \$4.1 million increase in the amortization of upfront payments we received and a \$16.6 million increase in other revenue from development activities we completed in the period pursuant to our development and commercialization agreements with AstraZeneca and GSK. Our licensing and collaboration agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in product development or related activities 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 \$38.3 million remains in deferred revenue at September 30, 2007. Substantive milestone payments are recognized as revenue upon completion of the contractual events.

Research and development: Research and development expenses increased by \$14.2 million to \$30.6 million for the nine months ended September 30, 2007, as compared to the same period of 2006. The increase was due primarily to an increase in direct development costs for PN and PA program activities, partially offset by a decrease in direct development costs for the lornoxicam program, as compared to the same period of 2006. Direct development costs for the PN program increased by \$12.9 million to \$19.4 million, primarily due to Phase 3 clinical trial activities and other PN product development activities pursuant to the AstraZeneca agreement during the nine months ended September 30, 2007, as compared to the same period of 2006. Direct development costs for the PA program increased to \$4.9 million during the nine months ending September 30, 2007, as compared to the same period of 2006. Direct development costs for the lornoxicam program decreased by \$3.4 million primarily due to Phase I/II clinical trial activities during the nine months ending September 30, 2006. Other direct development costs and departmental expenses decreased by \$1.1 million primarily due to a reduction in personnel costs including reductions in non-cash stock based compensation expense, as compared to the same period of 2006. 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 decreased by \$2.0 million to \$8.4 million for the nine months ended September 30, 2007, as compared to the same period of 2006. The decrease was due primarily to a reduction in non-cash stock based compensation expense, as a result of the reversal of previously expensed stock-based compensation expense related to the Trexima incentive program, and a decrease in public company legal expenses as compared to the same period of 2006. 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 \$0.9 million for the nine months ended September 30, 2007 as compared to \$0.7 million for the nine months ended September 30, 2006. Investment income from bond amortization for the nine month period ended September 30, 2007 totaled \$1.4 million as compared to \$0.6 million during the same period of 2006.

#### **Income Taxes**

We estimate an annual effective tax rate of 15.6% for the year ended December 31, 2007 based upon financial results and annual forecasts available at September 30, 2007. Our effective tax rate is 15.6% for the nine month period ended September 30, 2007. Although we have significant loss carryforwards, we project that we will be subject to Alternative Minimum Tax in 2007. Based upon the company's historic losses, management has recorded a valuation allowance on the net deferred tax assets. Accordingly, the company has not recognized a deferred tax benefit in the current year associated with the projected AMT credit generated. 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 limit our ability to utilize these carry forwards. We have experienced various ownership changes, as defined by the Act, as a result of, among other reasons, past financings. Accordingly, our ability to utilize the aforementioned carry forwards may be limited. Additionally, because tax laws limit the time during which these carry-forwards may be applied against future taxes, we may not be able to take full advantage of these carry-forwards for federal income tax purposes.

We currently file income tax returns in the U.S. federal jurisdiction, and the state of North Carolina. We are no longer subject to federal or North Carolina income tax examinations by tax authorities for years before 2003. However, the loss carryforwards generated from 1996 through 2002 are subject to change, if we subsequently begin utilizing these losses in a year that is open under statute and subject to federal or North Carolina income tax examinations by tax authorities.

We adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes ("FIN 48"), on January 1, 2007 and as a result, there were no material impacts to the financial statements.

We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the ninemonth periods ended September 30, 2007 and 2006, there were no such interest and penalties.

#### **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. Since 2003, we have received \$102.5 million from upfront and milestone payments from our collaborators. Additionally, since August 2006, we have received \$9.0 million for development activities pursuant to the terms of our agreement with AstraZeneca. At September 30, 2007, cash and cash equivalents, along with short-term investments, totaled \$78.8 million, an increase of \$16.2 million compared to December 31, 2006. The increase in cash was primarily due to the \$30 million payment received from AstraZeneca. Expenses for the period were also offset in part by cash receipts for development activities received from AstraZeneca pursuant to our PN collaboration agreement. There is a \$4.3 million accounts receivable from AstraZeneca at September 30, 2007. Our cash is invested in money market funds that invest primarily in short-term, highly rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short-term corporate fixed income obligations and U.S. Government agency obligations.

We received \$15.5 million in operating cash during the nine months ended September 30, 2007 pursuant to the terms of our collaboration agreement with AstraZeneca. In addition, our balance sheet includes \$4.3 million in accounts receivable for invoiced development activities under the terms of the AstraZeneca agreement. Cash received from financing activities during the period totaled \$2.1 million, reflecting net proceeds from the exercise of stock options.

Based upon the indirect method of presenting cash flow, as used in the Statement of Cash Flows included in our financial statements, cash provided by operating activities totaled \$12.6 million for the nine months ended September 30, 2007. Cash provided by operating activities was \$13.1 million for the fiscal year ended December 31, 2006 and \$6.7 million cash was used in operating activities for the fiscal year ended December 31, 2005. Net cash provided by investing activities during the nine months ended September 30, 2007 totaled \$6.5 million, reflecting investing activities associated with the sale of short-term securities. These holdings were reinvested in securities with maturities of three months or less and are classified on our balance sheet as cash and cash equivalents.

As of September 30, 2007, we had \$47.6 million in cash and cash equivalents and \$31.2 million in short-term investments. Our operating expenses for 2007 and 2008 are expected to increase from the level of our operating expenses in 2006. However, we believe that we will have sufficient cash reserves to maintain that level of business activities through 2008 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 sell shares of common stock in the future to fund additional development activities and increase our working capital. We have filed with the Securities and Exchange Commission (SEC), and the SEC has declared effective, a shelf registration statement on Form S-3 under which we may register up to 8,540,000 shares of our common stock for sale in one or more public offerings. Certain selling stockholders named in the prospectus for the registration statement may offer up to an aggregate of 540,000 of such shares, and we will not receive any of the proceeds from the sales of shares made by the selling stockholders. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

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

- the number and progress of our clinical trials and other trials and studies;
- our success, or any delays, in obtaining, 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; and
- our ability to negotiate favorable terms with various contractors assisting in our trials and studies.

#### 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 alleged, 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. On July 10, 2007 we announced that we had reached an agreement to amicably settle the consolidated class action lawsuit. All claims against us and Dr. Plachetka will be dismissed in their entirety without admission of liability or wrongdoing by any party. The settlement agreement, which was granted preliminary approval by the court on October 2, 2007, will be funded entirely with proceeds from our directors and officers' liability insurance and it is the current judgment of management that it is unlikely that this litigation will have a material adverse effect on our results of operations, financial condition or cash flows.

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of our securities against us, our chairman and chief executive officer and one of our directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Trexima, during the purported class period, July 31, 2006 through August 1, 2007. The Company and the individual defendants believe that the plaintiff's allegations are without merit, and intend to defend these claims vigorously.

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.

### 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, some of which required new studies. We submitted a full response to the FDA's approvable letter in November 2006. In December 2006, the FDA told us the full response was not a complete submission and requested that we provide additional analyses and supporting information relating to the data we submitted in our November response. The FDA also indicated that it is necessary to provide a complete and accurate presentation of these data, which had to sufficiently address their safety concerns, including cardiovascular safety. We worked with GSK to compile and format the additional data requested by the FDA and delivered a revised full response to the FDA in early February 2007. On August 1, 2007, we received a second approvable letter from the FDA for Trexima. In that letter, the FDA requested that POZEN further address the FDA's concern about the product's potential for genotoxicity. The companies met with the FDA in September and filed a response to the second approvable letter in October 2007. The FDA has notified us that it considers the response to be a complete, Class II response (six months) which could result in a new decision date of April 15, 2008. In addition, POZEN is conducting a seven day clinical evaluation of the genotoxic potential of Trexima in human volunteers in the event the FDA requires this information. Results from this evaluation are expected to be available during the first quarter of 2008. If these data are submitted to the FDA, the review period, and the time to approval, may be extended. There are no guarantees that the FDA will find our response to the second approvable letter to be sufficient, that further testing in addition to the short-term study in human volunteers we are conducting will not be needed to address the FDA's concerns described in the second approvable letter or to address other issues the FDA may raise in the future, that additional warnings will not be required on the product labeling, or that the FDA will approve the NDA. In the event that additional clinical trials or other research and development activities are required, under our agreement, GSK will be responsible for the costs of such additional trials or activities, except for our personnel-related costs. Further, we have no

assurance that GSK will continue with the development of the product in the event of additional delays in obtaining marketing approval.

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, 2007, we had an accumulated deficit of approximately \$122.9 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing 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 and notification of GSK's intent to commercialize Trexima, receipt of which will be delayed as a result of our receipt of a second approvable letter for the product on August 1, 2007. 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 longterm cardiovascular safety studies will be required for NDA approval of any oral lornoxicam product candidate we may develop. We do not know to what extent the FDA's actions may otherwise adversely affect or delay the approvability of our Trexima, PN or other product candidates that contain NSAIDs. The FDA is also reviewing the safety of two marketed proton-pump inhibitors with respect to the possibility of increased cardiovascular risk. Although, the FDA's preliminary conclusion was that an observed difference in the risk of heart attacks and other heart-related problems seen in two small studies was not a true effect, the agency has said it will continue to review the issue. Future regulatory action by the FDA could adversely affect or delay the approvability of our PA and PN product candidates that contain proton-pump inhibitors.

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

us or reduce or eliminate their payments to us under these agreements or we may be required to pay termination payments under these agreements.

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the 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. Except for MT 100, which has been approved for sale in the UK, none of our product candidates have been approved for sale in the U.S. or any foreign market and they may never be approved. For example, we have received two approvable letters relating to our NDA for Trexima which have communicated FDA's concerns that have delayed marketing approval. An approvable letter is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In June 2006, we received the first approvable letter in which the FDA requested additional safety information on Trexima, and in August 2007, we received a second approvable letter in which the FDA requested that we address their concern about the potential implications from one preclinical in vitro chromosomal aberration study in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan. 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. Both AstraZeneca and GSK have the right to terminate their respective agreement with us upon 90 days notice for any reason. 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. Based on the not-approvable letter received from the FDA with respect to MT 300, we began 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 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. If we or our partners wish or need to identify an alternative manufacturer, delays in obtaining FDA approval of the alternative manufacturing facility could cause an interruption in the supply of our products.

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

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, including Trexima, 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 respective agreements with us upon 90 days' notice for any reason. Additionally, both GSK and AstraZeneca have the right to reduce the royalties on net sales of products payable to us under their respective agreements if generic competitors attain a pre-determined share of the market for products marketed under the agreements, or if either GSK or AstraZeneca must pay a royalty to one or more third parties for rights it licenses from those third parties to commercialize products marketed under the agreements. AstraZeneca is also entitled to terminate its agreement with us if certain delays occur or specified development or regulatory objectives are not met. 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. Similarly, under our agreement with AstraZeneca, AstraZeneca has the right to manufacture clinical trial material itself or through a third party. If AstraZeneca experiences delays in supplying such clinical trial material, the start of pivotal studies could be delayed. If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated. Any delay or termination of clinical development or commercialization, such as the delay in FDA approval we are currently experiencing as a result of approvable letters we received from the FDA in June 2006 and August 2007 related to our Trexima NDA, would delay or possibly eliminate our potential product revenues. Further, our collaborators may be able to exercise

control, under certain circumstances, over our ability to protect our patent rights under patents covered by the applicable collaboration agreement. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements and would have exclusive control over such enforcement litigation.

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

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

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

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

We have entered into collaboration and license agreements, and expect to continue to enter into such agreements, with companies that have products and are developing new product candidates that compete or may compete with our product candidates or which have greater commercial potential. If one of our collaborators should decide that the product or a product candidate that the collaborator is developing would be more profitable for the collaborator than our product candidate covered by the collaboration or license agreement, the collaborator may withdraw support for our product candidate or may cease to perform under our agreement. In the event of a termination of the collaborator's agreement upon such cessation of performance, we would need to negotiate an agreement with another collaborator in order to continue the development and commercialization efforts for the product candidate. If we were unsuccessful in negotiating another agreement, we might have to cease development activities of the particular product candidate. For example, our development and commercialization agreement with GSK is subject to this risk. GSK has publicly disclosed that it is exploring the development of several compounds for the treatment of migraine. If GSK decides to focus its development and commercialization efforts on its own products rather than continuing to 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. In such a case, we would need to enter into 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.

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 U. S.

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. After our receipt of the not-approvable letter, we 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.

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

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

It should be noted that the results of any of our preclinical and clinical trial testing are not necessarily predictive of results we will obtain in subsequent or more extensive clinical trials or testing. This may occur for many reasons, including, among others, differences in study design, including inclusion/exclusion criteria, the variability of patient characteristics, including patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, our results from the first of our two Phase 3 pivotal clinical trials of 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 any of our clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that 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.

Further, even though we may have completed all clinical trials for a product candidate that were planned for submission in support of a marketing application, we may be required to conduct additional clinical trials, studies or investigations or to submit additional data to support our marketing applications. In addition, we and/or our marketing or development partners may determine that pre-approval marketing support studies should be conducted. Unanticipated adverse outcomes of such studies, including recognition of certain risks to human subjects, could 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, in reviewing our NDA for Trexima the FDA has expressed concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan. While we have submitted data from additional pre-clinical studies conducted by GSK to the FDA and we plan to conduct a short-term clinical study

in healthy human volunteers in the event such a clinical study is required by the FDA, we have no guarantee that such data will adequately address the FDA's concerns.

Once submitted, an NDA requires FDA approval before the product described in the application can be distributed or commercialized. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, the FDA requested additional safety information on Trexima in the approvable letter we received in June 2006 relating to our NDA for Trexima, which required conduct of additional studies. We submitted a full response to the FDA's approvable letter in November 2006, but were told by the FDA that it was not a complete submission and that additional analyses and supporting information relating to the new data were required. The FDA also indicated that it was necessary to provide a complete and accurate presentation of these data, which must sufficiently address their safety concerns, including cardiovascular safety. We worked with GSK to compile and format the additional data requested by the FDA and delivered a revised full response to the FDA in early February 2007. On August 1, 2007, we received a second approvable letter in which the FDA raised an additional concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which genotoxicity was seen for the combination of naproxen sodium and sumatriptan.

Further, although we 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 in May 2004 and October 2003, respectively, and based upon our understandings from our most recent communication with the FDA and our understanding of the FDA's current standards for approval of migraine drugs, we do not believe it is possible to reverse the not approvable status of the NDA for MT 300. In addition, based upon our receipt of the not approvable letter for MT 100 and the outcome of an August 2005 FDA Advisory Committee meeting relating to the potential risk of tardive dyskinesia associated with the use of one of the components of MT 100, we made the decision to discontinue further development of MT 100 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 and our partners to supply us with our product candidates. We also need supply contracts to sell our products commercially. There is no guarantee that manufacturers that enter into commercial supply contracts with us will be financially viable entities going forward, or will not otherwise breach or terminate their agreements with us. If we do not have the necessary commercial supply contracts, or if our current manufacturer is, or any of our future manufacturers are, unable to satisfy our requirements or meet any regulatory requirements, and we are required to find alternative sources of supply, there may be additional costs and delays in product development and commercialization of our product candidates or we may be required to comply with additional regulatory requirements.

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

Our product candidates will have to compete with existing and any newly developed migraine therapies or therapies for any newly developed product candidates for the treatment of other diseases. There are also likely to be numerous competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non-competitive. For example, our primary competitors will likely include large pharmaceutical companies (including, based upon their current migraine portfolios, GSK, Merck & Co., AstraZeneca, Johnson & Johnson, Pfizer, Inc. and Endo Pharmaceuticals), biotechnology companies, universities and public and private research institutions. The competition for our PN products that receive regulatory approval will come from the oral NSAID market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC<sup>TM</sup>), 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 have experienced as a result of the approvable letters we received from the FDA in June 2006 and August 2007 relating to the Trexima NDA, and as we have 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.

Five purported class action lawsuits claiming violations of securities laws were filed during 2004 by holders of our securities against us and certain of our current and former officers. These actions were consolidated for pre-trial purposes and a lead plaintiff appointed by the court filed a consolidated amended complaint (amended complaint) on December 20, 2004. The defendants named in the amended complaint were POZEN and John R. Plachetka, our chairman and chief executive officer. The complaint alleged 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 alleged that we made false and misleading statements concerning our product candidates MT 100 and MT 300 during the class period. On July 10, 2007, we announced that the Company has reached an agreement to amicably settle this action. All claims against the Company and Dr. Plachetka will be dismissed in their entirety without admission of liability or wrongdoing by any party. We believe that the settlement agreement will be funded entirely with proceeds form the Company's directors and officers' liability insurance. The settlement agreement was granted preliminary court approval on October 2, 2007.

A purported class action lawsuit claiming violations of securities laws was filed on August 10, 2007 in the U.S. District Court for the Middle District of North Carolina by a holder of our securities against us, our chairman and chief executive officer and one of our directors. The complaint alleges, among other claims, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly false and misleading statements made by the Company concerning its migraine drug candidate, Trexima, during the purported class period, July 31, 2006 through August 1, 2007. The Company and the individual defendants believe that the plaintiff's allegations are without merit, and intend to defend these claims vigorously.

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, test and obtain regulatory approval for our products, any patents that protect our product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. In certain territories outside the U.S., our issued patents may be subject to opposition by competitors within a certain time after the patent is issued. 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 was the case with one of our patents covering MT 100, which we submitted for reissue after determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. In April 2006, we received an office action on the reissue application and, consistent with our decision not to devote further resources to the development of this product in the U.S., the reissue application was abandoned in January 2007.

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

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know-how, or determine the scope and validity of others' patent or proprietary rights. 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 has 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 products may be accepted by the market.

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

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

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

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

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

Our operating expenses for the year ended December 31, 2006 totaled \$35.2 million, including non-cash compensation expense of \$5.5 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 2004 through 2006, our average annual operating expenses (including average non-cash deferred compensation of \$2.4 million) were \$30.7 million. We are currently in discussions with AstraZeneca on the timing and scope of marketing studies to support the commercialization of PN 400. These marketing studies may impact revenue and expenses for the

2007 year. At the end of the third quarter 2007 we estimated operating expenses for the 2007 fiscal year to be between \$52.0 million and \$54.0 million, including \$4.2 million of non-cash compensation expenses, related to stock options and other stock-based awards, resulting from our adoption of SFAS 123(R) on January 1, 2006. Increased operating expenses, under that estimate, were expected to be partially offset by revenue of between \$18.0 million and \$20.0 million for work performed under our collaborative agreement. As of September 30, 2007, we had an aggregate of \$78.8 million in cash and cash equivalents and short-term investments. If our operating expenses for the remainder of 2007 and 2008 remain at the level of our operating expenses in the first nine months of 2007, we believe that we will have sufficient cash reserves to maintain that level of business activities through 2008 provided certain increased development expenses are paid by AstraZeneca, as outlined in the agreement. However, our expenses might increase during that period beyond currently expected levels if we decide to, or any regulatory agency requires us to, conduct additional clinical trials, studies or investigations for any of our product candidates, including in connection with the agency's consideration, or reconsideration, of our regulatory filings for our product candidates. In addition, we may be required to pay Valeant NA a withdrawal fee of \$1.0 million if we do not prevail in our current dispute with them as to whether a withdrawal fee is payable under our MT 300 collaboration agreement.

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

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

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

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

#### Factors That May Affect Our Stockholders

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

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

- fluctuations in our operating results;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- commercial success of products in the marketplace once approved;

- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- 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 National Market (now known as The NASDAQ Global Market), through September 30, 2007, the high and low sales prices of our common stock ranged from \$2.25 to \$21.75. Broad market fluctuations may also adversely affect the market price of our common stock.

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

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market and four of our stockholders and their affiliates beneficially hold approximately 33% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, our chief executive officer and one of our directors may sell up to an aggregate of 1,180,000 shares pursuant to Rule 10b5-1 trading plans. Sales under those plans began in October 2006. 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
3.1	Second Amended and Restated Bylaws of POZEN Inc., approved September 19, 2007 (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 20, 2007).
10.1	First Amendment to Second Amended and Restated Executive Employment Agreement with John R. Plachetka, dated September 28, 2007.
10.2	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated May 4, 2004, between Registrant and John R. Plachetka.
10.3	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated February 14, 2007, between the Registrant and John R. Plachetka.
10.4	First Amendment to Long Term Incentive Cash Award Agreement, dated September 28, 2007, between the Registrant and John R. Plachetka.
10.5	First Amendment to Executive Employment Agreement with William L. Hodges, dated September 28, 2007.
10.6	First Amendment to Executive Employment Agreement with Marshal E. Reese, Ph.D., dated September 28, 2007.
10.7	First Amendment to Executive Employment Agreement with John E. Barnhardt, dated September 28, 2007.
10.8†	Amendment No. 1 to the Collaboration and License Agreement, dated September 6, 2007, between the Registrant and AstraZeneca, AB.
10.9†	Side Letter Agreement, dated October 1, 2007, between the Registrant 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.

<sup>†</sup> Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

### **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 5, 2007 By: /s/ JOHN R. PLACHETKA

John R. Plachetka

President and Chief Executive Officer

November 5, 2007 By: /s/ WILLIAM L. HODGES

William L. Hodges Chief Financial Officer

November 5, 2007 By: /s/ JOHN E. BARNHARDT

John E. Barnhardt

Principal Accounting Officer

# **EXHIBIT INDEX**

Exhibit Number	Description
3.1	Second Amended and Restated Bylaws of POZEN Inc., approved September 19, 2007 (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 20, 2007).
10.1	First Amendment to Second Amended and Restated Executive Employment Agreement with John R. Plachetka, dated September 28, 2007.
10.2	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated May 4, 2004, between Registrant and John R. Plachetka.
10.3	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated February 14, 2007, between the Registrant and John R. Plachetka.
10.4	First Amendment to Long Term Incentive Cash Award Agreement, dated September 28, 2007, between the Registrant and John R. Plachetka.
10.5	First Amendment to Executive Employment Agreement with William L. Hodges, dated September 28, 2007.
10.6	First Amendment to Executive Employment Agreement with Marshal E. Reese, Ph.D., dated September 28, 2007.
10.7	First Amendment to Executive Employment Agreement with John E. Barnhardt, dated September 28, 2007.
10.8†	Amendment No. 1 to the Collaboration and License Agreement, dated September 6, 2007, between the Registrant and AstraZeneca, AB.
10.9†	Side Letter Agreement, dated October 1, 2007, between the Registrant 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.

<sup>†</sup> Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

### FIRST AMENDMENT TO SECOND AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This FIRST AMENDMENT TO SECOND AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT (the "First Amendment"), is entered into as of September 28, 2007 (the "Effective Date"), by and between POZEN Inc. (the "Company") and John R. Plachetka ("Executive").

#### WITNESSETH:

WHEREAS, the Company and Executive previously entered into a Second Amended and Restated Executive Employment Agreement dated March 14, 2006 (the "Employment Agreement"); and

WHEREAS, the Company and Executive desire to amend certain terms of the Employment Agreement, as set forth herein, in order to facilitate compliance with Section 409A of the Internal Revenue Code of 1986, as amended.

NOW, THEREFORE, in consideration of the foregoing and the provisions and mutual promises herein contained and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereby agree as follows:

- 1. Any capitalized terms not defined herein shall have the meanings ascribed to such terms in the Employment Agreement.
  - 2. Sections 4(b) and (c) of the Employment Agreement are hereby amended and restated in their entirety as follows:
  - "(b) Bonus. Executive shall be eligible to receive an annual cash incentive bonus (the "Annual Bonus") based on performance. Executive's annual target bonus shall be sixty-five percent (65%) of Executive's annual base salary with the amount of the actual Annual Bonus anticipated to range between thirty-two and one-half percent (32.5%) and one hundred percent (100%) of Executive's then-current annual base salary. Executive's entitlement to such Annual Bonus shall be based in part upon Executive's achievement of certain performance goals to be mutually agreed upon by the Executive and the Board annually (the "Performance Goals"). The determination of the actual Annual Bonus earned, if any, shall be determined in the discretion of the Committee and shall be based on the Committee's assessment of Executive's performance, the achievement of the Performance Goals and other relevant factors as determined by the Committee. Nothing in this Section 4(b) shall be construed as granting or guaranteeing Executive a bonus in any amount. The Annual Bonus shall be paid, in the year following the year for which it was earned, on or before March 15 of such year.
  - (c) <u>Long-Term Incentive Compensation</u>. Each year during the Term, Executive shall be eligible to participate in and to receive annual awards (the "Incentive Award") under a long-term incentive program with a target value of One Million Seven Hundred Thousand Dollars \$1,700,000 for the first year of the Term, subject to annual review by the Committee. The determination of the actual Incentive Award earned, if any, shall be determined in the discretion of the Committee and shall be based on the Committee's assessment of Executive's overall performance, the achievement of the Performance Goals and other relevant factors as determined by the Committee. Nothing in this Section 4(c) shall be construed as granting or guaranteeing Executive an Incentive Award in any amount. Any such Incentive Awards shall be made or be paid, as applicable, in the year following the year to which such Incentive Awards relate, on or before March 15 of such year.
- 3. The final sentence of Section 4(e) of the Employment Agreement shall be amended and restated in its entirety as follows:

"In the event that Executive does not qualify for any such life insurance, the Company shall pay directly to Executive an amount equal to such premiums that the Company would have paid to any insurance company to obtain such life insurance on an annual basis, such payment to be made no later than December 31 of each year in which payment would otherwise have been made to the insurance company."

- 4. Sections 4(h) and 4(i) of the Employment Agreement are hereby amended and restated in their entirety as follows:
- "(h) <u>Disability</u>. In each year during the Term of this Agreement, the Company will pay Executive as additional compensation, payable in accordance with the Company's standard payroll schedule, an amount equal to the premium costs

of an individual long term disability insurance plan. The plan shall provide for a benefit indemnity payment schedule equal to 70% of Executive's annual Base Salary. The Company shall also pay Executive for such long term disability plan an amount as additional salary, payable in accordance with the Company's standard payroll schedule, sufficient to cover the additional income taxes owed on such compensation payments.

- (i) Estate Planning and Similar Costs. During the term of this Agreement, the Company will reimburse Executive for legal fees and expenses incurred by Executive in connection with (A) estate and tax planning, and other legal expenses incurred by Executive, specifically including those associated with this Agreement, up to a maximum of \$30,000 per calendar year, and (B) the establishment and administration of a Rule 10b5-1 securities selling program, up to a maximum of \$15,000 per calendar year. Executive shall provide evidence of such reimbursable expenditures by no later than forty-five (45) days after the end of the calendar year in which such expenditures were incurred, and the Company shall reimburse the Executive by no later than March 15 of the year following the year in which such expenditures were incurred."
- 5. Sections 5(d)(iv), (v) and (vii) of the Employment Agreement are hereby amended and restated in their entirety as follows:
  - "(iv) A reduction in Executive's then Base Salary or a material reduction of any material employee benefit or perquisite enjoyed by him (other than as consented to by Executive or as part of an across-the-board change or reduction applicable to all senior executives of the Company); provided such reduction continues uncorrected for a period of thirty (30) calendar days after the Company shall have received written notice from Executive stating the nature of such reduction;
  - (v) Failure of the Company to obtain the assumption in writing of its obligation to perform this Agreement by any purchaser of all or substantially all of the assets of the Company within fifteen (15) calendar days after a sale or transfer of such assets; provided such failure continues uncorrected for a period of thirty (30) calendar days after receipt of written notice of same from Executive:
  - (vii)A relocation of Executive's office location, as assigned to him by the Company, to a location more than fifty (50) miles from the current location of the Company in Chapel Hill, North Carolina, unless corrected within thirty (30) calendar days after the Company shall have received written notice from Executive notifying the Company of same. In the event that Executive elects not to terminate his employment under this Subsection 5(d)(vii), the Company shall, within thirty (30) days after receipt from Executive of evidence of such reimbursable expenses but in no event later than March 15<sup>th</sup> of the year following the year in which such expenses were incurred, reimburse Executive for the reasonable expenses he incurs in relocating from his then-current location to the location of his new office, including, without limitation, all moving expenses, reasonable legal expenses and commissions associated with selling his primary residence and all closing costs relating to his acquisition of a residence in the area of his new office."
  - 6. Section 5(g) of the Employment Agreement is hereby amended and restated in its entirety as follows:
  - "(g) <u>Change of Control</u>. For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred as of the first day any one or more of the following shall have occurred:
    - (i) If any person (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (other than the Company or any trustee or fiduciary holding securities under an employee benefit plan of the Company) becomes a beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or
    - (ii) Upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote), or (B) a sale or other disposition of all or substantially all of the assets of the Company."

- 7. Sections 6(a) and (b) of the Employment Agreement are hereby amended and restated in their entirety as follows:
- "(a) Accrued Compensation and Benefits. Upon termination of Executive's employment by either party for any reason, Executive (or his heirs, successors, personal representatives or assigns) will receive from the Company: (i) payment for any accrued, unpaid Base Salary through the termination date; (ii) payment for any accrued, unpaid vacation time through the termination date; (iii) reimbursement for any previously incurred unreimbursed expenses in accordance with the Company's policies; and (iv) participation in any Company benefit plans or programs through the termination date. Such amounts shall be paid on the Company's next regularly scheduled payroll date unless any such amount is not then calculable, in which case payment of such amount shall be made on the first regularly scheduled payroll date after the amount is calculable, but no later than March 15 of the year following the year in which the Executive's employment terminated.
- (b) Termination by the Company Without Cause or by Executive for Good Reason. In addition to the compensation and benefits described in Section 6(a) hereof, if the Company terminates Executive's employment without Cause during the Term (other than due to Executive's death or disability) or if Executive terminates his employment for Good Reason (except pursuant to Section 5(d)(ii)), and, subject to Executive's executing and not revoking a general release in a form acceptable to the Company (the "Release"), the Company will provide the following severance benefits to Executive, to be paid when and as described below, subject in each case to Section 6(g) hereof:
- (i) The Company will make a lump sum payment equal to two (2) times the average of the Annual Bonuses actually awarded to Executive over the previous two years, less any required taxes and withholdings, with payment to be made within ninety (90) calendar days of the termination date; provided, however, that such payment shall in no event be made later than March 15 of the year following the year in which Executive's employment terminated, or in the event of termination pursuant to Section 5(d)(ii), by no later than March 15 of the year following the year in which the Change of Control occurred;
- (ii) The Company will continue paying Executive his annual Base Salary at the rate in effect on the termination date, less any required taxes and withholdings, for a period of twenty-four (24) months after the termination date. Such Base Salary shall be paid, subject to Section 6(g), on the fifth business day of each month commencing with the second month following the month in which Executive's termination of employment occurred;
- (iii) The Company will continue Executive's participation in the Company's health benefits at the same level as in effect on the termination date for a period of eighteen (18) months after the termination date or until Executive is eligible for equivalent health benefits from another employer, whichever is sooner. If the Company's health benefit plans or programs do not allow for Executive's continued participation in such plans or programs after termination of employment, the Company agrees to reimburse Executive for continuing coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"); provided, however, that such reimbursement will be conditioned upon Executive's timely election of continued coverage under COBRA and payment of all such reimbursements shall be made to Executive within the applicable COBRA period; and
- (iv) Executive will be entitled to twelve (12) months acceleration of the vesting of all shares subject to any stock option, such that all options will be exercisable and vested on Executive's termination date as if Executive's termination date were twelve (12) months later. After giving effect to the acceleration provided for in the preceding sentence, any unvested shares will be forfeited as of the termination date.

Notwithstanding the foregoing, if Executive terminates his employment for Good Reason pursuant to Section 5(d)(ii), then Executive shall be entitled to the compensation and benefits described in Section 6(a) hereof, payable when and as described in Section 6(a), and, provided that Executive executes and does not revoke the Release, all of the benefits specified in Section 6(b), payable when and as described in Section 6(b), except that (i) he shall only be entitled to a lump sum payment equal to one (1) times the average of the Annual Bonus actually awarded to Executive over the previous two years and (ii) the Company shall continue paying his annual Base Salary at the rate in effect on the termination date (less any required taxes and withholdings) for a period of twelve (12) months after the termination date.

All compensation and benefits to which Executive is entitled upon termination of employment pursuant to the succeeding subsections of this Section 6 shall be paid at such time and in such manner as is described in Section 6(a) or Section 6(b), as applicable."

8. Section 6(g) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(g) <u>Excise Tax.</u> Notwithstanding the foregoing provisions of this Section 6, if Executive is on the termination date a "specified employee" (as defined in Section 409A of the Internal Revenue Code, as amended (the "Code"), and the

regulations promulgated under such Section 409A ("Code Section 409A") and as determined in accordance with the permissible method then in use by the Company, or, if none, in accordance with the applicable default provisions of Code Section 409A, relating to "specified employees"), then, if and to the extent required in order to avoid the imposition on Executive of any excise tax, the payment of any severance or other payments under Sections 5 or 6 shall not commence until, and shall be made on, the first business day after the date that is six (6) months following the date of Executive's termination of employment, and in such event the initial payment shall include a catch-up amount covering amounts that would otherwise have been paid during the six-month period following Executive's termination date."

- 9. Section 7(d) of the Employment Agreement is hereby amended and restated in its entirety as follows:
- "(d) Any Gross-Up Payment, as determined pursuant to this Section 7, shall be paid by the Company to Executive as and when the Excise Tax is incurred on a Payment, or at such later date as mutually agreed by the parties hereto, but in no event later than the end of Executive's taxable year next following the taxable year in which Executive remits the applicable Excise Tax to the IRS and any applicable state taxing authorities. The Gross-Up Payment shall be paid in accordance with Code Section 409A, to the extent applicable, including, to the extent applicable, subject to and in compliance with Section 6(g). As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made ("Underpayment"), consistent with the calculations required to be made hereunder. In the event that the Company exhausts its remedies pursuant to Section 7(e) and Executive thereafter is required to make a Payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be paid by the Company to or for the benefit of Executive within thirty (30) days after such determination, or at such later date as mutually agreed by the parties hereto, but in no event later than the end of Executive's taxable year next following the taxable year in which Executive remits the applicable Excise Tax to the IRS and any applicable state taxing authorities."
- 10. Section 7(e) of the Employment Agreement is hereby amended to add the following sentence as the last sentence of such section:

"Any payments required to be made pursuant to the Company's indemnification obligations as set forth in this Section 7(e) shall be paid as and when any such Excise Tax or income or other tax is incurred, or at such later date as mutually agreed by the parties hereto, but in no event later than the end of Executive's taxable year next following the taxable year in which Executive remits the applicable Excise Tax or income or other tax to the IRS and any applicable state taxing authorities."

- 11. Except as herein amended, the terms and provisions of the Employment Agreement shall remain in full force and effect as originally executed.
- 12. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of North Carolina, without reference to the choice of law provisions of such laws.
- 13. This First Amendment may be executed in any number of counterparts, each of which shall constitute one agreement binding on all parties hereto.
- 14. This First Amendment and the Employment Agreement, as amended and modified by this First Amendment, shall constitute and be construed as a single agreement.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment to Second Amended and Restated Executive Employment Agreement and affixed their seals as of the day and year first above written.

# **EMPLOYER:**

POZEN INC.

By: /s/ William L. Hodges

Name: William L. Hodges

Title: Sr. Vice President and Chief Financial Officer

# **EXECUTIVE:**

/s/ John R. Plachetka

John R. Plachetka, Pharm.D.

# FIRST AMENDMENT TO RESTRICTED STOCK UNIT AGREEMENT

This FIRST AMENDMENT TO RESTRICTED STOCK UNIT AGREEMENT (the "First Amendment"), is entered into as of September 28, 2007, by and between POZEN Inc. ("POZEN") and John R. Plachetka (the "Grantee").

WHEREAS, a Restricted Stock Unit Agreement dated as of May 4, 2004, and issued under the POZEN Inc. 2000 Equity Compensation Plan, as amended and restated, was delivered by POZEN to the Grantee (the "Original Agreement"); and

WHEREAS, POZEN and the Grantee desire to amend certain terms of the Original Agreement as set forth below.

NOW, THEREFORE, in consideration of the foregoing and the provisions and mutual promises herein contained and other good and valuable consideration, the parties hereby agree as follows:

- 1. Any capitalized terms not defined herein shall have the meanings ascribed to such terms in the Original Agreement.
- 2. Section 2 is hereby amended and restated in its entirety as follows:

"Restricted Unit Account. Restricted Units represent hypothetical shares of Common Stock, and not actual shares of stock. POZEN shall establish and maintain a Restricted Unit account, as a bookkeeping account on its records, for the Grantee and shall record in such account the number of Restricted Units granted to the Grantee. No shares of stock shall be issued to the Grantee at the time the grant is made, and the Grantee shall not be, nor have any of the rights or privileges of, a stockholder of POZEN with respect to any Restricted Units recorded in the account. The Grantee shall not have the right to receive any dividends or other distributions with respect to hypothetical shares of stock recorded in the Restricted Unit account; provided, however, that the Committee shall appropriately adjust the number and kind of Restricted Units in the event of a stock split, stock dividend or other change in capitalization of POZEN, as described in the Plan. The Grantee shall not have any interest in any fund or specific assets of POZEN by reason of this award or the Restricted Unit account established for the Grantee."

- 3. Section 5(a) of the Restricted Stock Unit Agreement is hereby amended and restated in its entirety as follows:
- "(a)(i) It is intended that the Restricted Units will be distributed in accordance with Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder ("Section 409A"). On the fifth business day after the Grantee separates from service with POZEN (as defined under Section 409A), POZEN will issue to the Grantee one share of Common Stock for each whole vested Restricted Unit credited to the Restricted Unit Account, subject to satisfaction of the Grantee's tax withholding obligations as described below, and except as described below.
- (ii) If a Change of Control (as defined below) occurs before the Grantee has separated from service with POZEN, on the closing date of the Change of Control, subject to and in accordance with Paragraph 6 below and the provisions of the Plan applicable to a Change of Control, POZEN will issue to the Grantee one share of Common Stock for each whole vested Restricted Unit credited to the Restricted Unit Account, subject to satisfaction of the Grantee's tax withholding obligations as described below. Any vested amounts representing partial shares shall be paid in cash on the closing date.
- (iii) Notwithstanding the foregoing provisions of this Section 5, if the Grantee on the date of Grantee's separation from service is a "specified employee" as defined under Section 409A and as determined in accordance with the permissible method then in use by POZEN, or, if none, in accordance with the applicable default provisions of Section 409A, relating to "specified employees," then if and to the extent required in order to avoid the imposition on the Grantee of any tax under Section 409A, the foregoing shares of Common Stock shall not be issued by the Company until the first business day after the date that is six (6) months after the date of Grantee's separation from service."
- 4. Section 6 of the Restricted Stock Unit Agreement is hereby amended and restated in its entirety as follows:

<u>"Change of Control</u>. The provisions of the Plan applicable to a Change of Control shall apply to the Restricted Units; provided, however, that for purposes of this Agreement, a "Change of Control" shall be deemed to have occurred:

- (i) if any "person" (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) (other than the Company or any trustee or fiduciary holding securities under an employee benefit plan of the Company) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or
- (ii) upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to less than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote) or (B) a sale or other disposition of all or substantially all of the assets of the Company.

In the event of a Change of Control, the Committee may take such actions as it deems appropriate pursuant to the Plan, provided that all payment in settlement of the Restricted Units pursuant to the Plan shall be made on or within thirty (30) days of the occurrence of the Change of Control, notwithstanding anything to the contrary set forth in Section 15(c) of the Plan."

5. Section 10 of the Original Agreement is hereby amended and restated in its entirety as follows:

"Assignment and Transfers. The rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Restricted Units or any right hereunder, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, POZEN may terminate the Restricted Units by notice to the Grantee, and the Restricted Units and all rights hereunder shall thereupon become null and void. The rights and protections of POZEN hereunder shall extend to any successors or assigns of POZEN and to POZEN's parents, subsidiaries, and affiliates. This Agreement may be assigned by POZEN without the Grantee's consent."

- 6. Except as herein amended, the terms and provisions of the Original Agreement shall remain in full force and effect as originally executed.
- 7. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, without reference to the choice of law provisions of such laws.
- 8. This First Amendment may be executed in any number of counterparts, each of which shall constitute one agreement binding on all parties hereto.
- 9. This First Amendment and the Original Agreement, as amended and modified by this First Amendment, shall constitute and be construed as a single agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment to Second Amended and Restated Executive Employment Agreement and affixed their seals as of the day and year first above written.

### **POZEN:**

POZEN INC.

By: /s/ William L. Hodges

Name: William L. Hodges

Title: Sr. Vice President & Chief Financial Officer

## **GRANTEE:**

/s/ John R. Plachetka

John R. Plachetka, Pharm.D.

# FIRST AMENDMENT TO RESTRICTED STOCK UNIT AGREEMENT

This FIRST AMENDMENT TO RESTRICTED STOCK UNIT AGREEMENT (the "First Amendment"), is entered into effective September 28, 2007, by and between POZEN Inc. ("POZEN" or the "Company"), and John R. Plachetka (the "Grantee").

#### **RECITALS**

WHEREAS, a Restricted Stock Unit Agreement dated as of February 14, 2007, and issued under the POZEN Inc. 2000 Equity Compensation Plan, as amended and restated, was delivered by POZEN to the Grantee (the "Original Agreement"); and

WHEREAS, POZEN and the Grantee desire to amend certain terms of the Original Agreement as set forth below.

NOW, THEREFORE, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

- 1. Any capitalized terms not defined herein shall have the meanings ascribed to such terms in the Original Document.
- 2. Section 5(a) of the Original Agreement is hereby amended and restated in its entirety as follows:
  - "(a) (i) It is intended that the Restricted Units will be distributed in accordance with Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder ("Section 409A"). On the fifth (5<sup>th</sup>) business day after the Grantee separates from service with POZEN (as defined under Section 409A), POZEN will issue to the Grantee one share of Common Stock for each whole Restricted Unit credited to the Restricted Unit Account that was vested on the date of Grantee's separation from service (without regard to any acceleration of vesting provided for in Paragraph 4(b)), subject to satisfaction of the Grantee's tax withholding obligations as described below, and except as described below. If applicable, on the ninetieth (90<sup>th</sup>) day after the Grantee separates from service with POZEN, POZEN will issue to the Grantee one additional share of Common Stock for each whole Restricted Unit that shall have vested pursuant to the acceleration provisions of Paragraph 4(b), provided that Grantee has executed and not revoked the Release and subject to satisfaction of the Grantee's tax withholding obligations as described below, and except as described below.
  - (ii) If a Change of Control (as defined below) occurs before the Grantee has separated from service with POZEN, on the closing date of the Change of Control, subject to and in accordance with Paragraph 6 below and the other provisions of the Plan applicable to a Change of Control, POZEN will issue to the Grantee one share of Common Stock for each whole vested Restricted Unit credited to the Restricted Unit Account, subject to satisfaction of the Grantee's tax withholding obligations as described below. Any vested amounts representing partial shares shall be paid in cash.
  - (iii) Notwithstanding the foregoing provisions of this Section 5, if the Grantee on the date of Grantee's separation from service is a "specified employee" (as defined under Section 409A and as determined in accordance with the permissible method then in use by POZEN, or, if none, in accordance with the applicable default provisions of Section 409A, relating to "specified employees)," then if and to the extent required in order to avoid the imposition on the Grantee of any tax under Section 409A, the foregoing shares of Common Stock shall not be issued by the Company until the first business day after the date that is six (6) months after the date of Grantee's separation from service."
- 3. Section 6 of the Original Agreement is hereby amended and restated in its entirety as follows:
  - "Change of Control. The provisions of the Plan applicable to a Change of Control shall apply to the Restricted Units; provided, however, that for purposes of this Agreement, a "Change of Control" shall be deemed to have occurred:
  - (i) if any "person" (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) (other than the Company or any trustee or fiduciary holding securities under an employee benefit plan of the Company) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of

all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or

(ii) upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to less than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote) or (B) a sale or other disposition of all or substantially all of the assets of the Company.

In the event of a Change of Control, the Committee may take such actions as it deems appropriate pursuant to the Plan, provided that all payments in settlement of the Restricted Units pursuant to the Plan shall be made on or within 30 days of the occurrence of the Change of Control, notwithstanding anything to the contrary set forth in Section 15(c) of the Plan."

4. Section 10 of the Original Agreement is hereby amended and restated in its entirety as follows:

"Assignment and Transfers. The rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Restricted Units or any right hereunder, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, POZEN may terminate the Restricted Units by notice to the Grantee, and the Restricted Units and all rights hereunder shall thereupon become null and void. The rights and protections of POZEN hereunder shall extend to any successors or assigns of POZEN and to POZEN's parents, subsidiaries, and affiliates. This Agreement may be assigned by POZEN without the Grantee's consent."

- 5. Except as herein amended, the terms and provisions of the Original Agreement shall remain in full force and effect as originally executed.
- 6. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, without reference to the choice of law provisions of such laws.
- 7. This First Amendment may be executed in any number of counterparts, each of which shall constitute one agreement binding on all parties hereto.
- 8. This First Amendment and the Original Agreement, as amended and modified by this First Amendment, shall constitute and be construed as a single agreement.

[Signature page follows.]

IN WITNESS WHEREOF, POZEN has caused its duly authorized officer to execute this First Amendment to Restricted Stock Unit Agreement, and the Grantee has placed his signature hereon, effective as of the date first written above.

## POZEN INC.

By: /s/ William L. Hodges

Name: William L. Hodges

Title: Sr. Vice President & Chief Financial Officer

## **GRANTEE:**

/s/ John R. Plachetka

John R. Plachetka, Pharm.D.

# FIRST AMENDMENT TO POZEN INC. LONG TERM INCENTIVE CASH AWARD AGREEMENT

This FIRST AMENDMENT TO LONG TERM INCENTIVE CASH AWARD AGREEMENT (the "First Amendment") is entered into effective as of September 28, 2007, by and between POZEN Inc. ("POZEN" or the "Company") and John R. Plachetka ("Executive").

WHEREAS, a Long Term Incentive Cash award Agreement dated February 14, 2007 (the "Original Agreement") was entered into between the Company and Executive; and

WHEREAS, POZEN and Executive desire to amend certain terms of the Original Agreement as set forth below.

NOW THEREFORE, the parties hereto agree as follows:

- 1. Any capitalized terms not defined herein shall have the meanings ascribed to such terms in the Original Agreement.
- 2. Section 2 of the Original Agreement is hereby amended and restated in its entirety as follows:

"Change of Control. Notwithstanding anything to the contrary herein, in the event of and conditioned upon a Change of Control (as defined below) and unless otherwise determined by the Committee, the Award, to the extent not previously paid, shall accelerate and become payable in full, subject to (i) Executive's continuing to be employed by or provide service to the Company to such date, and (ii) with respect to the Contingent Portion, the satisfaction of the performance conditions set forth in Section 1(a)(ii) above, subject to the discretion of the Committee. Notwithstanding the foregoing, if a Change of Control occurs prior to December 31, 2007 and receipt of the Trexima Approval has not occurred, the Contingent Portion shall accelerate and become payable in full. Payment of any portion of the Award that becomes payable pursuant to this Section 2 shall be made in a lump sum payment on the date of closing of the Change of Control.

For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred:

- (i) if any "person" (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) (other than the Company or any trustee or fiduciary holding securities under an employee benefit plan of the Company) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or
- (ii) upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to less than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote) or (B) a sale or other disposition of all or substantially all of the assets of the Company."
- 3. Section 3(b) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(b) Payment of any amounts payable pursuant to this Section 3 shall be made to Executive in a lump sum payment on the ninetieth (90<sup>th</sup>) day following the date of Executive's termination of employment, provided that Executive has executed and not revoked the Release. Notwithstanding the foregoing, if Executive on the date of such termination is a "specified employee" (as defined in Section 409A of the Internal Revenue Code, as amended, and the regulations promulgated thereunder ("Section 409A") and as determined in accordance with the permissible method then in use by POZEN or, if none, in accordance with the applicable default provisions of Section 409A, relating to "specified employees"), then if and to the

extent required in order to avoid the imposition on Executive of any excise tax under Section 409A, such payment, if any, shall not be made until, and shall be made on, the second business day after the date that is six (6) months following the date of Executive's termination of employment, provided that Executive has executed and not revoked the Release."

- 4. Except as herein amended, the terms and provisions of the Original Agreement shall remain in full force and effect as originally executed.
- 5. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, without reference to the choice of law provisions of such laws.
- 6. This First Amendment may be executed in any number of counterparts, each of which shall constitute one agreement binding on all parties hereto.
- 7. This First Amendment and the Original Agreement, as amended and modified by this First Amendment, shall constitute and be construed as a single agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this First Amendment to Long Term Incentive Cash Award Agreement as of the day and year first above written.

## POZEN INC.

/s/ William L. Hodges By:

Name: William L. Hodges
Title: Sr. Vice President & Chief Financial Officer

## **GRANTEE:**

/s/ John R. Plachetka

John R. Plachetka, Pharm.D.

# FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

This FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "First Amendment"), is entered into as of September 28, 2007, by and between POZEN Inc. (the "Company") and William L. Hodges ("Executive").

#### WITNESSETH:

WHEREAS, the Company and Executive entered into that certain Executive Employment Agreement dated August 3, 2004 (the "Original Agreement"); and

WHEREAS, the Company and Executive desire to amend certain terms of the Original Agreement, as set forth below, in order to facilitate compliance with Section 409A of the Internal Revenue Code of 1986, as amended.

NOW, THEREFORE, in consideration of the foregoing and the provisions and mutual promises herein contained and other good and valuable consideration, the parties hereby agree as follows:

- 3. All capitalized terms that are not defined herein shall have the meanings ascribed to such terms in the Original Agreement.
  - 4. Section 4(b) of the Original Agreement is hereby amended and restated in its entirety as follows:
  - "(b) <u>Bonus</u>. Executive shall be eligible to receive an annual cash incentive bonus of up to forty percent (40%) of Executive's annual base salary as may be set by the Committee by March 31 of each year. The determination of the actual bonus earned, if any, shall be at the sole discretion of the Committee and shall be based upon the Committee's assessment of Executive's performance and the achievement of certain objectives which shall be set by the Committee from time to time. Executive's performance shall be evaluated by the Committee on an annual basis, and the Committee shall adjust Executive's salary in its sole discretion. Nothing in this section shall be construed as guaranteeing Executive a bonus in any amount. If an annual bonus is awarded, it shall be paid in the year following the year in which such bonus was earned, on or before March 15 of such following year."
  - 5. Section 5(c) of the Original Agreement is hereby amended and restated in its entirety as follows:
  - "(c) <u>Obligations upon Certain Terminations</u>. Upon voluntary termination of this Agreement, or termination of Executive's employment by the Company for Cause (as defined above) or upon Executive's death or disability, or termination by Executive for other than Good Reason (as defined below), the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to Executive through the date of such termination. Such amounts shall be paid on the Company's next regularly scheduled payroll date unless any such amount is not then calculable, in which case payment of such amount shall be made on the first regularly scheduled payroll date after the amount is calculable but no later than March 15 of the year following the year in which the Executive's employment terminated."
  - 6. Section 5(d) of the Original Agreement is amended and restated in its entirety as follows:
  - "(d) <u>Severance</u>.
  - (i) In the event of termination of Executive's employment (A) by the Company for reasons other than Cause or Executive's death or disability, or (B) by Executive for Good Reason, and provided Executive executes and does not revoke a Release and Settlement Agreement (the "Release") in a form acceptable to the Company, Executive shall receive a severance benefit, subject to any applicable taxes and withholdings, in an amount equal to one (1) year's base salary (the "Salary Benefit") plus the average annual bonus awarded Executive over the previous two (2) years (the "Bonus", and, together with the Salary Benefit, the "Severance Benefit"). Subject to Section 5(d)(ii) below, the Company shall pay the Salary Benefit, in monthly installments, on the fifth business day of each month commencing with the second month following the month in which Executive's termination of employment occurred. The Company shall pay the Bonus in a lump sum payment within ninety (90) days of the date of termination of Executive's employment (the "Termination Date"), but in no event later than March 15 of the year following the year in which such termination of employment occurred, or in the event of termination pursuant to Section 5(e)(iv), no later than March 15 of the year following the year in which the Change

of Control occurred. Executive shall also continue to be entitled to receive all Company nontaxable health and other nontaxable employee benefits to which Executive was entitled as of the Termination Date, subject to the terms of all applicable benefit plans and to the extent such benefits can be provided to non-employees (or to the extent such benefits cannot be provided to non-employees, then the amount the Company was paying for those benefits immediately prior to the Termination Date), at the same average level and on the same terms and conditions which applied immediately prior to the Termination Date, for the shorter of (i) one year following the Termination Date or (ii) until Executive obtains comparable coverage from another employer (the "Continuing Benefits").

- (ii) Notwithstanding the foregoing, if Executive is on the termination date a "specified employee" (as defined in Section 409A of the Internal Revenue Code, as amended (the "Code"), and the regulations promulgated under such Section 409A ("Code Section 409A") and as determined in accordance with the permissible method then in use by the Company, or, if none, in accordance with the applicable default provisions of Code Section 409A, relating to "specified employees"), then if and to the extent required in order to avoid the imposition on Executive of any excise tax under Code Section 409A, the payment of any Severance Benefit, Continuing Benefits or other payments under this Section 5 shall not commence until, and shall be made on, the first business day after the date that is six (6) months following the Termination Date, and in such event the initial payment shall include a catch-up amount covering amounts that would otherwise have been paid during the six-month period following the Termination Date."
- 7. Section 5(f) of the Original Agreement is hereby amended and restated in its entirety as follows:

#### "(f) <u>Tax Gross-Up for Parachute Payments.</u>

- (A) If at any time or from time to time it shall be determined that any payment to Executive pursuant to this Agreement or any other payment or benefit hereunder or under any other plan or agreement or otherwise ("Potential Parachute Payment") would constitute an "excess parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and thus would be subject to the excise tax imposed by Section 4999 of the Code, or any similar tax payable under any United States federal, state, local, foreign or other law ("Excise Tax"), then Executive shall receive and the Company shall pay or cause to be paid a Tax Gross-Up Payment with respect to all Taxes as defined below. The Tax Gross-Up Payment is intended to compensate Executive for all such excise taxes and federal, state, local, foreign or other income, employment or excise taxes or other taxes ("Taxes") payable by Executive with respect to the Tax Gross-Up Payment and shall be in an amount such that after payment of Taxes on such amount there remains a balance sufficient to pay the taxes being reimbursed. For purposes of determining the amount of the Tax Gross-Up Payment, Executive shall be deemed to pay federal income tax and employment taxes at the highest marginal rate of federal income and employment taxation in the calendar year in which the Tax Gross-Up Payment is to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of Executive's residence (or, if greater, the state and locality in which Executive is required to file a nonresident income tax return with respect to the Potential Parachute Payment), net of the maximum reduction in federal income taxes that may be obtained from the deduction of such state and local taxes.
- (B) The determinations to be made under this Section 5(f) shall be made by the Company's independent public accountants (the "Accounting Firm"), which firm shall provide its determinations and any supporting calculations both to the Company and to Executive. Any such determination by the Accounting Firm shall be binding upon the Company and Executive. All fees and expenses of the Accounting Firm in performing the determinations referred to in this Section 5(f) shall be borne solely by the Company, and the Company shall indemnify and hold harmless the Accounting Firm of and from any and all claims, damages and expenses resulting therefrom, except for claims, damages or expenses resulting from the gross negligence or willful misconduct of the Accounting Firm.
- (C) Any Tax Gross-Up Payment, as determined pursuant to this Section 5(f), shall be paid by the Company to Executive as and when the Excise Tax is incurred on a Potential Parachute Payment, or at such later date as mutually agreed by the parties hereto, but in no event later than the end of Executive's taxable year next following the taxable year in which Executive remits the applicable Excise Tax to the IRS and any applicable state taxing authorities. The Tax Gross-Up Payment shall be paid in accordance with Code Section 409A, to the extent applicable, including, to the extent applicable, subject to and in compliance with Section 5(d)(ii)."
- 8. Section 5(h) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(h) <u>Change of Control</u>. For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred:
- (i) If any person (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (other than the Company or any trustee or fiduciary holding securities under an

56

employee benefit plan of the Company) becomes a beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or

- (ii) Upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote), or (B) a sale or other disposition of all or substantially all of the assets of the Company."
- 9. Except as herein amended, the terms and provisions of the Original Agreement shall remain in full force and effect as originally executed.
- 10. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of North Carolina, without reference to the choice of law provisions of such laws.
- 11. This First Amendment may be executed in any number of counterparts, each of which shall constitute one agreement binding on all parties hereto.
- 12. This First Amendment and the Original Agreement, as amended and modified by this First Amendment, shall constitute and be construed as a single agreement.

[Signature page follows]

IN WITNESS WI	HEREOF, the	parties hereto	have executed	this First	Amendment t	o Executive	Employment	Agreement	as
of the day and year first abo	ove written.							_	

**COMPANY:** 

POZEN INC.

/s/ John R. Plachetka By:

John R. Plachetka, Pharm.D. Chairman, President and CEO

**EXECUTIVE:** 

/s/ William L. Hodges
William L. Hodges

# FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

This FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "First Amendment"), is entered into as of September 28, 2007, by and between POZEN Inc. (the "Company") and Marshall E. Reese, Ph.D. ("Executive").

#### WITNESSETH:

WHEREAS, the Company and Executive entered into that certain Executive Employment Agreement dated November 8, 2004 (the "Original Agreement"); and

WHEREAS, the Company and Executive desire to amend certain terms of the Original Agreement, as set forth below, in order to facilitate compliance with Section 409A of the Internal Revenue Code of 1986, as amended.

NOW, THEREFORE, in consideration of the foregoing and the provisions and mutual promises herein contained and other good and valuable consideration, the parties hereby agree as follows:

- 1. All capitalized terms that are not defined herein shall have the meanings ascribed to such terms in the Original Agreement.
- 2. Section 4(b) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(b) <u>Bonus</u>. Executive shall be eligible to receive an annual cash incentive bonus of up to forty percent (40%) of Executive's annual base salary as may be set by the Committee by March 31 of each year. The determination of the actual bonus earned, if any, shall be at the sole discretion of the Committee and shall be based upon the Committee's assessment of Executive's performance and the achievement of certain objectives which shall be set by the Committee from time to time. Executive's performance shall be evaluated by the Committee on an annual basis, and the Committee shall adjust Executive's salary in its sole discretion. Nothing in this section shall be construed as guaranteeing Executive a bonus in any amount. If an annual bonus is awarded, it shall be paid in the year following the year in which such bonus was earned, on or before March 15 of such following year."
- 3. Section 5(c) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(c) Obligations upon Certain Terminations. Upon voluntary termination of this Agreement, or termination of Executive's employment by the Company for Cause (as defined above) or upon Executive's death or disability, or termination by Executive for other than Good Reason (as defined below), the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to Executive through the date of such termination. Such amounts shall be paid on the Company's next regularly scheduled payroll date unless any such amount is not then calculable, in which case payment of such amount shall be made on the first regularly scheduled payroll date after the amount is calculable but no later than March 15 of the year following the year in which the Executive's employment terminated."
- 4. Section 5(d) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(d) <u>Severance</u>.
- (i) In the event of termination of Executive's employment (A) by the Company for reasons other than Cause or Executive's death or disability, or (B) by Executive for Good Reason, and provided Executive executes and does not revoke a Release and Settlement Agreement (the "Release") in a form acceptable to the Company, Executive shall receive a severance benefit, subject to any applicable taxes and withholdings, in an amount equal to one (1) year's base salary (the "Salary Benefit") plus the average annual bonus awarded Executive over the previous two (2) years (the "Bonus", and, together with the Salary Benefit, the "Severance Benefit"). Subject to Section 5(d)(ii) below, the Company shall pay the Salary Benefit, in monthly installments, on the fifth business day of each month commencing with the second month following the month in which Executive's termination of employment occurred. The Company shall pay the Bonus in a lump sum payment within ninety (90) days of the date of termination of Executive's employment (the "Termination Date"), but in no event later than March 15 of the year following the year in which such termination of employment occurred, or in the event of termination pursuant to Section 5(e)(iv), no later than March 15 of the year following the year in which the Change

of Control occurred. Executive shall also continue to be entitled to receive all Company nontaxable health and other nontaxable employee benefits to which Executive was entitled as of the Termination Date, subject to the terms of all applicable benefit plans and to the extent such benefits can be provided to non-employees (or to the extent such benefits cannot be provided to non-employees, then the amount the Company was paying for those benefits immediately prior to the Termination Date), at the same average level and on the same terms and conditions which applied immediately prior to the Termination Date, for the shorter of (i) one year following the Termination Date or (ii) until Executive obtains comparable coverage from another employer (the "Continuing Benefits").

- (ii) Notwithstanding the foregoing, if Executive is on the termination date a "specified employee" (as defined in Section 409A of the Internal Revenue Code, as amended (the "Code"), and the regulations promulgated under such Section 409A ("Code Section 409A") and as determined in accordance with the permissible method then in use by the Company, or, if none, in accordance with the applicable default provisions of Code Section 409A, relating to "specified employees"), then if and to the extent required in order to avoid the imposition on Executive of any excise tax under Code Section 409A, the payment of any Severance Benefit, Continuing Benefits or other payments under this Section 5 shall not commence until, and shall be made on, the first business day after the date that is six (6) months following the Termination Date, and in such event the initial payment shall include a catch-up amount covering amounts that would otherwise have been paid during the six-month period following the Termination Date."
- 5. Section 5(f) of the Original Agreement is hereby amended and restated in its entirety as follows:

#### "(f) Tax Gross-Up for Parachute Payments.

- (A) If at any time or from time to time it shall be determined that any payment to Executive pursuant to this Agreement or any other payment or benefit hereunder or under any other plan or agreement or otherwise ("Potential Parachute Payment") would constitute an "excess parachute payment" within the meaning of Section 280G of the Code, and thus would be subject to the excise tax imposed by Section 4999 of the Code, or any similar tax payable under any United States federal, state, local, foreign or other law ("Excise Tax"), then Executive shall receive and the Company shall pay or cause to be paid a Tax Gross-Up Payment with respect to all Taxes as defined below. The Tax Gross-Up Payment is intended to compensate Executive for all such excise taxes and federal, state, local, foreign or other income, employment or excise taxes or other taxes ("Taxes") payable by Executive with respect to the Tax Gross-Up Payment and shall be in an amount such that after payment of Taxes on such amount there remains a balance sufficient to pay the taxes being reimbursed. For purposes of determining the amount of the Tax Gross-Up Payment, Executive shall be deemed to pay federal income tax and employment taxes at the highest marginal rate of federal income and employment taxation in the calendar year in which the Tax Gross-Up Payment is to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of Executive's residence (or, if greater, the state and locality in which Executive is required to file a nonresident income tax return with respect to the Potential Parachute Payment), net of the maximum reduction in federal income taxes that may be obtained from the deduction of such state and local taxes.
- (B) The determinations to be made under this Section 5(f) shall be made by the Company's independent public accountants (the "Accounting Firm"), which firm shall provide its determinations and any supporting calculations both to the Company and to Executive. Any such determination by the Accounting Firm shall be binding upon the Company and Executive. All fees and expenses of the Accounting Firm in performing the determinations referred to in this Section 5(f) shall be borne solely by the Company, and the Company shall indemnify and hold harmless the Accounting Firm of and from any and all claims, damages and expenses resulting therefrom, except for claims, damages or expenses resulting from the gross negligence or willful misconduct of the Accounting Firm.
- (C) Any Tax Gross-Up Payment, as determined pursuant to this Section 5(f), shall be paid by the Company to Executive as and when the Excise Tax is incurred on a Potential Parachute Payment, or at such later date as mutually agreed by the parties hereto, but in no event later than the end of Executive's taxable year next following the taxable year in which Executive remits the applicable Excise Tax to the IRS and any applicable state taxing authorities. The Tax Gross-Up Payment shall be paid in accordance with Code Section 409A, to the extent applicable, including, to the extent applicable, subject to and in compliance with Section 5(d)(ii)."
- 6. Section 5(h) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(h) <u>Change of Control</u>. For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred:
- (i) If any person (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (other than the Company or any trustee or fiduciary holding securities under an

employee benefit plan of the Company) becomes a beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or

- (ii) Upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote), or (B) a sale or other disposition of all or substantially all of the assets of the Company."
- 7. Except as herein amended, the terms and provisions of the Original Agreement shall remain in full force and effect as originally executed.
- 8. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of North Carolina, without reference to the choice of law provisions of such laws.
- 9. This First Amendment may be executed in any number of counterparts, each of which shall constitute one agreement binding on all parties hereto.
- 10. This First Amendment and the Original Agreement, as amended and modified by this First Amendment, shall constitute and be construed as a single agreement.

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment to Executive Employment Agreement as of the day and year first above written.

COMPAN	Y	:

POZEN INC.

By: /s/ John R. Plachetka

John R. Plachetka, Pharm.D. Chairman, President and CEO

**EXECUTIVE:** 

/s/ Marshall E. Reese

Marshall E. Reese. Ph.D.

# FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

This FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "First Amendment"), is entered into as of September 28, 2007, by and between POZEN Inc. (the "Company") and John E. Barnhardt ("Executive").

#### WITNESSETH:

WHEREAS, the Company and Executive entered into that certain Executive Employment Agreement dated July 25, 2001 (the "Original Agreement"); and

WHEREAS, the Company and Executive desire to amend certain terms of the Original Agreement in order to facilitate compliance with Section 409A of the Internal Revenue Code of 1986, as amended, and to add a requirement that Executive execute a release in connection with termination of employment, all as set forth below.

NOW, THEREFORE, in consideration of the foregoing and the provisions and mutual promises herein contained and other good and valuable consideration, the parties hereby agree as follows:

- 1. All capitalized terms that are not defined herein shall have the meanings ascribed to such terms in the Original Agreement.
- 2. Section 4(b) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(b) <u>Bonus</u>. Executive shall be eligible to receive an annual cash incentive bonus of up to forty percent (40%) of annual base salary, or such greater amount up to eighty percent (80%) of annual base salary, as may be set by the Committee by March 31 of each year. The determination of the actual bonus earned, if any, shall be at the sole discretion of the Committee and shall be based upon the Committee's assessment of Executive's performance and the achievement of certain objectives which shall be set by the Committee from time to time. Executive's performance shall be evaluated by the Committee on an annual basis, and the Committee shall adjust Executive's salary in its sole discretion. Nothing in this section shall be construed as guaranteeing Executive a bonus in any amount. If an annual bonus is awarded, it shall be paid in the year following the year for which such bonus was earned, on or before March 15 of such following year."
- 3. Section 5(c) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(c) <u>Obligations upon Certain Terminations</u>. Upon voluntary termination of this Agreement, or termination of Executive's employment by the Company for Cause (as defined above) or upon Executive's death or disability, or termination by Executive for other than Good Reason (as defined below), the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to Executive through the date of such termination. Such amounts shall be paid on the Company's next regularly scheduled payroll date unless any such amount is not then calculable, in which case payment of such amount shall be made on the first regularly scheduled payroll date after the amount is calculable but no later than March 15 of the year following the year in which the Executive's employment terminated.."
- 4. Section 5(d) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(d) Severance.
- (i) In the event of termination of Executive's employment (A) by the Company for reasons other than Cause or Executive's death or disability, or (B) by Executive for Good Reason, and provided Executive executes and does not revoke a Release and Settlement Agreement (the "Release") in a form acceptable to the Company, Executive shall receive a severance benefit, subject to any applicable taxes and withholdings, in an amount equal to one (1) year's base salary (the "Salary Benefit") plus the average annual bonus awarded Executive over the previous two (2) years (the "Bonus", and, together with the Salary Benefit, the "Severance Benefit"). Subject to Section 5(d)(ii) below, the Company shall pay the Salary Benefit, in monthly installments, on the fifth business day of each month commencing with the second month following the month in which Executive's termination of employment occurred. The Company shall pay the Bonus in a lump sum payment within ninety (90) days of the date of termination of Executive's employment (the "Termination Date"), but in no event later than March 15 of the year following the year in which such termination of employment occurred, or in the

event of termination pursuant to Section 5(e)(iv), no later than March 15 of the year following the year in which the Change of Control occurred. Executive shall also continue to be entitled to receive all Company nontaxable health and other nontaxable employee benefits to which Executive was entitled as of the Termination Date, subject to the terms of all applicable benefit plans and to the extent such benefits can be provided to non-employees (or to the extent such benefits cannot be provided to non-employees, then the amount the Company was paying for those benefits immediately prior to the Termination Date), at the same average level and on the same terms and conditions which applied immediately prior to the Termination Date, for the shorter of (i) one year following the Termination Date or (ii) until Executive obtains comparable coverage from another employer (the "Continuing Benefits").

- (ii) Notwithstanding the foregoing, if Executive is on the termination date a "specified employee" (as defined in Section 409A of the Internal Revenue Code, as amended (the "Code"), and the regulations promulgated under such Section 409A ("Code Section 409A") and as determined in accordance with the permissible method then in use by the Company, or, if none, in accordance with the applicable default provisions of Code Section 409A, relating to "specified employees"), then if and to the extent required in order to avoid the imposition on Executive of any excise tax under Code Section 409A, the payment of any Severance Benefit, Continuing Benefits or other payments under this Section 5 shall not commence until, and shall be made on, the first business day after the date that is six (6) months following the Termination Date, and in such event the initial payment shall include a catch-up amount covering amounts that would otherwise have been paid during the six-month period following the Termination Date."
- 5. Section 5(f) of the Original Agreement is hereby amended and restated in its entirety as follows:
  - "(f) Tax Gross-Up for Parachute Payments.
- (A) If at any time or from time to time it shall be determined that any payment to Executive pursuant to this Agreement or any other payment or benefit hereunder or under any other plan or agreement or otherwise ("Potential Parachute Payment") would constitute an "excess parachute payment" within the meaning of Section 280G of the Code, and thus would be subject to the excise tax imposed by Section 4999 of the Code, or any similar tax payable under any United States federal, state, local, foreign or other law ("Excise Tax"), then Executive shall receive and the Company shall pay or cause to be paid a Tax Gross-Up Payment with respect to all Taxes as defined below. The Tax Gross-Up Payment is intended to compensate Executive for all such excise taxes and federal, state, local, foreign or other income, employment or excise taxes or other taxes ("Taxes") payable by Executive with respect to the Tax Gross-Up Payment and shall be in an amount such that after payment of Taxes on such amount there remains a balance sufficient to pay the taxes being reimbursed. For purposes of determining the amount of the Tax Gross-Up Payment, Executive shall be deemed to pay federal income tax and employment taxes at the highest marginal rate of federal income and employment taxation in the calendar year in which the Tax Gross-Up Payment is to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of Executive's residence (or, if greater, the state and locality in which Executive is required to file a nonresident income tax return with respect to the Potential Parachute Payment), net of the maximum reduction in federal income taxes that may be obtained from the deduction of such state and local taxes.
- (B) The determinations to be made under this Section 5(f) shall be made by the Company's independent public accountants (the "Accounting Firm"), which firm shall provide its determinations and any supporting calculations both to the Company and to Executive. Any such determination by the Accounting Firm shall be binding upon the Company and Executive. All fees and expenses of the Accounting Firm in performing the determinations referred to in this Section 5(f) shall be borne solely by the Company, and the Company shall indemnify and hold harmless the Accounting Firm of and from any and all claims, damages and expenses resulting therefrom, except for claims, damages or expenses resulting from the gross negligence or willful misconduct of the Accounting Firm.
- (C) Any Tax Gross-Up Payment, as determined pursuant to this Section 5(f), shall be paid by the Company to Executive as and when the Excise Tax is incurred on a Potential Parachute Payment, or at such later date as mutually agreed by the parties hereto, but in no event later than the end of Executive's taxable year next following the taxable year in which Executive remits the applicable Excise Tax to the IRS and any applicable state taxing authorities. The Tax Gross-Up Payment shall be paid in accordance with Code Section 409A, to the extent applicable, including, to the extent applicable, subject to and in compliance with Section 5(d)(ii)."
- 6. Section 5(h) of the Original Agreement is hereby amended and restated in its entirety as follows:
- "(h) <u>Change of Control</u>. For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred:

63

- (i) If any person (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (other than the Company or any trustee or fiduciary holding securities under an employee benefit plan of the Company) becomes a beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); or
- (ii) Upon the consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote), or (B) a sale or other disposition of all or substantially all of the assets of the Company."
- 7. Except as herein amended, the terms and provisions of the Original Agreement shall remain in full force and effect as originally executed.
- 8. This First Amendment shall be governed by and construed and enforced in accordance with the laws of the State of North Carolina, without reference to the choice of law provisions of such laws.
- 9. This First Amendment may be executed in any number of counterparts, each of which shall constitute one agreement binding on all parties hereto.
- 10. This First Amendment and the Original Agreement, as amended and modified by this First Amendment, shall constitute and be construed as a single agreement.

[Signature page follows]

IN WITNESS WH	EREOF, the parties	hereto have execut	ed this First Ar	mendment to Exe	ecutive Employment A	Agreement as
of the day and year first abo						_

**COMPANY:** 

POZEN INC.

By: /s/ John R. Plachetka

John R. Plachetka, Pharm.D. Chairman, President and CEO

**EXECUTIVE:** 

/s/ John E. Barnhardt

John E. Barnhardt

#### AMENDMENT NO. 1 TO THE COLLABORATION AND LICENSE AGREEMENT

This Amendment No. 1 to the Collaboration and License Agreement (this "<u>Amendment</u>") is made effective as of September 6, 2007 (the "<u>Amendment Effective Date</u>") by and between POZEN INC., a Delaware corporation having offices at 1414 Raleigh Road, Suite 400, Chapel Hill, North Carolina ("<u>POZEN"</u>), and ASTRAZENECA AB, a Swedish corporation having an office at SE-431 83, Mölndal, Sweden ("<u>AstraZeneca"</u>). POZEN and AstraZeneca may be referred to herein individually as a "<u>Party</u>," or collectively as the "<u>Parties</u>."

#### RECITALS

- A. POZEN and AstraZeneca entered into that certain Collaboration and License Agreement, dated as of August 1, 2006, and effective as of September 7, 2006 (as amended hereby, the "Agreement").
- B. POZEN and AstraZeneca desire to amend the Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the parties hereto agree to amend the Agreement as follows:

Capitalized terms used herein have the respective meanings assigned to them as defined in this Amendment. Other capitalized terms not otherwise defined herein have the meaning ascribed thereto in the Agreement.

#### **ARTICLE 1 - AMENDMENTS**

**1.1 Amendment to Section 1.77.** Section 1.77 of the Agreement is hereby amended and restated to read in its entirety as follows:

""\*\*, \*\*\*, and \*\*\* Studies" means the \*\*\*, \*\*\*, \*\*\*, and \*\*\* Studies described in the U.S. Development Plan, each of which may be referred to individually (e.g., the "\*\*\* Study") to describe that particular study in the U.S. Development Plan."

- **1.2 Amendment to Section 1.82(b).** Section 1.82(b) of the Agreement is hereby amended and restated to read in its entirety as follows:
  - "(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 \*\*\* Study or \*\*\* Study shall not be counted toward such \$\*\*\* limit;"
- **1.3 Amendment to Section 1.104.** Section 1.104 of the Agreement is hereby amended and restated to read in its entirety as follows:
  - "1.104 "TPP Studies" means the studies entitled \*\*\*, \*\*\*, \*\*\* in the U.S. Development Plan."
- **1.4 Amendment to Section 2.2.1(a).** Section 2.2.1(a) of the Agreement is hereby amended and restated to read in its entirety as follows:
  - "(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. Attendance of POZEN representatives at GPT meetings shall be agenda-driven, as determined in the sole discretion of AstraZeneca. 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

with 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."

**1.5 Amendment to Section 2.2.1(c).** Section 2.2.1(c) of the Agreement is hereby amended and restated to read in its entirety as follows:

"(c) Meetings. The GPT will hold meetings when called by the GPT Chair. Meetings may be held in person or by means of telecommunication (telephone, video, or web conference). Face-to-face GPT meetings that require POZEN attendance will be convened on an as-needed basis as mutually agreed by AstraZeneca and POZEN, but in any event, at least twice per annum. The location of these meetings, will be based on business requirements and determined by mutual agreement between AstraZeneca and POZEN. Following any GPT meeting, the GPT Chair will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. When POZEN has participated in the meeting, 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."

**1.6 Amendment to Section 3.3.3.** In Section 3.3.3 of the Agreement, the phrase "(including upon finalization of the scope of the \*\*\* and \*\*\* studies)" is hereby deleted and replaced with the following:

"(including upon the finalization of the design of the \*\*\*, \*\*\*, \*\*\*, and \*\*\* Studies, and any agreed Additional New Studies referenced in Section 1.15 of this Amendment)"

**1.7 Amendment to Section 8.2**. Section 8.2 of the Agreement is hereby amended and restated to read in its entirety with the following:

**"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.

	Milestone Event	Milestone Payment
1.	Execution of this Amendment.	\$10,000,000
2.	Achievement of *** ***, and achievement of ***.	\$20,000,000
3.	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.).	\$***
4.	Receipt of the first NDA Approval for a POZEN Product in the U.S.	\$***
5.	*** of the first *** to *** a *** in a *** that includes *** and/or *** (if available) at an *** of the POZEN Product *** than the *** of (a) the *** for a *** in such ***, or (b) ***.	\$***

"POZEN shall notify AstraZeneca in writing upon the achievement of Milestones Events 3 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 #3 and 4, and (ii) the occurrence of the Milestone Event #5. The Parties agree that Milestone Event #2 above has been achieved as of the Amendment Effective Date, and that development Milestone Event #1 previously set forth in Section 8.2 the Agreement will be deemed to have been achieved through the performance and achievement of Milestone Event #2 above. Milestone Events #1 and 2 shall be payable within \*\*\* (\*\*\*) Business Days after the execution of this Amendment. 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."** 

"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."

# **1.8** Amendment to Section 8.3. Section 8.3 of the Agreement is hereby amended and restated and replaced in its entirety with the following:

**"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 thirty (30) 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 \$***	
4.	End of first calendar year during which aggregate annual	\$***
	Net Sales of Products were at least \$***	

<sup>&</sup>quot;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."

- **1.9 Amendment to Section 8.4.1**. Section 8.4.1 of the Agreement is hereby amended and restated and replaced in its entirety with the following:
- **"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) \*\*\*% of the portion of aggregate Net Sales of Products sold in the United States during a calendar year.
  - "(b) For Net Sales of Products sold outside the United States:
    - "(i) For Net Sales \*\*\*:
      - "1. \*\*\*% of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than \$\*\*\*;
      - "2. \*\*\*% of the portion of aggregate Net Sales of Products during a calendar year that is greater than \$\*\*\* but equal to or less than \$\*\*\*; and
      - "3. \*\*\*% of the portion of aggregate Net Sales of Products during a calendar year that is greater than \$\*\*\*."
    - "(ii) For Net Sales \*\*\*:
      - "1. \*\*\*% of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than \$\*\*\*; and
      - "2. \*\*\*% 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 \*\*\*, 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 8.41(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 \*\*\*, such that \*\*\* percent (\*\*\*%) of the Net Sales of each \*\*\* shall be added to the Segregated Royalty Amount, and the remaining \*\*\* percent (\*\*\*%) of each \*\*\* shall be combined only with the remaining \*\*\* percent (\*\*\*%) of Net Sales of the other \*\*\* (i.e., \*\*\*) 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)."
- **1.10** Amendment to Section 8.4.3. Section 8.4.3 of the Agreement is hereby amended and restated and replaced in its entirety with the following:
  - "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 \*\*\* in the \*\*\*, and \*\*\* and \*\*\* for \*\*\* of the \*\*\*). 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 \*\*\* in such \*\*\* 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."
- **1.11 Amendment to Section 12.9.** Section 12.9 of the Agreement is hereby amended and restated and replaced in its entirety with the following:
  - "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 \*\*\* then, for a period of \*\*\* 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."
- **1.12** Amendment to U.S. Development Plan. The U.S. Development Plan of the Agreement is hereby amended and restated to read in its entirety as set forth in Exhibit B attached hereto.
- **1.13 Amendment to US. Development Plan Timeline.** The U.S. Development Plan Timeline of the Agreement is hereby amended and restated to read in its entirety as set forth in Exhibit C attached hereto.
- **1.14 Amendment to Exhibit F (TPP Profile and TPP Studies).** Exhibit F of the Agreement is hereby amended and restated to read in its entirety as set forth in Exhibit F attached hereto.

- **1.15 Amendment to Schedules 8.4.1 and 8.4.3.** Schedule 8.4.1 and Schedule 8.4.3 of the Agreement is hereby amended and restated to read in its entirety as set forth in <u>Schedule 8.4.1</u> and <u>Schedule 8.4.3</u> attached hereto.
- **1.16 Termination of \*\*\*.** Promptly after execution of this Amendment, POZEN will terminate \*\*\* \*\*\*, including \*\*\*. POZEN shall terminate these activities in a professional manner and will use reasonable efforts to minimize termination expenses. AstraZeneca will be responsible for the costs associated with the termination of such activities in accordance with Section 3.3.3 (Expenses) of the Agreement. Due to the extraordinary nature of these expenses, AstraZeneca will use commercially reasonable efforts to pay POZEN within \*\*\* (\*\*\*) days, but in any event within \*\*\* (\*\*\*) days, following receipt of invoice for such termination costs. To allow rapid approval of the invoice, copies of vendor documentation of work performed and billing will be included in the invoice.

#### 1.17 New Studies.

- (a) As promptly as practicable following the execution of this Amendment, the Parties agree to update the U.S. Development Plan to reflect \*\*\* of the \*\*\*, in a manner that is consistent with \*\*\* in the \*\*\*. AstraZeneca will pay POZEN for its costs for \*\*\* in accordance with Section 3.3.3 of the Agreement (Expenses); provided, however, that in no event will \*\*\* for the \*\*\* in the \*\*\*. The Parties will \*\*\*. The Parties will use Diligent Efforts to \*\*\* and to \*\*\* in the \*\*\* for the \*\*\* within the \*\*\*.
- **(b)** To the extent that \*\*\* in the \*\*\*, the GPT will agree upon \*\*\* of the \*\*\* <u>provided, however,</u> that \*\*\* for the \*\*\* in the \*\*\*, if any, may include, but would not be limited to, \*\*\* and a \*\*\* of the \*\*\* of the \*\*\*. If the \*\*\* in the \*\*\* as an \*\*\*. AstraZeneca will conduct \*\*\* for the \*\*\* taking into account \*\*\* to the \*\*\* of the \*\*\*. Assessments \*\*\* for this purpose will include \*\*\*. Representatives from POZEN will participate \*\*\* to the \*\*\*. AstraZeneca will be obligated to \*\*\* if the \*\*\*. In the event that AstraZeneca's and POZEN's representatives on the GPT \*\*\* of a \*\*\* will be \*\*\* of the \*\*\* to be \*\*\* of the \*\*\*. AstraZeneca will conduct \*\*\*, but in any event will \*\*\*.
- (c) \*\*\* of the \*\*\* but if \*\*\*. \*\*\* of the \*\*\*. Promptly after execution of this Amendment by both Parties, the Parties will \*\*\* for the \*\*\* and will \*\*\* after the \*\*\* of the \*\*\*. The expenses \*\*\* in the \*\*\*.
  - (d) AstraZeneca will \*\*\*, at AstraZeneca's expense, \*\*\* with the \*\*\* of the \*\*\* in the \*\*\* in the \*\*\*.
- **1.18** Operating Principles. Promptly after the Amendment Effective Date, the GPT will review, discuss and adopt new operating principles consistent with the draft principles attached hereto as Exhibit G that will guide the conduct of the GPT and clinical subteam meetings. To the extent there is any conflict between the attached operating principles and the terms and conditions of the Agreement (as amended by this Amendment), then the Agreement will control.

#### ARTICLE 2 - REFERENCE TO AND EFFECT ON THE AGREEMENT

- **2.1** Reference to Agreement. Upon and after the effectiveness of this Amendment, each reference in the Agreement to "this Agreement," "hereunder," "hereof" or words of like import referring to the Agreement shall mean and be a reference to the Agreement as modified and amended hereby.
- **2.2** Effectiveness of Agreement. The amendments set forth above shall not be effective until execution and delivery of this Amendment by both parties. Except as specifically amended above, the Agreement, as amended, is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed and shall constitute the legal, valid, binding and enforceable obligations of the parties.
- **2.3 No Waiver.** The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of either Party under the Agreement, nor constitute a waiver of any provision of the Agreement.

# **ARTICLE 3 - MISCELLANEOUS**

- **3.1** Governing Law; Dispute Resolution. Section 15.4 of the Agreement governs any dispute arising out of or related to this Amendment.
- **3.2** <u>Notices.</u> All notices or other communications that are required or permitted hereunder will be made according to Section 15.5 of the Agreement.

- **3.3** <u>Headings</u>. The headings for each Article and Section in this Amendment have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.
- **3.4** <u>Counterparts.</u> This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 3.5 No Strict Construction. This Amendment 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.

**IN WITNESS WHEREOF,** the Parties have executed this Amendment in duplicate originals by their duly authorized representatives as of the Amendment Effective Date.

POZEN INC.	ASTRAZENECA AB
By:	By:
Print Name:	Print Name:
Title:	Title:

# (Exhibit A to Agreement Unchanged)

# **EXHIBIT B**

# U.S. DEVELOPMENT PLAN

Study Number	<u>Title</u>	<u>Endpoints</u>	Design/Comment	Responsibility to Conduct/Pay			
NONCLINICAL:	NONCLINICAL:						
***	***	***	***	***			
***	***	***	***	***			
PHASE 1							
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			
PHASE 2 ***							
***	***	***	***	***			
***	***	***	***	***			
***	***	***	***	***			

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

# EXHIBIT C U.S. DEVELOPMENT PLAN TIMELINE \*\*\*

# **EXHIBIT F**

# TPP STUDIES

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

\*\*\*

## **EXHIBIT G OPERATING PRINCIPLES**

# **GPT Meetings:**

\*\*\*.

# **CPT Meetings:**

# Face-to-Face GPT Meetings: \*\*\*.

#### **SCHEDULE 8.4.1**

(i) For Products sold outside the U.S.: In \*\*\*, AstraZeneca 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 (outside the U.S.) the total Net Sales of Products are \$\*\*\* million, and Net Sales do not occur in any other country for \*\*\*. 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 (outside of the US) would be \$\*\*\*

(ii) For Products sold in the U.S.: In \*\*\*, AstraZeneca has Net Sales for \*\*\* in the U.S. in the amounts of \$\*\*\* for the first Product and \$\*\*\* for \*\*\*. The total royalty payable for all U.S. Net Sales would be \$\*\*\* (Net Sales for \*\*\* would be charged a royalty of \*\*\*%).

#### **SCHEDULE 8.4.3**

(i) For Products sold outside the U.S.: Assume that in the \*\*\* the total ex-U.S. Net Sales of Products are \$\*\*\*n. In that example the following royalties would be payable prior to application of any Market Reduction:

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

Assume that in country X during the first \*\*\* a Competing Product had commenced sales in country X, and in the first \*\*\* 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 ex-U.S. royalty payable for Product Net Sales would be \$\*\*\*

#### (ii) For Products sold in the United States:

Assume that in the U.S. during the first \*\*\* a Competing Product had commenced sales in the U.S., and in the first \*\*\* 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 the U.S. were \$\*\*\* in \*\*\*. The Market Reduction is applied to Net Sales in the U.S. by reducing the royalty rates set forth in Section 8.4.1(a) by \*\*\*%. The total royalty payable for all U.S. Net Sales would be \$\*\*\* (net sales would be charged at a royalty of \*\*\*%).

## [AstraZeneca Letterhead]

October 1, 2007

By Facsimile: (919) 913-1039

Gilda Thomas Senior Vice President & General Counsel POZEN, Inc. 1414 Raleigh Road, Suite 400 Chapel Hill, NC 27517 USA

Re: Amendment No. 1 dated as of September 6, 2007 (the "Amendment") to the Collaboration and License Agreement dated as of August 1, 2006 by and between POZEN INC. and AstraZeneca AB (the "Agreement")

## Dear Gilda:

As you discussed with our counsel, David McIntosh of Ropes & Gray, due to a clerical error in preparing the Amendment, Exhibit G in the executed version of the Amendment was incomplete. Attached to this letter is the complete version of Exhibit G that should have been attached to the Amendment.

If this new Exhibit G attached to this letter is acceptable to Pozen, please execute this letter memorializing the parties' agreement that this new Exhibit G will replace the Exhibit G attached to the executed Amendment. Accordingly, upon execution of this letter, this new attached Exhibit G will become Exhibit G to the Amendment, and the Exhibit G originally attached to the Amendment will be superseded and replaced and be of no further force and effect.

Except as otherwise expressly provided in this letter, the terms of the 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.

[This space left intentionally blank]

If this letter reflects your understanding, please countersign in the space provided below and return one original copy to my attention by facsimile at (302) 885-6862.

# Sincerely,

By: /s/ Richard J. Kenny
Name: Richard J. Kenny

Assistant General Counsel Title:

## **AGREED:**

# POZEN INC.

By: /s/ Gilda Thomas\_\_\_\_\_

Name: Gilda Thomas

Senior Vice President & General Counsel Title:

## EXHIBIT G OPERATING PRINCIPLES

# **GPT Meetings:**

\*\*\*

\*\*\*

\*\*\*

# **CPT Meetings:**

\*\*\*

\*\*\*

\*\*\*

\*\*\*

\*\*\*

\*\*\*

\*\*\*

\*\*\*

\*\*\*

# **Face-to-Face GPT Meetings:**

\*\*\*

\*\*\*

# **Regulatory:**

\*\*\*

\*\*\*

\*\*\*

\*\*\*

## **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:
  - 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 5, 2007

/s/ John R. Plachetka

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

#### **Section 302 Certification**

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

Date: November 5, 2007

/s/ William L. Hodges

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

#### CEO CERTIFICATION PURSUANT TO

#### SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

## (18 U.S.C. SECTION 1350)

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

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

Date: November 5, 2007

/s/ John R. Plachetka John R. Plachetka, Pharm.D.

Chief Executive Officer

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

#### CFO CERTIFICATION PURSUANT TO

## SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

(18 U.S.C. SECTION 1350)

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

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

Date: November 5, 2007

/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.