

PROGENICS PHARMACEUTICALS INC  
Form 10-Q  
November 08, 2007

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2007

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number **000-23143**

**PROGENICS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

**13-3379479**  
(I.R.S. Employer  
Identification No.)

**777 Old Saw Mill River Road**  
**Tarrytown, New York 10591**  
(Address of principal executive offices)  
(Zip Code)

**(914) 789-2800**  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

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Yes  No

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

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer

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

As of November 6, 2007 there were 29,708,958 shares of common stock, par value \$.0013 per share, of the registrant outstanding.

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Index**PART I — FINANCIAL INFORMATION****Item 1. Consolidated Financial Statements**

**PROGENICS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(amounts in thousands, except for par value and share amounts)  
(Unaudited)

	September 30, 2007	December 31, 2006
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 64,368	\$ 11,947
Marketable securities	81,293	113,841
Accounts receivable	2,204	1,699
Other current assets	2,555	3,181
Total current assets	150,420	130,668
Marketable securities	37,918	23,312
Fixed assets, at cost, net of accumulated depreciation and amortization	13,602	11,387
Restricted cash	549	544
Total assets	\$ 202,489	\$ 165,911
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,613	\$ 11,852
Deferred revenue <sup>3</sup> / <sub>4</sub> current	16,675	26,989
Other current liabilities	57	
Total current liabilities	32,345	38,841
Deferred revenue — long term	12,163	16,101
Other liabilities	355	123
Total liabilities	44,863	55,065
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$.001 par value; 20,000,000 shares authorized; issued and outstanding — none		
Common stock, \$.0013 par value; 40,000,000 shares authorized; issued and outstanding — 29,612,583 in 2007 and 26,199,016 in 2006	38	34
Additional paid-in capital	396,371	321,315
Accumulated deficit	(238,774)	(210,358)
Accumulated other comprehensive (loss)	(9)	(145)
Total stockholders' equity	157,626	110,846
Total liabilities and stockholders' equity	\$ 202,489	\$ 165,911

**The accompanying notes are an integral part of these condensed financial statements.**



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**PROGENICS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(amounts in thousands, except net loss per share)  
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenues:				
Contract research and development from collaborator	\$ 14,540	\$ 14,527	\$ 52,987	\$ 40,060
Research grants and contract	2,471	3,316	7,077	7,842
Product sales	7	5	48	70
Total revenues	17,018	17,848	60,112	47,972
Expenses:				
Research and development	24,247	15,751	69,999	43,079
In-process research and development				13,209
General and administrative	9,275	6,610	21,746	16,138
Loss in joint venture				121
Depreciation and amortization	845	381	2,144	1,106
Total expenses	34,367	22,742	93,889	73,653
Operating loss	(17,349)	(4,894)	(33,777)	(25,681)
Other income:				
Interest income	1,749	1,959	5,361	5,775
Net loss	\$ (15,600)	\$ (2,935)	\$ (28,416)	\$ (19,906)
Net loss per share - basic and diluted	\$ (0.58)	\$ (0.11)	\$ (1.07)	\$ (0.78)
Weighted-average shares - basic and diluted	26,976	25,783	26,639	25,570

**The accompanying notes are an integral part of these condensed financial statements.**

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**PROGENICS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE**  
**LOSS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2007**

(amounts in thousands)  
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)	Total Stockholders' Equity	Comprehensive (Loss)
	Shares	Amount					
<b>Balance at December 31, 2006</b>	26,199	\$ 34	\$ 321,315	\$ (210,358)	\$ (145)	\$ 110,846	
Compensation expense for vesting of share-based payment arrangements			11,840			11,840	
Issuance of restricted stock, net of forfeitures	245						
Sale of common stock in a public offering (\$23.15 per share, net of underwriting discounts and commissions and other offering expenses of \$3,058)	2,600	3	57,129			57,132	
Sale of Common Stock under employee stock purchase plans and exercise of stock options	569	1	6,106			6,107	
Repurchase of restricted stock			(19)			(19)	

Net (loss)				(28,416)			(28,416)	\$	(28,416)				
Change in unrealized loss on marketable securities						136		136	136				
<b>Balance at September 30, 2007</b>	29,613	\$	38	\$	396,371	\$	(238,774)	\$	(9)	\$	157,626	\$	(28,280)

The accompanying notes are an integral part of these condensed financial statements.



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**PROGENICS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(amounts in thousands)  
(Unaudited)

	<b>For the Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
Cash flows from operating activities:		
Net loss	\$ (28,416)	\$ (19,906)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,144	1,106
Amortization of discounts, net of premiums, on marketable securities	(354)	27
Noncash expenses incurred in connection with vesting of share-based compensation awards	11,840	9,132
Expense of purchased technology related to PSMA LLC		13,209
Loss in joint venture		121
Write-off of fixed assets		2
Changes in assets and liabilities, net of effects of purchase of PSMA LLC:		
(Increase) decrease in accounts receivable	(505)	301
Decrease (increase) in other current assets	626	(8)
Increase in accounts payable and accrued expenses	3,761	1,073
(Decrease) in amount due to joint venture		(194)
Decrease in investment in joint venture		250
(Decrease) in deferred revenue	(14,252)	(14,466)
Increase (decrease) in other current liabilities	57	(790)
Increase in other liabilities	232	51
Net cash (used in) operating activities	(24,867)	(10,092)
Cash flows from investing activities:		
Capital expenditures	(4,359)	(6,511)
Sales of marketable securities	188,997	236,212
Purchase of marketable securities	(170,565)	(264,425)
Acquisition of PSMA LLC, net of cash acquired		(13,128)
Increase in restricted cash	(5)	(5)
Net cash provided by (used in) investing activities	14,068	(47,857)
Cash flows from financing activities:		
Proceeds from the sale of common stock in a public offering (see Note 5)	60,190	
Expenses related to the sale of common stock in a public offering	(3,058)	
Proceeds from the exercise of stock options and sale of common stock under the Employee Stock Purchase Plan	6,107	5,309
Repurchase of restricted stock	(19)	
Net cash provided by financing activities	63,220	5,309
Net increase (decrease) in cash and cash equivalents	52,421	(52,640)
Cash and cash equivalents at beginning of period	11,947	67,072
Cash and cash equivalents at end of period	\$ 64,368	\$ 14,432
Supplemental disclosure of noncash investing activity:		
Fair value of assets, including purchased technology, acquired from PSMA LLC		\$ 13,674

Cash paid for acquisition of PSMA LLC	(13,459)
Liabilities assumed from PSMA LLC	\$ 215

**The accompanying notes are an integral part of these condensed financial statements.**

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**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)**  
(amounts in thousands, except per share amounts or unless otherwise noted)

**1. Interim Financial Statements**

Progenics Pharmaceuticals, Inc. (the “Company” or “Progenics”) is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. The Company’s principal programs are directed toward gastroenterology, virology and oncology. The Company was incorporated in Delaware on December 1, 1986. On April 20, 2006, the Company acquired full ownership of PSMA Development Company LLC (“PSMA LLC”) by acquiring from CYTOGEN Corporation (“Cytogen”) its 50% interest in PSMA LLC. Certain of the Company’s intellectual property rights are held by wholly owned subsidiaries of Progenics. None of the Company’s subsidiaries, other than PSMA LLC, had operations during the nine months ended September 30, 2007. Currently, all of the Company’s operations are conducted at one location in New York State. The Company’s chief operating decision maker reviews financial analyses and forecasts relating to all of the Company’s research programs as a single unit and allocates resources and assesses performance of such programs as a whole. Therefore, the Company operates under a single research and development segment.

The Company’s lead product candidate is methylnaltrexone. The Company has entered into a license and co-development agreement with Wyeth Pharmaceuticals (“Wyeth”) for the development and commercialization of methylnaltrexone. Under that agreement, the Company (i) has received an upfront payment from Wyeth, (ii) has received, and is entitled to receive further, additional payments as certain developmental milestones for methylnaltrexone are achieved, (iii) has been and will be reimbursed by Wyeth for expenses the Company incurs in connection with the development of methylnaltrexone under the development plan for methylnaltrexone agreed to between the Company and Wyeth, and (iv) will receive commercialization payments and royalties if, and when, methylnaltrexone is sold. These payments will depend on the successful development and commercialization of methylnaltrexone, which is itself dependent on the actions of Wyeth and the U.S. Food and Drug Administration (“FDA”) and other regulatory bodies and the outcome of clinical and other testing of methylnaltrexone. Many of these matters are outside the control of the Company. Manufacturing and commercialization expenses for methylnaltrexone will be funded by Wyeth.

During March 2007, the Company submitted a New Drug Application with the FDA for marketing approval in the United States for a subcutaneous formulation of methylnaltrexone for the treatment of opioid-induced constipation in patients receiving palliative care. In May 2007, Wyeth submitted a regulatory marketing application in the European Union for the same indication. Both applications were accepted for review in May 2007, which resulted in the Company earning a total of \$9.0 million in milestone payments under its Collaboration Agreement with Wyeth. In August 2007, Wyeth submitted a marketing application to the Therapeutic Goods Administration division of the Australian government, and in October 2007, Wyeth announced that it had submitted a New Drug Submission marketing application for subcutaneous methylnaltrexone to Health Canada, the Health Products and Food branch of the Canadian regulatory agency. The Company and Wyeth are also developing intravenous and oral formulations of methylnaltrexone.

The Company’s other product candidates are not as advanced in development as methylnaltrexone, and the Company does not expect any recurring revenues from sales or otherwise with respect to these product candidates in the near term. As a result of Wyeth’s agreement to reimburse Progenics for methylnaltrexone development expenses, the Company is able to devote its current and future resources to its other research and development programs. The Company expects that its research and development expenses with respect to these other product candidates will

increase significantly during the remainder of 2007 and beyond.

As a result of its development expenses and other needs, the Company may require additional funding to continue its operations. The Company may enter into a collaboration agreement, or a license or sale transaction, with respect to its product candidates other than methylnaltrexone. The Company may also seek to raise additional capital through the sale of its common stock or other securities (see Note 5) and expects to fund certain aspects of its operations through government grants and contracts.

The Company has had recurring losses. At September 30, 2007, the Company had an accumulated deficit of \$238.8 million and had cash, cash equivalents and marketable securities, including non-current portion, totaling \$183.6 million. The Company expects that cash, cash equivalents and marketable securities at September 30, 2007 will be sufficient to fund current operations beyond one year. During the nine months ended September 30, 2007, the Company had a net loss of \$28.4 million and used cash in operating activities of \$24.9 million.

Index**PROGENICS PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —  
continued (unaudited)**

(amounts in thousands, except per share amounts or unless otherwise noted)

The interim condensed consolidated financial statements of the Company included in this report have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect all adjustments, consisting primarily of normal recurring accruals, necessary for a fair statement of results for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006. All terms used but not defined elsewhere herein have the meaning ascribed to them in that Annual Report. The year end condensed consolidated balance sheet data were derived from audited financial statements but do not include all disclosures required by accounting principles generally accepted in the United States of America.

**2. Share-Based Payment Arrangements**

On January 1, 2007, the Company began to estimate the expected term of stock options granted to employees and to officers and directors by using historical data for each of those two groups. During 2006, in accordance with Staff Accounting Bulletin 107, the Company had used the simplified method for that purpose. The Company changed its method of estimating expected term because sufficient historical data related to stock option exercise and post-employment cancellation activity had been accumulated to effectively anticipate future activity. During 2007, the expected term for options granted to the two groups mentioned above was 5.25 and 7.5 years, respectively. During 2006, the expected term for both groups, using the simplified method, was 6.5 years. The expected term for stock options granted to non-employee consultants was ten years, which was equal to the contractual term of those options. The expected volatility of stock options granted to each group was calculated based upon the periods of the respective expected terms. The impact of the change in estimate on net loss and net loss per share was immaterial.

The assumptions used by the Company in the Black-Scholes option pricing model to estimate the grant date fair values of stock options granted under the Plans during the nine months ended September 30, 2007 and 2006 were as follows:

	<b>For the Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
Expected volatility	52% - 85%	88%
Expected dividends	zero	zero
Expected term (in years)	5.25 - 10	6.5
Weighted average expected term (years)	6.75	6.5
Risk-free rate	4.77% - 4.93%	4.74%

During the nine months ended September 30, 2007 and 2006, the fair value of shares purchased under the Purchase Plans was estimated on the date of grant in accordance with FASB Technical Bulletin No. 97-1 *Accounting under Statement 123 for Certain Employee Stock Purchase Plans with a Look-Back Option*, using the same option valuation model used for options granted under the Plans, except that the assumptions noted in the following table were used for the Purchase Plans:

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>
Expected volatility	43%	43%
Expected dividends	zero	zero
Expected term	6 months	6 months
Risk-free rate	4.78%	4.47%

Index**PROGENICS PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —  
continued (unaudited)**

(amounts in thousands, except per share amounts or unless otherwise noted)

The total fair value of shares under all of the Company's share-based payment arrangements that vested during the three months ended September 30, 2007 and 2006 was \$6.1 million and \$4.4 million, respectively; \$1.8 million and \$1.7 million, respectively, of which was reported as research and development expense and \$4.3 million and \$2.7 million, respectively, of which was reported as general and administrative expense. The total fair value of shares under all of the Company's share-based payment arrangements that vested during the nine months ended September 30, 2007 and 2006 was \$11.8 million and \$9.1 million, respectively; \$5.0 million and \$4.2 million, respectively, of which was reported as research and development expense and \$6.8 million and \$4.9 million, respectively, of which was reported as general and administrative expense.

No tax benefit was recognized related to such compensation cost during the three and nine months ended September 30, 2007 and 2006 because the Company had a net loss for each of those periods and the related deferred tax assets were fully offset by a valuation allowance. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the nine months ended September 30, 2007 and 2006.

In applying the treasury stock method for the calculation of diluted earnings per share ("EPS"), amounts of unrecognized compensation expense and windfall tax benefits are required to be included in the assumed proceeds in the denominator of the diluted earnings per share calculation unless they are anti-dilutive. The Company incurred a net loss for the three and nine months ended September 30, 2007 and 2006 and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for each of those periods.

**3. Accounts Receivable**

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
National Institutes of Health	\$ 2,200	\$ 1,697
Other	4	2
<b>Total</b>	<b>\$ 2,204</b>	<b>\$ 1,699</b>

**4. Accounts Payable and Accrued Expenses**

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
Accounts payable	\$ 1,528	\$ 1,559
Accrued consulting and clinical trial costs	9,829	7,404
Accrued payroll and related costs	2,115	990
Legal and professional fees	1,559	1,301
Other	582	598

Total	\$	15,613	\$	11,852
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## 5. Stockholders' Equity

On September 25, 2007, the Company completed a public offering of 2,600 shares of its common stock, pursuant to a shelf registration statement that had been filed with the Securities and Exchange Commission in 2006, which had registered 4,000 shares. The Company received proceeds, before expenses, of \$57,304 or \$22.04 per share, which was net of underwriting discounts and commissions of \$2,886. The Company also paid approximately \$172 in other offering expenses.



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continued (unaudited)**

(amounts in thousands, except per share amounts or unless otherwise noted)

**6. Revenue Recognition**

In January 2006, the Company began recognizing revenues from Wyeth both (i) for reimbursement of its development expenses for methyl naltrexone as incurred under the development plan agreed between the Company and Wyeth and (ii) for a portion of the \$60 million upfront payment the Company received from Wyeth, based on the proportion of the Company's expected total effort to complete its development obligations, as reflected in the most recent budget approved by both the Company and Wyeth, that was actually expended during each fiscal quarter. During the third quarter of 2007, the estimate of the Company's total remaining effort to complete its development obligations was increased based upon a revised development budget approved by both the Company and Wyeth and the period over which those obligations will extend and over which the upfront payment will be amortized was extended from the end of 2008 to the end of 2009. As a result, the amount of revenue recognized from the upfront payment in the third quarter of 2007 declined to \$3.2 million from \$5.1 million in the third quarter of 2006. In prior quarters during 2006 and 2007, the Company had recognized an amount of revenue similar to that in the third quarter of 2006.

During the three and nine month periods ended September 30, 2007, the Company recognized \$3.2 million and \$13.1 million, respectively, of revenue from the \$60 million upfront payment and \$11.3 million and \$30.8 million, respectively, as reimbursement for its out-of-pocket development costs. During the three and nine month periods ended September 30, 2006, the Company recognized \$5.1 million and \$14.5 million, respectively, of revenue from the \$60 million upfront payment and \$9.4 million and \$25.6 million, respectively, as reimbursement for its out-of-pocket development costs.

In addition, during May 2007, the Company earned \$9.0 million upon achievement of the two milestones anticipated in the Collaboration Agreement with Wyeth in connection with the submission and acceptance for review of an NDA for a subcutaneous formulation of methyl naltrexone with the FDA and a comparable submission in the European Union. The Company considered those two milestones to be substantive based on the degree of risk at the inception of the Collaboration Agreement of not achieving the milestones, the amount of the payment received relative to the costs incurred since inception of the Collaboration Agreement to achieve the milestones and the passage of seventeen months from inception of the Collaboration Agreement and the achievement of those two milestones. Therefore, the Company recognized as revenue, in the quarter ended June 30, 2007, the \$9.0 million earned from those two milestones. There were no milestones or contingent events that were achieved during the nine months ended September 30, 2006 for which revenue was recognized.

**7. Net Loss Per Share**

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of common shares outstanding during the respective periods. For the three and nine months ended September 30, 2007 and 2006, the Company reported a net loss and, therefore, no other potential common stock was included in the computation of diluted net loss per share since such inclusion would have been anti-dilutive. The calculations of net loss per share, basic and diluted, are as follows:

Net Loss	Shares	Per Share
(Numerator)	(Denominator)	Amount

**Three months ended September 30,  
2007**

Basic and Diluted	\$ (15,600)	26,976	\$ (0.58)
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**Nine months ended September 30,  
2007**

Basic and Diluted	\$ (28,416)	26,639	\$ (1.07)
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**Three months ended September 30,  
2006**

Basic and Diluted	\$ (2,935)	25,783	\$ (0.11)
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**Nine months ended September 30,  
2006**

Basic and Diluted	\$ (19,906)	25,570	\$ (0.78)
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continued (unaudited)**

(amounts in thousands, except per share amounts or unless otherwise noted)

Other potential common stock, which has been excluded from the diluted per share amounts because their effect would have been antidilutive, consist of the following:

	For the Three Months Ended September 30, 2007		2006	
	Wtd. Avg. Number	Wtd. Avg. Exercise Price	Wtd. Avg. Number	Wtd. Avg. Exercise Price
Stock options	4,832	\$ 17.90	4,856	\$ 15.74
Nonvested shares	512		369	
Total	5,344		5,225	

	For the Nine Months Ended September 30, 2007		2006	
	Wtd. Avg. Number	Wtd. Avg. Exercise Price	Wtd. Avg. Number	Wtd. Avg. Exercise Price
Stock options	4,688	\$ 17.36	4,625	\$ 14.79
Nonvested shares	428		286	
Total	5,116		4,911	

**8. Uncertain Tax Positions**

On January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement 109* (“FIN 48”). FIN 48 prescribes a comprehensive model for the manner in which a company should recognize, measure, present and disclose in its financial statements all material uncertain tax positions that the Company has taken or expects to take on a tax return. FIN 48 applies to income taxes and is not intended to be applied by analogy to other taxes, such as sales taxes, value-add taxes, or property taxes.

The Company has reviewed its nexus in various tax jurisdictions and its tax positions related to all open tax years for events that could change the status of its FIN 48 liability, if any, or require an additional liability to be recorded. Such events may be the resolution of issues raised by a taxing authority, expiration of the statute of limitations for a prior open tax year or new transactions for which a tax position may be deemed to be uncertain. Those positions, for which management’s assessment is that there is more than a 50 percent probability of sustaining the position upon challenge by a taxing authority based upon its technical merits, are subjected to the measurement criteria of FIN 48. The Company records the largest amount of tax benefit that is greater than 50 percent likely of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. Any FIN 48 liabilities for which the Company expects to make cash payments within the next twelve months are classified as “short term”.

Upon adoption of FIN 48 and through September 30, 2007, the Company had no unrecognized tax benefits. As of the date of adoption, there were no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months from the date of adoption of FIN 48 or from September 30, 2007. As of September 30, 2007, the Company is subject to federal and state income tax in the United States. Open tax years relate to years in which unused net operating losses were generated or, if used, for which the statute of limitation for examination by taxing authorities has not expired. Thus, upon adoption of FIN 48, the Company's open tax years extend back to 1995, with the exception of 1997, during which the Company reported net income. In the event that the Company concludes that it is subject to interest and/or penalties arising from uncertain tax positions, the Company will record interest and penalties as a component of income taxes. No amounts of interest or penalties were recognized in the Company's Condensed Consolidated Statements of Operations or Condensed Consolidated Balance Sheets upon adoption of FIN 48 or as of and for the nine months ended September 30, 2007.

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continued (unaudited)**

(amounts in thousands, except per share amounts or unless otherwise noted)

**9. Comprehensive Loss**

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. For the three and nine months ended September 30, 2007 and 2006, the components of comprehensive loss were:

	<b>For the Three Months Ended September 30,</b>		<b>For the Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net loss	\$ (15,600)	\$ (2,935)	\$ (28,416)	\$ (19,906)
Change in net unrealized gain (loss) on marketable securities	206	73	136	(123)
Comprehensive loss	\$ (15,394)	\$ (2,862)	\$ (28,280)	\$ (20,029)

**10. Commitments and Contingencies**

In the ordinary course of its business, the Company enters into agreements with third parties that include indemnification provisions which, in its judgment, are normal and customary for companies in its industry sector. These agreements are typically with business partners, clinical sites and suppliers. Pursuant to these agreements, the Company generally agrees to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to the Company's products or product candidates, use of such products or other actions taken or omitted by the Company. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is not limited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, the Company has no liabilities recorded for these provisions as of September 30, 2007.

**11. Impact of Recently Issued Accounting Standards**

On September 15, 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* ("FAS 157"), which addresses how companies should measure the fair value of assets and liabilities when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. FAS 157 does not expand the use of fair value in any new circumstances. Under FAS 157, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. FAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. In support of this principle, the standard establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data, for example, the reporting entity's own data. FAS 157 requires disclosures intended to provide information about (1) the extent to which companies measure assets and liabilities at fair value, (2) the methods and assumptions used to

measure fair value, and (3) the effect of fair value measures on earnings. The Company will adopt FAS 157 on January 1, 2008. The Company does not expect the impact of the adoption of FAS 157 to be material to its financial position or results of operations.

In February 2007, the FASB issued FASB Statement No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities* ("FAS 159"), which provides companies with an option to report certain financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. FAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The objective of FAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. FAS 159 is effective for fiscal years beginning after November 15, 2007. The Company does not expect the impact of the adoption of FAS 159 to be material to its financial position or results of operations.

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**PROGENICS PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —  
continued (unaudited)**

(amounts in thousands, except per share amounts or unless otherwise noted)

The Emerging Issues Task Force has issued an Exposure Draft on Issue 07-1, *Accounting for Collaborative Arrangements* (“EITF 07-1”). This issue impacts entities that have entered into arrangements which are not conducted through a separate legal entity. The Task Force reached a tentative conclusion that a collaborative arrangement is within the scope of EITF 07-1 if the arrangement meets the following two criteria: (i) the parties are active participants in the arrangement and (ii) the participants are exposed to significant risks and rewards that depend on the endeavor’s ultimate commercial success. The Task Force also reached a tentative conclusion that transactions with third parties (i.e., revenue generated and costs incurred by the partners) should be reported in the appropriate line item in each company’s financial statement pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Task Force also concluded tentatively that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. Comments will be considered by the Task Force at the November 28-29, 2007 EITF meeting. If the tentative conclusions are approved as a consensus, the guidance in EITF 07-1 would go into effect for periods that begin after December 15, 2007 and be accounted for as a change in accounting principle through retrospective application. The Company does not expect that there will be a material impact to its financial position or results of operations if the Exposure Draft is approved in its current form.

On September 27, 2007, the FASB reached a final consensus on Emerging Issues Task Force Issue 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (“EITF 07-03”). Currently, under FASB Statement No. 2, *Accounting for Research and Development Costs*, non-refundable advance payments for future research and development activities for materials, equipment, facilities, and purchased intangible assets that have no alternative future use are expensed as incurred. EITF 07-03 addresses whether such non-refundable advance payments for goods or services that have no alternative future use and that will be used or rendered for research and development activities should be expensed when the advance payments are made or when the research and development activities have been performed. The consensus reached by the FASB requires companies involved in research and development activities to capitalize such non-refundable advance payments for goods and services pursuant to an executory contractual arrangement because the right to receive those services in the future represents a probable future economic benefit. Those advance payments will be capitalized until the goods have been delivered or the related services have been performed. Entities will be required to evaluate whether they expect the goods or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment will be charged to expense. The consensus on EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Entities are required to recognize the effects of applying the guidance in EITF 07-03 prospectively for new contracts entered into after the effective date. The Company is in the process of evaluating the expected impact of EITF 07-03 on its financial position and results of operations following adoption.

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

**Special Note Regarding Forward-Looking Statements**

Certain statements in this Quarterly Report on Form 10-Q constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements contained herein that are not statements of historical fact may be forward-looking statements. When we use the words 'anticipates,' 'plans,' 'expects' and similar expressions, it is identifying forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, or industry results, to be materially different from any expected future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the risks associated with our dependence on Wyeth to fund and to conduct clinical testing, to make certain regulatory submissions and to manufacture and market products containing methylnaltrexone, the uncertainties associated with product development, the risk that clinical trials will not commence, proceed or be completed as planned, the risk that our products will not receive marketing approval from regulators, the risks and uncertainties associated with the dependence upon the actions of our corporate, academic and other collaborators and of government regulatory agencies, the risk that our licenses to intellectual property may be terminated because of our failure to have satisfied performance milestones, the risk that products that appear promising in early clinical trials are later found not to work effectively or are not safe, the risk that we may not be able to manufacture commercial quantities of our products, the risk that our products, if approved for marketing, do not gain market acceptance sufficient to justify development and commercialization costs, the risk that we will not be able to obtain funding necessary to conduct our operations, the uncertainty of future profitability and other factors set forth more fully in our Annual Report on Form 10-K for the year ended December 31, 2006 and in this Form 10-Q, including those described under the caption "Risk Factors", and other periodic filings with the Securities and Exchange Commission, to which investors are referred for further information.

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this Form 10-Q as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

**Overview**

*General*

We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. We commenced principal operations in late 1988, and since that time we have been engaged primarily in research and development efforts, development of our manufacturing capabilities, establishment of corporate collaborations and raising capital. We do not currently have any commercial products. In order to commercialize the principal products that we have under development, we will need to address a number of technological and clinical challenges and comply with comprehensive regulatory requirements. Accordingly, we cannot predict the amount of funds that we will require, nor the length of time that will pass, before we receive significant revenues from sales of any of our products, if ever.

*Gastroenterology*

Our most advanced product candidate and likeliest source of product revenue is methylnaltrexone. In December 2005, we entered into a License and Co-development Agreement (the "Collaboration Agreement") with Wyeth



Pharmaceuticals (“Wyeth”) to develop and commercialize methylnaltrexone. The Collaboration Agreement involves the development and commercialization of three formulations: (i) a subcutaneous formulation of methylnaltrexone, to be used in patients with opioid-induced constipation; (ii) an intravenous formulation of methylnaltrexone, to be used in patients with post-operative ileus (“POI”) and (iii) an oral formulation of methylnaltrexone, to be used in patients with opioid-induced constipation. Once marketing approval for each product is obtained, Wyeth is responsible for commercializing each of the three forms of methylnaltrexone worldwide.

Our work with methylnaltrexone has proceeded farthest as a treatment for opioid-induced constipation. We have successfully completed two pivotal phase 3 clinical trials of the subcutaneous formulation of methylnaltrexone in patients receiving palliative care, including patients with cancer, Acquired Immunodeficiency Syndrome (“AIDS”) and heart disease. We achieved positive results from our two pivotal phase 3 clinical trials (studies 301 and 302). All primary and secondary efficacy endpoints of both of the phase 3 studies were met and were statistically significant. The drug was generally well tolerated in both phase 3 trials.

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During March 2007, we submitted a New Drug Application (“NDA”) with the FDA for marketing approval in the United States for a subcutaneous formulation of methylnaltrexone for the treatment of opioid-induced constipation in patients receiving palliative care. In May 2007, Wyeth submitted a regulatory marketing application in the European Union for the same indication. Both applications were accepted for review in May 2007, which resulted in the Company earning a total of \$9.0 million in milestone payments under its Collaboration Agreement with Wyeth. The FDA review is expected to be completed by its Prescription Drug User Fee Act (“PDUFA”) date of January 30, 2008. In June 2007, the Company and Wyeth announced positive results in a three-month extension of the 302 study of a subcutaneous formulation of methylnaltrexone. In August 2007, Wyeth submitted a marketing application to the Therapeutic Goods Administration division of the Australian government, and in October 2007, the Company announced that Wyeth had submitted a New Drug Submission marketing application for subcutaneous methylnaltrexone to Health Canada, the Health Products and Food branch of the Canadian regulatory agency.

In September 2007, we and Wyeth announced the commencement of two additional clinical trials of the subcutaneous formulation of methylnaltrexone in patients outside of the palliative care population included in the first NDA submission: a phase 3 trial, conducted by Wyeth, in patients with chronic pain not related to cancer, such as chronic severe back pain that requires treatment with opioids; and a phase 2 trial, conducted by us, in patients rehabilitating from an orthopedic surgical procedure in whom opioids are used to control post-operative pain.

We are also developing an intravenous formulation of methylnaltrexone in collaboration with Wyeth for the management of POI, a serious condition of the gastrointestinal tract. We and Wyeth are conducting two global pivotal phase 3 clinical trials to evaluate the safety and efficacy of an intravenous formulation of methylnaltrexone for the treatment of POI. In September 2007, we and Wyeth announced the initiation of an additional phase 3 intravenous methylnaltrexone study, being conducted by Wyeth, in patients with POI following a ventral hernia repair via laparotomy or laparoscopy. Development of the intravenous formulation of methylnaltrexone for POI has been granted Fast Track status from the U.S. Food and Drug Administration.

Under the Collaboration Agreement, Wyeth is also developing an oral formulation of methylnaltrexone for the treatment of opioid-induced constipation in patients with chronic pain. Prior to the Collaboration Agreement, we had completed phase 1 clinical trials of an oral formulation of methylnaltrexone in healthy volunteers, which indicated that methylnaltrexone was well tolerated. In August 2006, Wyeth initiated a phase 2 clinical trial to evaluate once-daily dosing of an oral formulation of methylnaltrexone. Preliminary results from the phase 2 trial, conducted by Wyeth, showed that the initial oral formulation of methylnaltrexone was generally well tolerated but did not exhibit sufficient clinical activity to advance into phase 3 testing. In March 2007, Wyeth began clinical testing of a new oral formulation of methylnaltrexone for the treatment of opioid-induced constipation, and in July 2007 we announced positive preliminary results from a phase 1 clinical trial of this new oral formulation of methylnaltrexone. In October 2007, we announced plans to initiate two, four-week phase 2 clinical trials to evaluate daily dosing of oral methylnaltrexone in patients with chronic, non-malignant pain who are being treated with opioids and are experiencing opioid-induced constipation. Each study will separately evaluate a different oral formulation of methylnaltrexone, including the formulation that exhibited positive preliminary results in a phase 1 study announced in July 2007.

Wyeth made a \$60 million non-refundable upfront payment to us under the Collaboration Agreement at the time it was entered into, for which we deferred the recognition of revenue at December 31, 2005 since work under the Collaboration Agreement did not commence until January 2006. Wyeth has made \$14.0 million in milestone payments since that time and is obligated to make up to \$342.5 million in additional payments to us upon the achievement of milestones and contingent events in the development and commercialization of methylnaltrexone. Costs for the development of methylnaltrexone incurred by Wyeth or us starting January 1, 2006 are being paid by Wyeth. We are being reimbursed for our out-of-pocket development costs by Wyeth based on the number of our full time equivalent employees (“FTE’s”) devoted to the development project. Wyeth is obligated to pay to us royalties on the

sale by Wyeth of methylnaltrexone throughout the world during the applicable royalty periods.

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***Virology***

In the area of virology, we are developing viral-entry inhibitors for HIV and Hepatitis C virus infection, which are molecules designed to inhibit a virus' ability to enter certain types of immune cells and liver cells, respectively. In mid-2005, we announced positive phase 1 clinical findings related to PRO 140, a monoclonal antibody designed to target the HIV co-receptor CCR5, in healthy volunteers. On May 1, 2007, we announced positive results from the phase 1b trial of an intravenous formulation of PRO 140 in HIV-infected patients. Patients receiving a single 5.0 mg/kg dose of PRO 140, which was the highest dose tested, achieved an average maximum decrease of viral concentrations in the blood of 98.5% ( $1.83 \log_{10}$ ). In these patients, reductions in viral load of greater than 90% ( $1.0 \log_{10}$ ) on average persisted for two to three weeks after dosing. In addition, PRO 140 was generally well tolerated in this phase 1b proof-of-concept study. We are also developing a subcutaneous formulation of PRO 140 with the goal of developing a long-acting, self-administered therapy for HIV infection. PRO 140 has been granted Fast Track status from the U.S. Food and Drug Administration. We plan to initiate additional clinical testing of PRO 140 in the fourth quarter of 2007. We are also conducting research into therapeutics for hepatitis C virus infection that block viral entry into cells.

***Oncology***

We are developing immunotherapies for prostate cancer, including a monoclonal antibody-drug conjugate directed against prostate-specific membrane antigen ("PSMA"), a protein found on the surface of prostate cancer cells. We are also developing vaccines designed to stimulate an immune response to PSMA.

Index**Results of Operations (amounts in thousands)****Revenues:**

Our sources of revenue during the three and nine months ended September 30, 2007 and 2006 included our collaboration with Wyeth, our research grants and contracts and, to a small extent, our sale of research reagents.

Sources of Revenue	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2007	2006	Percent Change	2007	2006	Percent Change
Contract research from collaborator	\$ 14,540	\$ 14,527	0%	\$ 52,987	\$ 40,060	32%
Research grants and contract	2,471	3,316	(25%)	7,077	7,842	(10%)
Product sales	7	5	40%	48	70	(31%)
Total	\$ 17,018	\$ 17,848	(5%)	\$ 60,112	\$ 47,972	25%

**Contract research from collaborator**

During the three months ended September 30, 2007 and 2006, we recognized \$14,540 and \$14,527, respectively, of revenue from Wyeth, including \$3,219 and \$5,103, respectively, of the \$60,000 upfront payment we received upon entering into our collaboration in December 2005 and \$11,321 and \$9,424, respectively, as reimbursement of our development expenses, including our labor costs. During the nine months ended September 30, 2007 and 2006, we recognized \$52,987 and \$40,060, respectively, of revenue from Wyeth, including \$13,138 and \$14,466, respectively, of the \$60,000 upfront payment we received upon entering into our collaboration in December 2005, \$30,849 and \$25,594, respectively, as reimbursement of our development expenses, including our labor costs and \$9,000 of non-refundable milestone payments related to the acceptance for review of applications submitted for marketing approval of a subcutaneous formulation of methylnaltrexone in the U.S. and the European Union in the second quarter of 2007. From the inception of the Collaboration Agreement through September 30, 2007, we recognized \$31,968 of revenue from the \$60,000 upfront payment, \$65,433 as reimbursement for our out-of-pocket development costs, including our labor costs, and a total of \$14,000 for non-refundable milestone payments.

We recognize a portion of the upfront payment in each reporting period in accordance with the proportionate performance method, which is based on the percentage of actual effort performed on our development obligations in that period relative to total remaining effort estimated in the most recent budget approved by both us and Wyeth for our performance obligations under the arrangement. During the third quarter of 2007, the estimate of our total remaining effort to complete our development obligations was increased based upon a revised development budget approved by both us and Wyeth and the period over which those obligations will extend and over which the upfront payment will be amortized was extended from the end of 2008 to the end of 2009. As a result, the amount of revenue recognized from the upfront payment in the third quarter of 2007 declined to \$3,219 from \$5,103 in the third quarter of 2006. In prior quarters during 2006 and 2007, we had recognized an amount of revenue similar to that in the third quarter of 2006.

Reimbursement of development costs, including our labor costs, is recognized as revenue as the costs are incurred under the development plan agreed to by us and Wyeth. Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions

are met: (1) the milestone payment is non-refundable; (2) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved in achieving the milestone; (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and (5) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment. We have analyzed the facts and circumstances of the three milestones achieved since inception of the Collaboration Agreement with Wyeth and believe that they met those criteria for revenue recognition upon achievement of the respective milestones. See *Critical Accounting Policies –Revenue Recognition*, below.

Index**Research grants and contract**

Revenues from research grants and contract decreased to \$2,471 for the three months ended September 30, 2007 from \$3,316 for the three months ended September 30, 2006. Of those amounts, \$1,676 and \$2,585, respectively, were earned from grants and \$795 and \$731, respectively, were earned from the contract awarded to us by the National Institutes of Health in September 2003 (the "NIH Contract"). The decrease resulted from (i) an increase due to new grants awarded in 2007, offset by (ii) a decrease in remaining reimbursable expenses under some of the previously awarded grants, including \$13,100 in grants we were awarded during 2005, \$10,100 of which was to partially fund our PRO 140 program over a three and a half year period. In addition, there was increased activity under the NIH Contract. The NIH Contract provides for up to \$28,600 in funding to us over five years for preclinical research and development and early clinical testing of a vaccine designed to prevent HIV from infecting individuals exposed to the virus. A total of approximately \$3,700 is earmarked under the NIH Contract to fund such subcontracts. Funding under the NIH Contract is subject to compliance with its terms, including the annual approved budgets. The payment of an aggregate of \$1,600 in fees (of which \$180 had been recognized as revenue as of September 30, 2007) is subject to achievement of specified milestones.

Revenues from research grants and contract decreased slightly to \$7,077 for the nine months ended September 30, 2007 from \$7,842 for the nine months ended September 30, 2006. Of those amounts, \$4,256 and \$5,370 were earned from grants and \$2,821 and \$2,472 were earned from the NIH Contract for the nine months ended September 30, 2007 and 2006, respectively. The change resulted primarily from increased activity on the NIH Contract, which was partially offset by the completion of work on several grants prior to the first quarter of 2007 and the decrease in reimbursable grant expenses in the third quarter of 2007, as noted above.

**Product sales**

Revenues from product sales increased to \$7 for the three months ended September 30, 2007 from \$5 for the three months ended September 30, 2006. Revenues from product sales decreased to \$48 for the nine months ended September 30, 2007 from \$70 for the nine months ended September 30, 2006. We received fewer orders for research reagents during the first quarter of 2007 than in 2006, which was partially offset by an increase in orders for research reagents in the second and third quarters of 2007.

**Expenses:****Research and Development Expenses:**

Research and development expenses include scientific labor, supplies, facility costs, clinical trial costs, product manufacturing costs and license fees. Research and development expenses increased to \$24,247 for the three months ended September 30, 2007 from \$15,751 for the three months ended September 30, 2006 and increased to \$69,999 for the nine months ended September 30, 2007 from \$56,288 for the nine months ended September 30, 2006, as follows:

	<b>Three Months Ended</b>		<b>Percent</b>	<b>Nine Months Ended</b>		<b>Percent</b>
	<b>September 30,</b>		<b>Change</b>	<b>September 30,</b>		<b>Change</b>
	<b>2007</b>	<b>2006</b>		<b>2007</b>	<b>2006</b>	
<b>Salaries and benefits</b>						
<b>(cash)</b>	\$5,939	\$4,345	37%	\$17,876	\$12,150	47%

*Three Months:* Increase was due to Company-wide compensation increases and an increase in average headcount to 189 from 136 for the three months ended September 30, 2007 and 2006, respectively, in the research and development, manufacturing and clinical departments.

*Nine Months:* Increase was due to Company-wide compensation increases and an increase in average headcount to 186 from 129 for the nine months ended September 30, 2007 and 2006, respectively, in the research and development, manufacturing and clinical departments.



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	Three Months Ended September 30, 2007		Percent Change	Nine Months Ended September 30, 2007		Percent Change
<b>Share-based compensation (non-cash)</b>	\$1,829	\$1,655	11%	\$5,004	\$4,136	21%

*Three Months:* Increase due to increase in headcount and changes in the fair market value of our common stock (see *Critical Accounting Policies – Share-Based Payment Arrangements*, below). The amount of non-cash compensation expense is expected to increase in the future in conjunction with increased headcount.

*Nine Months:* Increase due to increase in headcount and changes in the fair market value of our common stock (see *Critical Accounting Policies – Share-Based Payment Arrangements*, below). The amount of non-cash compensation expense is expected to increase in the future in conjunction with increased headcount.

	Three Months Ended September 30, 2007		Percent Change	Nine Months Ended September 30, 2007		Percent Change
<b>Clinical trial costs</b>	\$6,124	\$1,896	223%	\$14,520	\$5,795	151%

*Three Months:* Clinical trial costs include the costs associated with conducting our clinical trials, but do not include the costs associated with manufacturing the compounds administered in the clinical trials, which costs are shown in Laboratory Supplies or Contract Manufacturing and Subcontractors, below. Increase primarily related to Methylantrexone (\$4,461) due to global pivotal phase 3 clinical trials for the intravenous formulation, which began in the fourth quarter of 2006. The increase was partially offset by decreases in HIV (\$195), resulting from a decrease in the PRO 140 phase 1b clinical trial activity in the 2007 period, and Cancer-related costs (\$38), due to a decrease in GMK-related costs resulting from our decision to terminate the GMK study in the second quarter of 2007. The decrease in GMK-related cancer costs was partially offset by an increase in PSMA-related costs in the 2007 period. During the remainder of 2007, clinical trial costs are expected to continue to increase as we conduct clinical trials of subcutaneous and intravenous formulations of methylantrexone and PRO 140.

*Nine Months:* Increase primarily related to Methylantrexone (\$9,511) due to global pivotal phase 3 clinical trials for the intravenous formulation, which began in the fourth quarter of 2006, and Other projects (\$2). The increases were partially offset by decreases in HIV (\$194), resulting from a decrease in the PRO 140 phase 1b clinical trial activity in 2007, and Cancer-related costs (\$594), due to a decrease in GMK-related costs resulting from our decision to terminate the GMK study in the second quarter of 2007. The decrease in GMK-related cancer costs was partially offset by an increase in PSMA-related costs in the 2007 period. During the remainder of 2007, clinical trial costs are expected to continue to increase as we conduct clinical trials of subcutaneous and intravenous formulations of methylantrexone and PRO 140.

	Three Months Ended September 30, 2007		Percent Change	Nine Months Ended September 30, 2007		Percent Change
<b>Laboratory supplies</b>	\$1,765	\$2,191	(19%)	\$5,616	\$4,261	32%

*Three Months:* Decrease primarily related to Methylnaltrexone (\$1,113) due to purchases of methylnaltrexone drug in the 2006 period for use in clinical trials but not in the 2007 period, and a decrease in basic research costs in 2007 for Cancer (primarily PSMA) (\$58), which were partially offset by an increase in HIV-related costs (\$369), due to internal manufacture of drug materials for use in future clinical trials in HIV and for Other projects (\$376).

*Nine Months:* Increase in HIV-related costs (\$800), due to internal manufacture of drug materials for use in future clinical trials, an increase in basic research costs in 2007 for Cancer (primarily PSMA) (\$197) and Other projects (\$1,040). The increases were partially offset by a decrease related to Methylnaltrexone (\$682) due to purchases of methylnaltrexone drug in the 2006 period for use in clinical trials but not in the 2007 period and computer software costs in 2007 but not in 2006 related to the preparation for submission of a New Drug Application in March 2007.

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	Three Months Ended September 30, 2007		Percent Change	Nine Months Ended September 30, 2007		Percent Change
<b>Contract manufacturing and subcontractors</b>	\$6,008	\$2,605	131%	\$17,906	\$8,651	107%

*Three Months:* Increase in HIV (\$1,470), Cancer (\$1,192), Methylalntrexone (\$30) and Other projects (\$711). These expenses include manufacture by third parties of materials for use in clinical trials as well as testing, analysis, formulation and toxicology services for the conduct of clinical trials and basic research, and vary as the timing and level of such services are required. We expect these costs to increase during the remainder of 2007 as we expand our clinical trial costs for methylalntrexone and PRO 140 and basic research for other projects.

*Nine Months:* Increase in HIV (\$4,430), Cancer (\$5,831) and Other projects (\$1,221), which were partially offset by a decrease in Methylalntrexone (\$2,227) related to clinical trials under our collaboration with Wyeth. These expenses include manufacture by third parties of materials for use in clinical trials as well as testing, analysis, formulation and toxicology services for the conduct of clinical trials and basic research, and vary as the timing and level of such services are required. We expect these costs to increase during the remainder of 2007 as we expand our clinical trial costs for methylalntrexone, PRO 140 and basic research for other projects.

	Three Months Ended September 30, 2007		Percent Change	Nine Months Ended September 30, 2007		Percent Change
<b>Consultants</b>	\$934	\$1,628	(43%)	\$3,636	\$3,722	(2%)

*Three Months:* Decrease in Methylalntrexone (\$957), partially offset by increases in HIV (\$218), Cancer (\$24), and Other projects (\$21). These expenses are related to the monitoring of clinical trials and analysis of data from completed clinical trials and basic research projects, which vary as the timing and level of such services are required. During the remainder of 2007, consultant expenses are expected to increase for all of our research and development programs.

*Nine Months:* Decrease in Methylalntrexone (\$682), partially offset by increases in HIV (\$322), Cancer (\$68) and Other projects (\$206). These expenses are related to the monitoring of clinical trials and analysis of data from completed clinical trials and basic research projects, which vary as the timing and level of such services are required. During 2007, consultant expenses are expected to increase for all of our research and development programs.

	Three Months Ended September 30, 2007		Percent Change	Nine Months Ended September 30, 2007		Percent Change
<b>License fees</b>	(\$16)	\$100	(116%)	\$833	\$528	58%

*Three Months:* Decrease primarily related to a reduction in the amount due in 2007 related to our HIV program (\$125), partially offset by an increase in payments under our programs in Cancer (\$9). The amounts of license fees for

the remainder of 2007 are expected to decrease relative to those for 2006.

*Nine Months:* Increase primarily related to payments in 2007 but not 2006 related to our Cancer program (\$428) and HIV program (\$31), partially offset by a decrease in Methylnaltrexone (\$154) related to payments to the University of Chicago. The amounts of license fees for the remainder of 2007 are expected to decrease relative to those for 2006.

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	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2007	2006		2007	2006	
<b>Other operating expenses</b>	\$1,664	\$1,331	25%	\$4,608	\$17,045	(73%)

*Three Months:* Increase primarily related to rent (\$377), which was partially offset by decreases in expenses related to travel (\$17), insurance (\$22), and other operating expenses (\$5). The increase in rent expense was due to additional space and rental rates in 2007. During the remainder of 2007 operating expenses are expected to increase over those of 2006, due to higher rent and facility expenses.

*Nine Months:* Decrease primarily due to \$13,209 of expense related to the acquisition of Cytogen's 50% interest in PSMA LLC during 2006 and an increase in expenses related to rent (\$382), facilities expenses (\$103), insurance (\$136) and other operating expenses (\$151). During the remainder of 2007, except for expenses related to the acquisition of Cytogen's interest in PSMA LLC, operating expenses are expected to increase over those of 2006, due to higher rent and facility expenses.

A major portion of our spending has been, and we expect will continue to be, associated with methylnaltrexone. Beginning in 2006, Wyeth has been reimbursing us for development expenses we incur related to methylnaltrexone under the development plan agreed to between us and Wyeth. Spending for our virology and oncology development programs is also expected to increase significantly during the remainder of 2007.

**General and Administrative Expenses:**

General and administrative expenses increased to \$9,275 for the three months ended September 30, 2007 from \$6,610 for the three months ended September 30, 2006 and to \$21,746 for the nine months ended September 30, 2007 from \$16,138 for the nine months ended September 30, 2006, as follows:

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2007	2006		2007	2006	
<b>Salaries and benefits (cash)</b>	\$1,641	\$1,556	5%	\$5,418	\$4,516	20%

*Three Months:* Increase due to compensation increases and an increase in average headcount to 42 from 34 in the general and administrative departments for the three months ended September 30, 2007 and 2006, respectively.

*Nine Months:* Increase due to compensation increases and an increase in average headcount to 42 from 30 in the general and administrative departments for the nine months ended September 30, 2007 and 2006, respectively, including the hiring of our Vice President, Commercial Development and Operations in January 2007.

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2007	2006		2007	2006	

<b>Share-based compensation (non-cash)</b>	\$4,337	\$2,731	59%	\$6,836	\$4,999	37%
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*Three Months:* Increase due to increased headcount and changes in the fair market value of our common stock (see *Critical Accounting Policies – Share-Based Payment Arrangements*, below). In addition, during the third quarter of 2007, stock options were granted to one new director and to the two co-chairmen of the Board of Directors. The amount of non-cash compensation expense is expected to increase in the future in conjunction with increased headcount.

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*Nine Months:* Increase due to increased headcount and changes in the fair market value of our common stock (see *Critical Accounting Policies – Share-Based Payment Arrangements*, below). In addition, during the third quarter of 2007, stock options were granted to one new director and to the two co-chairmen of the Board of Directors. The amount of non-cash compensation expense is expected to increase in the future in conjunction with increased headcount.

	Three Months Ended		Percent	Nine Months Ended		Percent
	September 30,		Change	September 30,		Change
	2007	2006		2007	2006	
<b>Consulting and professional fees</b>	\$1,856	\$1,461	27%	\$5,601	\$3,693	52%

*Three Months:* Increase due primarily to increases in legal and patent fees (\$458) and other miscellaneous costs (\$16), which were partially offset by decreases in consulting fees (\$20), recruiting fees (\$24) and audit and tax fees (\$35).

*Nine Months:* Increase due primarily to increases in consulting fees (\$638), recruiting fees (\$49), legal and patent fees (\$1,261) and other miscellaneous costs (\$51), which were partially offset by a decrease in audit and tax fees (\$91).

	Three Months Ended		Percent	Nine Months Ended		Percent
	September 30,		Change	September 30,		Change
	2007	2006		2007	2006	
<b>Other operating expenses</b>	\$1,441	\$862	67%	\$3,891	\$2,930	33%

*Three Months:* Increase in investor relations (\$40) and conference costs (\$19), corporate sales and franchise taxes (\$55), travel (\$54), computer supplies and software (\$47), rent (\$120) and other operating expenses (\$250) due to increased headcount, partially offset by a decrease in insurance (\$6). The increase in rent expense was due to additional space and increased rental rates in 2007. Other operating costs are expected to increase during the remainder of 2007.

*Nine Months:* Increase in investor relations (\$128) and conference costs (\$24), travel (\$102), computer supplies and software (\$142), rent (\$115) and other operating expenses (\$512) due to increased headcount, partially offset by a decrease in insurance (\$1) and corporate sales and franchise taxes (\$61). Other operating costs are expected to increase during the remainder of 2007.

We expect general and administrative expenses to increase during the remainder of 2007 due to an increase in headcount.

	Three Months Ended		Percent	Nine Months Ended		Percent
	September 30,		Change	September 30,		Change
	2007	2006		2007	2006	
<b>Loss in Joint Venture</b>	\$0	\$0	0%	\$0	\$121	(100%)

On April 20, 2006, PSMA LLC became our wholly owned subsidiary and, accordingly, we did not recognize loss in joint venture from the date of acquisition. During the nine months ended September 30, 2006, our 50% portion of the research and development expenses and general and administrative expenses of PSMA LLC was \$121.

	<b>Three Months Ended</b>		<b>Percent</b>	<b>Nine Months Ended</b>		<b>Percent</b>
	<b>September 30,</b>		<b>Change</b>	<b>September 30,</b>		<b>Change</b>
	<b>2007</b>	<b>2006</b>		<b>2007</b>	<b>2006</b>	
<b>Depreciation and amortization</b>	\$845	\$381	122%	\$2,144	\$1,106	94%

*Three Months:* Depreciation expense increased to \$845 for the three months ended September 30, 2007 from \$381 for the three months ended September 30, 2006. We purchased more capital assets and made more leasehold improvements in 2007 than in 2006 to increase our research and manufacturing capacity.



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*Nine Months:* Depreciation expense increased to \$2,144 for the nine months ended September 30, 2007 from \$1,106 for the nine months ended September 30, 2006. We purchased more capital assets and made more leasehold improvements in 2007 than in 2006 to increase our research and manufacturing capacity.

	Three Months Ended		Percent	Nine Months Ended		Percent
	September 30,		Change	September 30,		Change
	2007	2006		2007	2006	
<b>Other income</b>	\$1,749	\$1,959	(11%)	\$5,361	\$5,775	(7%)

*Three Months:* Interest income decreased to \$1,749 for the three months ended September 30, 2007 from \$1,959 for the three months ended September 30, 2006. Interest income, as reported, is primarily the result of investment income from our marketable securities, offset by the amortization of premiums and discounts we paid for those marketable securities. For the three months ended September 30, 2007 and 2006, investment income decreased to \$1,618 from \$1,931, respectively, due to a lower average balance of cash equivalents and marketable securities in 2007 than in 2006. Amortization of discounts net of premiums, which is included in interest income, increased to \$131 from \$28 for the three months ended September 30, 2007 and 2006, respectively.

*Nine Months:* Interest income decreased to \$5,361 for the nine months ended September 30, 2007 from \$5,775 for the nine months ended September 30, 2006. Interest income, as reported, is primarily the result of investment income from our marketable securities, offset by the amortization of premiums and discounts we paid for those marketable securities. For the nine months ended September 30, 2007 and 2006, investment income decreased to \$5,007 from \$5,802, respectively, due to a lower average balance of cash equivalents and marketable securities in 2007 than in 2006. Amortization of discounts net of premiums, which is included in interest income, decreased to (\$354) from \$27 for the nine months ended September 30, 2007 and 2006, respectively.

**Net Loss:**

Our net loss was \$15,600 for the three months ended September 30, 2007 compared to \$2,935 for the three months ended September 30, 2006 and \$28,416 for the nine months ended September 30, 2007 compared to \$19,906 for the nine months ended September 30, 2006.

**Liquidity and Capital Resources****Overview**

We have, to date, generated no meaningful amounts of product revenue, and consequently we have relied principally on external funding to finance our operations. We have funded our operations since inception primarily through private placements of equity securities, payments received under collaboration agreements, public offerings of common stock, funding under government research grants and contracts, interest on investments, the proceeds from the exercise of outstanding options and warrants and the sale of our common stock under our Employee Stock Purchase Plans. At September 30, 2007, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$183.6 million compared with \$149.1 million at December 31, 2006. Our existing cash, cash equivalents and marketable securities at September 30, 2007 are sufficient to fund current operations for at least one year. Our cash flow from operating activities was negative for the nine months ended September 30, 2007 and 2006 due primarily to the excess of expenditures on our research and development programs and general and administrative costs related to those programs over cash received from collaborators and government grants and contracts to fund such programs, as described below.

**Sources of Cash**

*Operating Activities*

Since January 2006, Wyeth has been reimbursing us for development expenses we incur related to methylnaltrexone under the development plan agreed to between us and Wyeth, which is currently expected to continue through 2009. Wyeth has and will continue to provide milestone and other contingent payments upon the achievement of certain events. Wyeth is also responsible for all commercialization activities related to methylnaltrexone products. For the nine months ended September 30, 2007, we received \$30.8 million of reimbursement of our development costs and \$9.0 million of milestone payments related to the acceptance for review of applications submitted for marketing approval of a subcutaneous formulation of methylnaltrexone in the U.S. and the European Union, which are within the development plan approved by the parties.

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The funding by Wyeth of our development costs for methylnaltrexone enables us to devote our current and future resources to our other research and development programs. We may also enter into collaboration agreements with respect to other of our product candidates. We cannot forecast with any degree of certainty, however, which products or indications, if any, will be subject to future collaborative arrangements, or how such arrangements would affect our capital requirements. The consummation of other collaboration agreements would further allow us to advance other projects with our current funds.

In September 2003, we were awarded a contract from the NIH. The NIH Contract provides for up to \$28.6 million in funding, subject to annual funding approvals, to us over five years for preclinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. These funds are being used principally in connection with our ProVax HIV vaccine program. A total of approximately \$3.7 million is earmarked under the NIH Contract to fund subcontracts. Funding under the NIH Contract is subject to compliance with its terms, and the payment of an aggregate of \$1.6 million in fees is subject to achievement of specified milestones. Through September 30, 2007, we had recognized revenue of \$12.2 million from this contract, including \$0.18 million for the achievement of two milestones.

We have also been awarded grants from the NIH, which provide ongoing funding for a portion of our virology and cancer research programs for periods including the nine months ended September 30, 2007 and 2006. Among those grants were an aggregate of \$4.4 million in grants made in 2006 and 2007. In addition, two awards were made during 2005, which provide for up to \$3.0 million and \$10.1 million, respectively, in support for our hepatitis C virus research program and PRO 140 HIV development program, respectively, to be awarded over a three year and a three and a half year period, respectively. Funding under all of our NIH grants and contract is subject to compliance with their terms, and is subject to annual funding approvals. For the nine months ended September 30, 2007 and 2006, we recognized \$4.3 million and \$5.4 million, respectively, of revenue from all of our NIH grants.

Changes in Accounts receivable and Accounts payable for the nine months ended September 2007 and 2006 resulted from the timing of receipts from the NIH and payments made to trade vendors in the normal course of business.

Other than amounts to be received from Wyeth and from currently approved grants and contracts, we have no committed external sources of capital. Other than potential revenues from methylnaltrexone, we expect no significant product revenues for a number of years as it will take at least that much time, if ever, to bring our products to the commercial marketing stage.

### ***Investing Activities***

We purchase and sell marketable securities in order to provide funding for our operations and to achieve appreciation of our unused cash in a low risk environment. Our marketable securities, which include corporate debt and securities of government-sponsored entities, are classified as available for sale. The majority of these investments have short maturities. Interest rate increases during 2007 have generally resulted in a minor decrease in the market value of our portfolio. Based upon our currently projected sources and uses of cash, we intend to hold these securities until a recovery of fair value, which may be maturity. Therefore, we do not consider these marketable securities to be other-than-temporarily impaired at September 30, 2007.

### ***Financing Activities***

On September 25, 2007, we completed a public offering of 2.6 million shares of our common stock, pursuant to a shelf registration statement that had been filed with the Securities and Exchange Commission in 2006, which had registered 4.0 million shares of our common stock. We received proceeds of \$57.3 million, or \$22.04 per share, which was net of underwriting discounts and commissions of approximately \$2.9 million, and paid approximately \$0.17

million in other offering expenses. We anticipate using the net proceeds to fund clinical trials of our product candidates and for research and development projects. We may also use the proceeds for other corporate purposes, including potential acquisitions of technology or companies in complementary fields.

Unless we obtain regulatory approval from the FDA for at least one of our product candidates and/or enter into agreements with corporate collaborators with respect to the development of our technologies in addition to that for methylnaltrexone, we will be required to fund our operations for periods in the future, by seeking additional financing through future offerings of equity or debt securities or funding from additional grants and government contracts. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize the future success of our business.

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During the nine months ended September 30, 2007 and 2006, we received cash of \$6.1 million and \$5.3 million, respectively, from the exercise of stock options by employees, directors and non-employee consultants and from the sale of our common stock under our Employee Stock Purchase Plans. The amount of cash we receive from these sources is greater with increases in headcount and with increases in the price of our common stock on the grant date for options exercised, and on the sale date for shares sold under our Employee Stock Purchase Plans.

**Uses of Cash*****Operating Activities***

Our total expenses for research and development from inception through September 30, 2007 have been approximately \$367.2 million. We currently have major research and development programs investigating gastroenterology, virology and oncology. In addition, we are conducting several smaller research projects in the areas of virology and oncology. For various reasons, many of which are outside of our control, including the early stage of certain of our programs, the timing and results of our clinical trials and our dependence in certain instances on third parties, we cannot estimate the total remaining costs to be incurred and timing to complete our research and development programs.

For the nine months ended September 30, 2007 and 2006, research and development costs incurred were as follows. Expenses for Cancer for the nine months ended September 30, 2006 include \$13.2 million related to our purchase of Cytogen's interest in our PSMA joint venture.

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(in millions)</b>	
Methylnaltrexone	\$ 30.9	\$ 23.2
HIV	19.1	11.3
Cancer	13.5	19.3
Other programs	6.5	2.5
<b>Total</b>	<b>\$ 70.0</b>	<b>\$ 56.3</b>

Although we expect that our spending on methylnaltrexone will increase during the remainder of 2007, our cash outlays in accordance with the agreed upon development plan will be reimbursed by Wyeth. We also expect that spending on our PRO 140 and other programs will increase substantially during 2007 and beyond. Consequently, we may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, for the cost of product in-licensing and for any possible acquisitions. Manufacturing and commercialization expenses for methylnaltrexone will be funded by Wyeth. However, if we exercise our option to co-promote methylnaltrexone products in the U.S., which must be approved by Wyeth, we will be required to establish and fund a sales force, which we currently do not have. If we commercialize any other product candidate other than with a corporate collaborator, we would also require additional funding to establish manufacturing and marketing capabilities.

Our purchase of rights from our methylnaltrexone licensors in December 2005 has extinguished our cash payments that would have been due to those licensors in the future upon the achievement of certain events, including sales of methylnaltrexone products. We continue, however, to be responsible to make payments (including royalties) to the University of Chicago upon the occurrence of certain events.

***Investing Activities***

During the nine months ended September 30, 2007 and 2006, we have spent \$4.4 million and \$6.5 million, respectively, on capital expenditures, including the expansion of our office, laboratories and manufacturing facilities and the purchase of more laboratory equipment for our ongoing and future research and development projects. During the remainder of 2007 and beyond, we expect further expenditures as we continue to lease and renovate additional laboratory, manufacturing and office space and increase headcount of our research and development and administrative staff.

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Our funding requirements, both for the next 12 months and beyond, will include required payments under operating leases and licensing and collaboration agreements. The following table summarizes our contractual obligations as of September 30, 2007 for future payments under these agreements:

	Total	Payments due by September 30,			
		2008	2009-2010	2011-2012	Thereafter
			(in millions)		
Operating leases	\$ 7.7	\$ 2.8	\$ 3.8	\$ 0.7	\$ 0.4
License and collaboration agreements (1)	99.4	3.0	6.5	4.2	85.7
Total	\$ 107.1	\$ 5.8	\$ 10.3	\$ 4.9	\$ 86.1

(1) Assumes attainment of milestones covered under each agreement, including those by PSMA LLC. The timing of the achievement of the related milestones is highly uncertain, and accordingly the actual timing of payments, if any, is likely to vary, perhaps significantly, relative to the timing contemplated by this table.

For each of our programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. Because of the uncertainties associated with research and development of these programs, the duration and completion costs of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements could significantly increase our capital requirements and adversely impact our liquidity.

Our cash requirements may vary materially from those now planned because of results of research and development and product testing, changes in existing relationships or new relationships with, licensees, licensors or other collaborators, changes in the focus and direction of our research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory approval process, manufacturing and marketing and other costs associated with the commercialization of products following receipt of regulatory approvals and other factors.

The above discussion contains forward-looking statements based on our current operating plan and the assumptions on which it relies. There could be changes that would consume our assets earlier than planned.

**Off-Balance Sheet Arrangements and Guarantees**

We have no off-balance sheet arrangements and do not guarantee the obligations of any other unconsolidated entity.

**Critical Accounting Policies**

We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America. Our significant accounting policies are disclosed in Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2006. The selection and application of these accounting principles and methods requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as certain financial statement disclosures. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our evaluation form the basis for making judgments about the carrying values of assets and liabilities that are not otherwise readily apparent. While we believe that the

estimates and assumptions we use in preparing the financial statements are appropriate, these estimates and assumptions are subject to a number of factors and uncertainties regarding their ultimate outcome and, therefore, actual results could differ from these estimates.

We have identified our critical accounting policies and estimates below. These are policies and estimates that we believe are the most important in portraying our financial condition and results of operations, and that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We have discussed the development, selection and disclosure of these critical accounting policies and estimates with the Audit Committee of our Board of Directors.



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*Revenue Recognition*

On December 23, 2005, we entered into a license and co-development agreement with Wyeth, which includes a non-refundable upfront license fee, reimbursement of development costs, research and development payments based upon our achievement of clinical development milestones, contingent payments based upon the achievement by Wyeth of defined events and royalties on product sales. We began recognizing contract research revenue from Wyeth on January 1, 2006. During the nine months ended September 30, 2007 and 2006, we also recognized revenue from government research grants and contracts, which are used to subsidize a portion of certain of our research projects (“Projects”), exclusively from the NIH. We also recognized revenue from the sale of research reagents during those periods. We recognize revenue from all sources based on the provisions of the Securities and Exchange Commission’s Staff Accounting Bulletin No. 104 (“SAB 104”) *Revenue Recognition*, Emerging Issues Task Force Issue No. 00-21 (“EITF 00-21”) *Accounting for Revenue Arrangements with Multiple Deliverables* and EITF Issue No. 99-19 (“EITF 99-19”) *Reporting Revenue Gross as a Principal Versus Net as an Agent*.

Non-refundable upfront license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables, which often include a license and performance obligations, such as research and steering committee services, can be separated in accordance with EITF 00-21. We would recognize upfront license payments as revenue upon delivery of the license only if the license had standalone value and the fair value of the undelivered performance obligations, typically including research or steering committee services, could be determined. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations could not be determined, the upfront license payments would be recognized as revenue over the estimated period of when our performance obligations are performed.

We must determine the period over which the performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents will typically be used as the measure of performance. Under the proportionate performance method, revenue related to upfront license payments is recognized in any period as the percent of actual effort expended in that period relative to total effort estimated in the most current budget approved by both Wyeth and us for all of our performance obligations under the arrangement. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement. Those judgments are based on the expertise of our project leaders regarding the estimated amount of effort, in terms of full-time equivalent employees, required to accomplish the development tasks specified in each approved budget. In turn, the approval by each party of the tasks that we are required to accomplish within the timeframe of an approved budget is the result of a process of discussion between the parties.

During the period of an approved budget, the amount of the upfront license payment that is recognized as revenue in any period will increase or decrease as the percentage of actual effort increases or decreases, as described above. When a new budget is approved, generally annually, the remaining unrecognized amount of the upfront license fee will be recognized prospectively, using the methodology described above to apply any changes in the total estimated effort or period of development that is specified in the revised approved budget. Although the amounts of the upfront license payment that we recognized as revenue for each fiscal quarter prior to the third quarter of 2007 were based upon several revised approved budgets, those amounts were not materially impacted by the revised budgets. During

the third quarter of 2007, the estimate of our total remaining effort to complete our development obligations was increased based upon a revised development budget approved by both us and Wyeth and the period over which those obligations will extend and over which the upfront payment will be amortized was extended from the end of 2008 to the end of 2009. As a result, the amount of revenue recognized from the upfront payment in the third quarter of 2007 declined to \$3.2 million from \$5.1 million in the third quarter of 2006. In prior quarters during 2006 and 2007, we had recognized an amount of revenue similar to that in the third quarter of 2006. The decline in revenue recognized from the upfront payment is expected to be similar in the fourth quarter of 2007. Due to the significant judgments involved in determining the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement, further changes in any of these judgments are reasonably likely to occur in the future which could have a material impact on our revenue recognition. If a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an upfront payment at the time of the termination.

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If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement and the performance obligations are provided on a best-efforts basis, then the total upfront license payments would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations.

In addition, if we are involved in a steering committee as part of a multiple element arrangement, we assess whether our involvement constitutes a performance obligation or a right to participate.

Collaborations may also contain substantive milestone payments. Substantive milestone payments are considered to be performance payments that are recognized upon achievement of the milestone only if all of the following conditions are met: (1) the milestone payment is non-refundable; (2) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved in achieving the milestone; (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and (5) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment (the “Substantive Milestone Method”).

Determination as to whether a milestone meets the aforementioned conditions involves management’s judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone and, therefore, the resulting payment would be recognized as revenue as such performance obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

We will recognize revenue for payments that are contingent upon performance solely by our collaborator immediately upon the achievement of the defined event if we have no related performance obligations.

Reimbursement of costs is recognized as revenue provided the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

Royalty revenue is recognized upon the sale of related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the arrangement. If royalties are received when we have remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and, therefore, would be recognized as such performance obligations are performed under either the proportionate performance or straight-line methods, as applicable, and in accordance with the policies described above.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year of the balance sheet date are classified as long-term deferred revenue. The estimate of the classification of deferred revenue as short-term or long-term is based upon management’s current operating budget for the Wyeth collaboration agreement for our total effort required to complete our performance obligations under that arrangement. That estimate may change in the future and such changes to estimates would result in a change in the amount of revenue recognized in future periods.

NIH grant and contract revenue is recognized as efforts are expended and as related subsidized Project costs are incurred. We perform work under the NIH grants and contract on a best-effort basis. The NIH reimburses us for costs associated with Projects in the fields of virology and cancer, including preclinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus, as requested by the NIH. Substantive at-risk milestone payments are uncommon in

these arrangements, but would be recognized as revenue on the same basis as the Substantive Milestone Method.

*Share-Based Payment Arrangements*

Our share-based compensation to employees includes non-qualified stock options, restricted stock (nonvested shares) and shares issued under our Employee Stock Purchase Plans (the "Purchase Plans"), which are compensatory under Statement of Financial Accounting Standards No. 123 (revised 2004) *Share-Based Payment* ("SFAS No. 123(R)"). We account for share-based compensation to non-employees, including non-qualified stock options and restricted stock (nonvested shares), in accordance with Emerging Issues Task Force Issue No. 96-18 *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Connection with Selling, Goods or Services*.

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We adopted SFAS No. 123(R) using the modified prospective application, under which compensation cost for all share-based awards that were unvested as of the adoption date and those newly granted or modified after the adoption date are recognized in our financial statements over the related requisite service periods; usually the vesting periods for awards with a service condition. Compensation cost is based on the grant-date fair value of awards that are expected to vest. We apply a forfeiture rate to the number of unvested awards in each reporting period in order to estimate the number of awards that are expected to vest. Estimated forfeiture rates are based upon historical data on vesting behavior of employees. We adjust the total amount of compensation cost recognized for each award, in the period in which each award vests, to reflect the actual forfeitures related to that award. Changes in our estimated forfeiture rate will result in changes in the rate at which compensation cost for an award is recognized over its vesting period. We have made an accounting policy decision to use the straight-line method of attribution of compensation expense, under which the grant date fair value of share-based awards will be recognized on a straight-line basis over the total requisite service period for the total award.

Under SFAS No. 123(R), the fair value of each non-qualified stock option award is estimated on the date of grant using the Black-Scholes option pricing model, which requires input assumptions of stock price on the date of grant, exercise price, volatility, expected term, dividend rate and risk-free interest rate.

- We use the closing price of our common stock on the date of grant, as quoted on The NASDAQ Stock Market LLC, as the exercise price.
- Historical volatilities are based upon daily quoted market prices of our common stock on The NASDAQ Stock Market LLC over a period equal to the expected term of the related equity instruments. We rely only on historical volatility since future volatility is expected to be consistent with historical; historical volatility is calculated using a simple average calculation; historical data is available for the length of the option's expected term and a sufficient number of price observations are used consistently. Since our stock options are not traded on a public market, we do not use implied volatility. For the nine months ended September 30, 2007 and 2006, the volatility of our common stock for periods equal to the expected term of options granted during those periods has been high, 52% - 85% and 88%, respectively, which is common for entities in the biotechnology industry that do not have commercial products. A higher volatility input to the Black-Scholes model increases the resulting compensation expense.
- The expected term of options granted represents the period of time that options granted are expected to be outstanding. For the nine months ended September 30, 2007, our expected term has been calculated based upon historical data related to exercise and post-termination cancellation activity for each of two groups of recipients of stock options: employees, and officers and directors. Accordingly, for grants made to each of the groups mentioned above, we are using expected terms of 5.25 and 7.5 years, respectively. For the nine months ended September 30, 2006, our expected term was calculated based upon the simplified method as detailed in Staff Accounting Bulletin No. 107 ("SAB 107"). We used an expected term of 6.5 years for options granted in 2006, based upon the vesting period of the outstanding options of four or five years and a contractual term of ten years. Expected term for options granted to non-employee consultants was ten years, which is the contractual term of those options. A shorter expected term would result in a lower compensation expense.
- We have never paid dividends and do not expect to pay dividends in the future. Therefore, our dividend rate is zero.
- The risk-free rate for periods within the expected term of the options is based on the U.S. Treasury yield curve in effect at the time of grant.

A portion of the options granted to our Chief Executive Officer on July 1, 2002, 2003, 2004 and 2005, on July 3, 2006 and July 2, 2007 cliff vests after nine years and eleven months from the respective grant date. Vesting of a defined

portion of each award will occur earlier if a defined performance condition is achieved; more than one condition may be achieved in any period. In accordance with SFAS No. 123(R), at the end of each reporting period, we will estimate the probability of achievement of each performance condition and will use those probabilities to determine the requisite service period of each award. The requisite service period for the award is the shortest of the explicit or implied service periods. In the case of the executive's options, the explicit service period is nine years and eleven months from the respective grant dates. The implied service periods related to the performance conditions are the estimated times for each performance condition to be achieved. Thus, compensation expense will be recognized over the shortest estimated time for the achievement of performance conditions for that award (assuming that the performance conditions will be achieved before the cliff vesting occurs). Changes in the estimate of probability of achievement of any performance condition will be reflected in compensation expense of the period of change and future periods affected by the change.

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The fair value of shares purchased under the Purchase Plans is estimated on the date of grant in accordance with FASB Technical Bulletin No. 97-1 *Accounting under Statement 123 for Certain Employee Stock Purchase Plans with a Look-Back Option*. The same option valuation model is used for the Purchase Plans as for non-qualified stock options, except that the expected term for the Purchase Plans is six months and the historical volatility is calculated over the six month expected term.

In applying the treasury stock method for the calculation of diluted earnings per share (“EPS”), amounts of unrecognized compensation expense and windfall tax benefits are required to be included in the assumed proceeds in the denominator of the diluted earnings per share calculation unless they are anti-dilutive. We incurred a net loss for the three and nine months ended September 30, 2007 and 2006, and, therefore, such amounts have not been included for those periods in the calculation of diluted EPS since they would be anti-dilutive. Accordingly, basic and diluted EPS are the same for those periods. We have made an accounting policy decision to calculate windfall tax benefits/shortfalls for purposes of diluted EPS calculations, excluding the impact of pro forma deferred tax assets. This policy decision will apply when we have net income.

For the nine months ended September 30, 2007, no tax benefit was recognized related to total compensation cost for share-based payment arrangements recognized in operations because we had a net loss for the period and the related deferred tax assets were fully offset by a valuation allowance. Accordingly, no amounts related to windfall tax benefits have been reported in cash flows from operations or cash flows from financing activities for the nine months ended September 30, 2007.

### *Research and Development Expenses Including Clinical Trial Expenses*

Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from our contracts with various clinical investigators and clinical research organizations in connection with conducting clinical trials for our product candidates. Such costs are expensed based on the expected total number of patients in the trial, the rate at which the patients enter the trial and the period over which the clinical investigators and clinical research organizations are expected to provide services. We believe that this method best approximates the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates. We expect that clinical trial expenses will increase significantly during 2007 as clinical trials progress or are initiated in the methylnaltrexone and HIV programs. Our collaboration agreement with Wyeth regarding methylnaltrexone in which Wyeth has assumed all of the financial responsibility for further development will mitigate those costs. In addition, we estimate the amounts of other research and development expenses, for which invoices have not been received at the end of a period, based upon communication with third parties that have provided services or goods during the period.

### **Impact of Recently Issued Accounting Standards**

On September 15, 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* (“FAS 157”), which addresses how companies should measure the fair value of assets and liabilities when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. FAS 157 does not expand the use of fair value in any new circumstances. Under FAS 157, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. FAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. In support of this principle, the standard establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data, for example, the reporting entity’s own data. FAS 157 requires disclosures intended to provide information about (1) the extent to which companies measure assets and liabilities at fair value, (2) the methods and assumptions used to

measure fair value, and (3) the effect of fair value measures on earnings. We will adopt FAS 157 on January 1, 2008. We do not expect the impact of the adoption of FAS 157 to be material to our financial position or results of operations.

In February, 2007, the FASB issued FASB Statement No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities* ("FAS 159"), which provides companies with an option to report certain financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. FAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The objective of FAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. FAS159 is effective for fiscal years beginning after November 15, 2007. We do not expect the impact of the adoption of FAS 159 to be material to our financial position or results of operations.



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The Emerging Issues Task Force has issued an Exposure Draft on Issue 07-1, *Accounting for Collaborative Arrangements* ("EITF 07-1"). This issue impacts entities that have entered into arrangements, which are not conducted through a separate legal entity. The Task Force reached a tentative conclusion that a collaborative arrangement is within the scope of EITF 07-1 if the arrangement meets the following two criteria: (i) the parties are active participants in the arrangement and (ii) the participants are exposed to significant risks and rewards that depend on the endeavor's ultimate commercial success. The Task Force also reached a tentative conclusion that transactions with third parties (i.e., revenue generated and costs incurred by the partners) should be reported in the appropriate line item in each company's financial statement pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Task Force also concluded tentatively that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. Comments will be considered by the Task Force at the November 28-29, 2007 EITF meeting. If the tentative conclusions are approved as a consensus, the guidance in EITF 07-1 would go into effect for periods that begin after December 15, 2007 and be accounted for as a change in accounting principle through retrospective application. We do not expect that there will be a material impact to our financial position or results of operations if the Exposure Draft is approved in its current form.

On September 27, 2007, the FASB reached a final consensus on Emerging Issues Task Force Issue 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-03"). Currently, under FASB Statement No. 2, *Accounting for Research and Development Costs*, non-refundable advance payments for future research and development activities for materials, equipment, facilities, and purchased intangible assets that have no alternative future use are expensed as incurred. EITF 07-03 addresses whether such non-refundable advance payments for goods or services that have no alternative future use and that will be used or rendered for research and development activities should be expensed when the advance payments are made or when the research and development activities have been performed. The consensus reached by the FASB requires companies involved in research and development activities to capitalize such non-refundable advance payments for goods and services pursuant to an executory contractual arrangement because the right to receive those services in the future represents a probable future economic benefit. Those advance payments will be capitalized until the goods have been delivered or the related services have been performed. Entities will be required to evaluate whether they expect the goods or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment will be charged to expense. The consensus on EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Entities are required to recognize the effects of applying the guidance in EITF 07-03 prospectively for new contracts entered into after the effective date. We are in the process of evaluating the expected impact of EITF 07-03 on our financial position and results of operations following adoption.

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

Our primary investment objective is to preserve principal while maximizing yield without significantly increasing our risk. Our investments consist of taxable auction securities, corporate notes and federal agency issues. Our investments totaled \$177.3 million at September 30, 2007. Approximately \$92.7 million of these investments had fixed interest rates, and \$84.6 million had interest rates that were variable.

Due to the conservative nature of our short-term fixed interest rate investments, we do not believe that we have a material exposure to interest rate risk for those investments. Our fixed-interest-rate long-term investments are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair values of these investments due to differences between the market interest rate and the rate at the date of purchase of the investment. A 100 basis point increase in the September 30, 2007 market interest rates would result in a decrease of approximately

\$0.07 million in the market values of these investments.

#### **Item 4. Controls and Procedures**

The Company maintains “disclosure controls and procedures,” as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, that are designed to ensure that information required to be disclosed in the Company’s Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the Company’s management, including its Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, the Company’s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and the Company’s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We also established a Disclosure Committee that consists of certain members of the Company’s senior management.

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The Disclosure Committee, under the supervision and with the participation of the Company's senior management, including the Company's Chief Executive Officer and Principal Financial and Accounting Officer, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Principal Financial and Accounting Officer concluded that the Company's disclosure controls and procedures were effective.

There have been no changes in the Company's internal control over financial reporting that occurred during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II - OTHER INFORMATION**

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

Our business and operations entail a variety of serious risks and uncertainties, including those described below.

#### **Our product development programs are inherently risky.**

We are subject to the risks of failure inherent in the development of product candidates based on new technologies.

Methylnaltrexone, which is designed to reverse certain side effects induced by opioids and to treat postoperative ileus and is being developed through a collaboration with Wyeth, is based on a novel method of action that has not yet been proven to be safe or effective. No drug with methylnaltrexone's method of action has ever received marketing approval. Additionally, our principal HIV product candidate, PRO 140, is designed to be effective by blocking viral entry. To our knowledge, no drug designed to treat HIV infection by blocking viral entry (with one exception) has been approved for marketing in the U.S. Our other research and development programs, including those related to PSMA, involve similarly novel approaches to human therapeutics. Consequently, there is little precedent for the successful commercialization of products based on our technologies. There are a number of technological challenges that we must overcome to complete most of our development efforts. We may not be able to develop successfully any of our products.

#### **We have granted to Wyeth the exclusive rights to develop and commercialize methylnaltrexone, our lead product candidate, and our resulting dependence upon Wyeth exposes us to significant risks.**

In December 2005, we entered into a license and co-development agreement with Wyeth. Under this agreement, we granted to Wyeth the exclusive worldwide right to develop and commercialize methylnaltrexone, our lead product candidate. As a result, we are dependent upon Wyeth to perform and fund development, including clinical testing, to make certain regulatory filings and to manufacture and market products containing methylnaltrexone. Our collaboration with Wyeth may not be scientifically, clinically or commercially successful.

Any revenues from the sale of methylnaltrexone, if approved for marketing by the FDA, will depend almost entirely upon the efforts of Wyeth. Wyeth has significant discretion in determining the efforts and resources it applies to sales of the methylnaltrexone products and may not be effective in marketing such products. In addition, Wyeth is a large, diversified pharmaceutical company with global operations and its own corporate objectives, which may not be consistent with our best interests. For example, Wyeth may change its strategic focus or pursue alternative technologies in a manner that results in reduced revenues to us. In addition, we will receive milestone and contingent payments from Wyeth only if methylnaltrexone achieves specified clinical, regulatory and commercialization

milestones, and we will receive royalty payments from Wyeth only if methylnaltrexone receives regulatory approval and is commercialized by Wyeth. Many of these milestone events will depend upon the efforts of Wyeth. We may not receive any milestone, contingent or royalty payments from Wyeth.

The Collaboration Agreement extends, unless terminated earlier, on a country-by-country and product-by-product basis, until the last-to-expire royalty period, as defined, for any product. Progenics may terminate the Collaboration Agreement at any time upon 90 days of written notice to Wyeth (30 days in the case of breach of a payment obligation) upon material breach that is not cured. Wyeth may, with or without cause, following the second anniversary of the first commercial sale, as defined, of the first commercial product in the U.S., terminate the Collaboration Agreement by providing Progenics with at least 360 days prior written notice of such termination. Wyeth may also terminate the agreement (i) upon 30 days written notice following one or more serious safety or efficacy issues that arise, as defined, and (ii) at any time, upon 90 days written notice of a material breach that is not cured by Progenics. Upon termination of the Collaboration Agreement, the ownership of the license we granted to Wyeth will depend on the party that initiates the termination and the reason for the termination.

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If our relationship with Wyeth were to terminate, we would have to either enter into a license and co-development agreement with another party or develop and commercialize methylnaltrexone ourselves. We may not be able to enter into such an agreement with another suitable company on acceptable terms or at all. To develop and commercialize methylnaltrexone on our own, we would have to develop a sales and marketing organization and a distribution infrastructure, neither of which we currently have. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability.

Moreover, a termination of our relationship with Wyeth could seriously compromise the development program for methylnaltrexone. For example, we could experience significant delays in the development of methylnaltrexone and would have to assume full funding and other responsibility for further development and eventual commercialization.

Any of these outcomes would result in delays in our ability to distribute methylnaltrexone and would increase our expenses, which would have a material adverse effect on our business, results of operations and financial condition.

Our collaboration with Wyeth is multi-faceted and involves a complex sharing of control over decisions, responsibilities, costs and benefits. There are numerous potential sources of disagreement between us and Wyeth, including with respect to product development, marketing strategies, manufacturing and supply issues and rights relating to intellectual property. Wyeth has significantly greater financial and managerial resources than we do, which it could draw upon in the event of a dispute. A disagreement between Wyeth and us could lead to lengthy and expensive litigation or other dispute-resolution proceedings as well as to extensive financial and operational consequences to us, and have a material adverse effect on our business, results of operations and financial condition.

**If testing does not yield successful results, our products will not be approved.**

We will need to obtain regulatory approval before we can market our product candidates. To obtain marketing approval from regulatory authorities, we or our collaborators must demonstrate a product's safety and efficacy through extensive preclinical and clinical testing. Numerous adverse events may arise during, or as a result of, the testing process, including the following:

- the results of preclinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- potential products may not have the desired efficacy or may have undesirable side effects or other characteristics that preclude marketing approval or limit their commercial use if approved;
- after reviewing test results, we or our collaborators may abandon projects, which we previously believed to be promising; and
- we, our collaborators or regulators may suspend or terminate clinical trials if we or they believe that the participating subjects or patients are being exposed to unacceptable health risks.

Clinical testing is very expensive and can take many years. Results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials. In addition, many of our products, such as PRO 140 and the PSMA product candidates, are at an early stage of development. The successful commercialization of early stage products will require significant further research, development, testing, approvals by regulators and additional investment. Our products in the research or preclinical development stage may not yield results that would permit or

justify clinical testing. Our failure to adequately demonstrate the safety and efficacy of a product under development would delay or prevent marketing approval of the product, which could adversely affect our operating results and credibility.

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**A setback in our clinical development programs could adversely affect us.**

We have successfully completed two pivotal phase 3 clinical trials of subcutaneous methylnaltrexone for the treatment of opioid-induced constipation in patients receiving palliative care. We submitted a New Drug Application to the FDA in March 2007 to market subcutaneous methylnaltrexone. We and Wyeth have initiated two global pivotal phase 3 clinical trials to evaluate the safety and efficacy of intravenous methylnaltrexone for the treatment of post-operative ileus. We had completed phase 1 clinical trials of oral methylnaltrexone in healthy volunteers prior to our Collaboration Agreement with Wyeth. Wyeth is responsible for the worldwide development of oral methylnaltrexone. Wyeth has conducted certain additional phase 1 clinical trials of oral methylnaltrexone in chronic-pain patients who experience opioid-induced constipation and in August 2006 initiated a phase 2 clinical trial to evaluate once-daily dosing of oral methylnaltrexone. Preliminary results from this phase 2 trial, conducted by Wyeth, showed that the initial formulation of oral methylnaltrexone was generally well tolerated but did not exhibit sufficient clinical activity to advance into phase 3 testing. In March 2007, Wyeth began clinical testing of a new oral formulation of methylnaltrexone for the treatment of opioid-induced constipation and in July 2007 announced preliminary results from a phase 1 clinical trial of this new formulation. In October 2007, we and Wyeth announced plans to initiate two, four-week phase 2 clinical trials to evaluate daily dosing of oral methylnaltrexone in patients with chronic, non-malignant pain who are being treated with opioids and are experiencing opioid-induced constipation. Each study will separately evaluate a different oral formulation of methylnaltrexone, including the formulation that exhibited positive preliminary results in a phase 1 study announced in July 2007. In September 2007, we and Wyeth announced the commencement of three additional clinical trials of methylnaltrexone in patients outside of the palliative care population included in the first NDA submission.

If the results of any of these ongoing trials or of other future trials of methylnaltrexone are not satisfactory, or if we encounter problems enrolling patients, or if clinical trial supply issues or other difficulties arise, our entire methylnaltrexone development program could be adversely affected, resulting in delays in commencing or completing clinical trials or in making our regulatory filing for marketing approval. The need to conduct additional clinical trials or significant revisions to our clinical development plan would lead to delays in filing for the regulatory approvals necessary to market methylnaltrexone. If the clinical trials indicate a serious problem with the safety or efficacy of a methylnaltrexone product, then Wyeth has the right under our license and co-development agreement to terminate the agreement or to stop the development or commercialization of the affected products. Since methylnaltrexone is our most clinically advanced product, any setback of these types would have a material adverse effect on our stock price and business.

We have announced positive phase 1b clinical findings related to PRO 140. If the results of our future clinical studies of PRO 140 or the preclinical and clinical studies involving the PSMA vaccine and antibody candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved.

**We have a history of operating losses, and we may never be profitable.**

We have incurred substantial losses since our inception. As of September 30, 2007, we had an accumulated deficit of \$238.8 million. We have derived no significant revenues from product sales or royalties. We may not achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur additional operating losses in the future, which could increase significantly as we expand our clinical trial programs and other product development efforts.

Our ability to achieve and sustain profitability is dependent in part on obtaining regulatory approval to market our products and then commercializing, either alone or with others, our products. We may not be able to develop and commercialize products. Moreover, our operations may not be profitable even if any of our products under

development are commercialized.

**We are likely to need additional financing, but our access to capital funding is uncertain.**

As of September 30, 2007, we had cash, cash equivalents and marketable securities, including non-current portion, totaling \$183.6 million. During the nine months ended September 30, 2007, we had a net loss of \$28.4 million and cash used in operating activities was \$24.9 million. Our net loss is expected to increase in the future.

Under our agreement with Wyeth, Wyeth is responsible for all future development and commercialization costs relating to methylnaltrexone starting January 1, 2006. As a result, although our spending on methylnaltrexone has increased and is expected to continue to increase significantly from the amounts expended in 2006, our net expenses for methylnaltrexone have been and will continue to be reduced.



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With regard to our other product candidates, however, we expect that we will continue to incur significant expenditures for their development, and we do not have committed external sources of funding for most of these projects. These expenditures will be funded from our cash on hand, or we may seek additional external funding for these expenditures, most likely through collaborative agreements, or other license or sale transactions, with one or more pharmaceutical companies, through the issuance and sale of securities or through additional government grants or contracts. We cannot predict with any certainty when we will need additional funds or how much we will need or if additional funds will be available to us. Our need for future funding will depend on numerous factors, many of which are outside our control.

Our access to capital funding is uncertain. We may not be able to obtain additional funding on acceptable terms, or at all. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize the future success of our business.

If we raise funds by issuing and selling securities, it may be on terms that are not favorable to our existing stockholders. If we raise additional funds by selling equity securities, our current stockholders will be diluted, and new investors could have rights superior to our existing stockholders. If we raise funds by selling debt securities, we could be subject to restrictive covenants and significant repayment obligations.

**Our clinical trials could take longer than we expect.**

Although for planning purposes we forecast the commencement and completion of clinical trials, and have included many of those forecasts in reports filed with the SEC and in other public disclosures, the actual timing of these events can vary dramatically. For example, we have experienced delays in our methylnaltrexone clinical development program in the past as a result of slower than anticipated patient enrollment. These delays may recur. Delays can be caused by, among other things:

- deaths or other adverse medical events involving patients or subjects in our clinical trials;
  - regulatory or patent issues;
  - interim or final results of ongoing clinical trials;
  - failure to enroll clinical sites as expected;
- competition for enrollment from clinical trials conducted by others in similar indications;
  - scheduling conflicts with participating clinicians and clinical institutions; and
  - manufacturing problems.

In addition, we may need to delay or suspend our clinical trials if we are unable to obtain additional funding when needed. Clinical trials involving our product candidates may not commence or be completed as forecasted.

Moreover, we have limited experience in conducting clinical trials, and we rely on others to conduct, supervise or monitor some or all aspects of some of our clinical trials. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. Under our agreement with Wyeth relating to methylnaltrexone, Wyeth has the responsibility to conduct some of the clinical trials for that product candidate, including all trials outside of the United States. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

As a result of these and other factors, our clinical trials may not commence or be completed as we expect or may not be conducted successfully, in which event investors' confidence in our ability to develop products may be impaired and our stock price may decline.

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**We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated fines and delays.**

We and our products are subject to comprehensive regulation by the FDA in the U.S. and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, the preclinical and clinical testing, safety, approval, manufacture, labeling, marketing, export, storage, record keeping, advertising and promotion of pharmaceutical products. If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences.

**Our products do not yet have, and may never obtain, the regulatory approvals needed for marketing.**

None of our products has been approved by applicable regulatory authorities for marketing. The process of obtaining FDA and foreign regulatory approvals often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We have had only limited experience in filing and pursuing applications and other submissions necessary to gain marketing approvals. Our products under development may never obtain the marketing approval from the FDA or any other regulatory authority necessary for commercialization.

Even if our products receive regulatory approval:

- they might not obtain labeling claims necessary to make the product commercially viable (in general, labeling claims  
define the medical conditions for which a drug product may be marketed, and are therefore very important to the commercial success of a product);
- we or our collaborators might be required to undertake post-marketing trials to verify the product's efficacy or safety;
- we, our collaborators or others might identify side effects after the product is on the market, or we or our collaborators might experience manufacturing problems, either of which could result in subsequent withdrawal of  
marketing approval, reformulation of the product, additional preclinical testing or clinical trials, changes in labeling of  
the product or the need for additional marketing applications; and
- we and our collaborators will be subject to ongoing FDA obligations and continuous regulatory review.

If our products fail to receive marketing approval or lose previously received approvals, our financial results would be adversely affected.

**Even if our products obtain marketing approval, they might not be accepted in the marketplace.**

The commercial success of our products will depend upon their acceptance by the medical community and third party payers as clinically useful, cost effective and safe. If health care providers believe that patients can be managed adequately with alternative, currently available therapies, they may not prescribe our products, especially if the alternative therapies are viewed as more effective, as having a better safety or tolerability profile, as being more convenient to the patient or health care providers or as being less expensive. For pharmaceuticals administered in an institutional setting, the ability of the institution to be adequately reimbursed could also play a significant role in

demand for our products. Even if our products obtain marketing approval, they may not achieve market acceptance. If any of our products do not achieve market acceptance, we will likely lose our entire investment in that product.

**Marketplace acceptance will depend in part on competition in our industry, which is intense.**

The extent to which any of our products achieves market acceptance will depend on competitive factors. Competition in our industry is intense, and it is accentuated by the rapid pace of technological development. There are products currently in the market that will compete with the products that we are developing, including AIDS drugs and chemotherapy drugs for treating cancer. As described below, Adolor Corporation is developing a drug that would compete with methylnaltrexone. Many of our competitors have substantially greater research and development capabilities and experience and greater manufacturing, marketing, financial and managerial resources than we do. These competitors may develop products that are superior to those we are developing and render our products or technologies non-competitive or obsolete. If our product candidates receive marketing approval but cannot compete effectively in the marketplace, our operating results and financial position would suffer.

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**One or more competitors developing an opioid antagonist may reach the market ahead of us and adversely affect the market potential for methylnaltrexone.**

We are aware that Adolor Corporation, in collaboration with Glaxo Group Limited, or Glaxo, a subsidiary of GlaxoSmithKline plc, is developing an opioid antagonist, Entereg™ (alvimopan), for postoperative ileus, which has completed phase 3 clinical trials, and for opioid-induced bowel dysfunction, which is in phase 3 clinical trials. Entereg is further along in the clinical development process than methylnaltrexone, and Adolor Corporation has received an approvable letter from the FDA for Entereg regarding the treatment of post-operative ileus. If Entereg reaches the market before methylnaltrexone, it could achieve a significant competitive advantage relative to our product. In any event, the considerable marketing and sales capabilities of Glaxo may impair our ability to penetrate the market.

Under the terms of our collaboration with Wyeth with respect to methylnaltrexone, Wyeth is developing the oral form of methylnaltrexone worldwide. We are leading the U.S. development of the subcutaneous and intravenous forms of methylnaltrexone, while Wyeth is leading development of these parenteral products outside the U.S. Decisions regarding the timelines for development of the three methylnaltrexone formulations are being made by a Joint Development Committee, and endorsed by the Joint Steering Committee, each committee formed under the terms of the license and co-development agreement, consisting of members from both Wyeth and Progenics.

**If we are unable to negotiate collaborative agreements, our cash burn rate could increase and our rate of product development could decrease.**

Our business strategy includes as an element entering into collaborations with pharmaceutical and biotechnology companies to develop and commercialize our products and technologies. We entered into such a collaboration with Wyeth. However, we may not be successful in negotiating additional collaborative arrangements. If we do not enter into new collaborative arrangements, we would have to devote more of our resources to clinical product development and product-launch activities, and our cash burn rate would increase or we would need to take steps to reduce our rate of product development.

**If we do not remedy our failure to achieve milestones or satisfy conditions regarding some of our product candidates, we may not maintain our rights under our licenses relating to these product candidates.**

We are required to make substantial cash payments, achieve specified milestones and satisfy other conditions, including filing for and obtaining marketing approvals and introducing products, to maintain rights under our intellectual property licenses. We may not be able to maintain our rights under these licenses.

If we do not comply with our obligations under our license agreements, the licensors may terminate them. Termination of any of our licenses could result in our losing our rights to, and therefore being unable to commercialize, any related product.

**We have limited manufacturing capabilities, which could adversely impact our ability to commercialize products.**

We have limited manufacturing capabilities, which may result in increased costs of production or delay product development or commercialization. In order to commercialize our product candidates successfully, we or our collaborators must be able to manufacture products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of our product candidates can be complex, difficult to accomplish even in small quantities, difficult to scale-up for large-scale production and subject to delays, inefficiencies and low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available to

us on a timely basis or at all, our clinical trials could be seriously delayed, since these materials are time consuming to manufacture and cannot be readily obtained from third-party sources.

We operate pilot-scale manufacturing facilities for the production of vaccines and recombinant proteins. We believe that, for these types of product candidates, these facilities will be sufficient to meet our initial needs for clinical trials. However, these facilities may be insufficient for late-stage clinical trials for these types of product candidates, and would be insufficient for commercial-scale manufacturing requirements. We may be required to expand further our manufacturing staff and facilities, obtain new facilities or contract with corporate collaborators or other third parties to assist with production.

In the event that we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with applicable regulations, which are extensive. We may not be able to build a manufacturing facility that both meets regulatory requirements and is sufficient for our clinical trials or commercial scale manufacturing.

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We have entered into arrangements with third parties for the manufacture of some of our products. Our third-party sourcing strategy may not result in a cost-effective means for manufacturing products. In employing third-party manufacturers, we will not control many aspects of the manufacturing process, including compliance by these third parties with the FDA's current Good Manufacturing Practices and other regulatory requirements. We may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs.

**We are dependent on our patents and other intellectual property rights. The validity, enforceability and commercial value of these rights are highly uncertain.**

Our success is dependent in part on obtaining, maintaining and enforcing patent and other intellectual property rights. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. Accordingly, the patent applications owned by or licensed to us may not result in patents being issued. We are aware of other groups that have patent applications or patents containing claims similar to or overlapping those in our patents and patent applications. We do not expect to know for several years the relative strength or scope of our patent position as compared to these other groups. Furthermore, patents that we own or license may not enable us to preclude competitors from commercializing drugs, and consequently may not provide us with any meaningful competitive advantage.

We own or have licenses to several issued patents. However, the issuance of a patent is not conclusive as to its validity or enforceability. The validity or enforceability of a patent after its issuance by the patent office can be challenged in litigation. Our patents may be successfully challenged. Moreover, we may incur substantial costs in litigation to uphold the validity of patents or to prevent infringement. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, third parties may avoid our patents through design innovation.

Most of our product candidates, including methylnaltrexone, PRO 140 and our PSMA and HCV program products, incorporate to some degree intellectual property licensed from third parties. We can lose the right to patents and other intellectual property licensed to us if the related license agreement is terminated due to a breach by us or otherwise. Our ability, and that of our collaboration partners, to commercialize products incorporating licensed intellectual property would be impaired if the related license agreements were terminated.

Generally, we have the right to defend and enforce patents licensed by us, either in the first instance or if the licensor chooses not to do so. In addition, our license agreement with the University of Chicago regarding methylnaltrexone gives us the right to prosecute and maintain the licensed patents. We bear the cost of engaging in some or all of these activities with respect to our license agreements with the University of Chicago for methylnaltrexone. Under our Collaboration Agreement, Wyeth has the right, at its expense, to defend and enforce the methylnaltrexone patents licensed to Wyeth by us. With most of our other license agreements, the licensor bears the cost of engaging in all of these activities, although we may share in those costs under specified circumstances. Historically, our costs of defending patent rights, both our own and those we license, have not been material.

We also rely on unpatented technology, trade secrets and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to our technology or disclose our technology, and we may be unable to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. However, these agreements may not provide effective protection in the event of unauthorized use or disclosure of confidential information.

**If we infringe third-party patent or other intellectual property rights, we may need to alter or terminate a product development program.**

There may be patent or other intellectual property rights belonging to others that require us to alter our products, pay licensing fees or cease certain activities. If our products infringe patent or other intellectual property rights of others, the owners of those rights could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any action brought against us, and any license required under any rights that we infringe may not be available on acceptable terms or at all. We are aware of intellectual property rights held by third parties that relate to products or technologies we are developing. For example, we are aware of other groups investigating methylnaltrexone and other peripheral opioid antagonists, PSMA or related compounds and CCR5 monoclonal antibodies and of patents held, and patent applications filed, by these groups in those areas. While the validity of these issued patents, patentability of these pending patent applications and applicability of any of them to our programs are uncertain, if asserted against us, any related patent or other intellectual property rights could adversely affect our ability to commercialize our products.



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The research, development and commercialization of a biopharmaceutical often involve alternative development and optimization routes, which are presented at various stages in the development process. The preferred routes cannot be predicted at the outset of a research and development program because they will depend on subsequent discoveries and test results. There are numerous third-party patents in our field, and we may need to obtain a license to a patent in order to pursue the preferred development route of one or more of our products. The need to obtain a license would decrease the ultimate profitability of the applicable product. If we cannot negotiate a license, we might have to pursue a less desirable development route or terminate the program altogether.

**We are dependent upon third parties for a variety of functions. These arrangements may not provide us with the benefits we expect.**

We rely in part on third parties to perform a variety of functions. We are party to numerous agreements which place substantial responsibility on clinical research organizations, consultants and other service providers for the development of our products. We also rely on medical and academic institutions to perform aspects of our clinical trials of product candidates. In addition, an element of our research and development strategy is to in-license technology and product candidates from academic and government institutions in order to minimize investments in early research. Furthermore, we entered into an agreement under which we will depend on Wyeth for the commercialization and development of methylnaltrexone, our lead product candidate. We may not be able to maintain any of these relationships or establish new ones on beneficial terms. Furthermore, we may not be able to enter new arrangements without undue delays or expenditures, and these arrangements may not allow us to compete successfully.

**We lack sales and marketing infrastructure and related staff, which will require significant investment to establish and in the meantime may make us dependent on third parties for their expertise in this area.**

We have no established sales, marketing or distribution infrastructure. If we receive marketing approval, significant investment, time and managerial resources will be required to build the commercial infrastructure required to market, sell and support a pharmaceutical product. Should we choose to commercialize any product directly, we may not be successful in developing an effective commercial infrastructure or in achieving sufficient market acceptance. Alternatively, we may choose to market and sell our products through distribution, co-marketing, co-promotion or licensing arrangements with third parties. We may also consider contracting with a third party professional pharmaceutical detailing and sales organization to perform the marketing function for our products. Under our license and co-development agreement with Wyeth, Wyeth is responsible for commercializing methylnaltrexone. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of our other products, any revenues we receive will depend primarily on the efforts of third parties. We will not control the amount and timing of marketing resources these third parties devote to our products.

**If we lose key management and scientific personnel on whom we depend, our business could suffer.**

We are dependent upon our key management and scientific personnel. In particular, the loss of Dr. Paul J. Maddon, our Chief Executive Officer and Chief Science Officer, could cause our management and operations to suffer. Our employment agreement with Dr. Maddon, the initial term of which ran through June 30, 2005, was automatically renewed for an additional period of two years through June 30, 2007, but has now expired. Dr. Maddon continues to be employed by us and is receiving compensation from us at the same rate as was specified in the expired contract. We are in discussions with Dr. Maddon regarding a new employment agreement. Employment agreements do not assure the continued employment of an employee. We maintain key-man life insurance on Dr. Maddon in the amount of \$2.5 million.

Competition for qualified employees among companies in the biopharmaceutical industry is intense. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we may be required to expand substantially our personnel, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development and marketing. We may not be successful in hiring or retaining qualified personnel.

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**If we are unable to obtain sufficient quantities of the raw and bulk materials needed to make our products, our product development and commercialization could be slowed or stopped.**

In accordance with our collaboration agreement with Wyeth, we have transferred to Wyeth the responsibility for manufacturing methylnaltrexone for clinical and commercial use. In addition, we currently obtain supplies of critical raw materials used in production of other of our product candidates from single sources. We do not have long-term contracts with any of these other suppliers. Wyeth may not be able to fulfill its manufacturing obligations, either on its own or through third-party suppliers. Furthermore, our existing arrangements with suppliers for our other product candidates may not result in the supply of sufficient quantities of our product candidates needed to accomplish our clinical development programs, and we may not have the right or capability to manufacture sufficient quantities of these products to meet our needs if our suppliers are unable or unwilling to do so. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product.

**A substantial portion of our funding comes from federal government grants and research contracts. We cannot rely on these grants or contracts as a continuing source of funds.**

A substantial portion of our revenues to date has been derived from federal government grants and research contracts. During 2006 and 2007, we were awarded, in the aggregate, approximately \$4.4 million in NIH grants. During 2005, we were also awarded a \$3.0 million and a \$10.1 million grant from the NIH to partially fund our hepatitis C virus and PRO 140 programs, respectively. Also, in 2004 we were awarded, in the aggregate, approximately \$9.2 million in NIH grants and research contracts in addition to previous years' awards. We cannot rely on grants or additional contracts as a continuing source of funds. Moreover, funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. For example, the \$28.6 million contract awarded to us by the NIH in September 2003 must be used by us in furtherance of our efforts to develop an HIV vaccine. The government's obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. Moreover, it is possible that Congress or the government agencies that administer these government research programs will decide to scale back these programs or terminate them due to their own budgetary constraints. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing grants or contracts may be less than those received to date.

**If health care reform measures are enacted, our operating results and our ability to commercialize products could be adversely affected.**

In recent years, there have been numerous proposals to change the health care system in the U.S. and in foreign jurisdictions. Some of these proposals have included measures that would limit or eliminate payments for medical procedures and treatments or subject the pricing of pharmaceuticals to government control. In some foreign countries, particularly countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In addition, as a result of the trend towards managed health care in the U.S., as well as legislative proposals to reduce government insurance programs, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drug products. Consequently, significant uncertainty exists as to the reimbursement status of newly approved health care products.

If we or any of our collaborators succeed in bringing one or more of our products to market, third party payers may establish and maintain price levels insufficient for us to realize an appropriate return on our investment in product development. Significant changes in the health care system in the U.S. or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our operating results and our ability to raise capital and commercialize products.

**We are exposed to product liability claims, and in the future we may not be able to obtain insurance against these claims at a reasonable cost or at all.**

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected.

Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all. We have obtained product liability insurance in the amount of \$10.0 million per occurrence, subject to a deductible and a \$10.0 million annual aggregate limitation. In addition, where local statutory requirements exceed the limits of our existing insurance or where local policies of insurance are required, we maintain additional clinical trial liability insurance to meet these requirements. Our present insurance coverage may not be adequate to cover claims brought against us. In addition, some of our license and other agreements require us to obtain product liability insurance. Adequate insurance coverage may not be available to us at a reasonable cost in the future.

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**We handle hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business. If we are involved in a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.**

Our research and development work and manufacturing processes involve the use of hazardous, controlled and radioactive materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Despite procedures that we implement for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure. In addition, we may be required to incur significant costs to comply with environmental laws and regulations in the future.

**Our stock price has a history of volatility. You should consider an investment in our stock as risky and invest only if you can withstand a significant loss.**

Our stock price has a history of significant volatility. Between January 1, 2005 and September 30, 2007, our stock price has ranged from \$14.09 to \$30.83 per share. Historically, our stock price has fluctuated through an even greater range. At times, our stock price has been volatile even in the absence of significant news or developments relating to us. Moreover, the stocks of biotechnology companies and the stock market generally have been subject to dramatic price swings in recent years. Factors that may have a significant impact on the market price of our common stock include:

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- the results of clinical trials and preclinical studies involving our products or those of our competitors;
- changes in the status of any of our drug development programs, including delays in clinical trials or program terminations;
- developments regarding our efforts to achieve marketing approval for our products;
- developments in our relationship with Wyeth regarding the development and commercialization of methylnaltrexone;
- announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
  - developments in our relationships with other collaborative partners;
    - developments in patent or other proprietary rights;
      - governmental regulation;
    - changes in reimbursement policies or health care legislation;
- public concern as to the safety and efficacy of products developed by us, our collaborators or our competitors;
  - our ability to fund on-going operations;
  - fluctuations in our operating results; and
    - general market conditions.

**Our principal stockholders are able to exert significant influence over matters submitted to stockholders for approval.**

At September 30, 2007, Dr. Maddon and stockholders affiliated with Tudor Investment Corporation together beneficially own or control approximately 16% of our outstanding shares of common stock. These persons, should they choose to act together, could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could have the effect of delaying or preventing a change in control of us and, consequently, could adversely affect the market price of our common stock.

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**Anti-takeover provisions may make the removal of our Board of Directors or management more difficult and discourage hostile bids for control of our company that may be beneficial to our stockholders.**

Our Board of Directors is authorized, without further stockholder action, to issue from time to time shares of preferred stock in one or more designated series or classes. The issuance of preferred stock, as well as provisions in certain of our stock options that provide for acceleration of exercisability upon a change of control, and Section 203 and other provisions of the Delaware General Corporation Law could:

- make the takeover of Progenics or the removal of our Board of Directors or management more difficult;
- discourage hostile bids for control of Progenics in which stockholders may receive a premium for their shares of common stock; and
- otherwise dilute the rights of holders of our common stock and depress the market price of our common stock.

**If there are substantial sales of our common stock, the market price of our common stock could decline.**

Sales of substantial numbers of shares of common stock could cause a decline in the market price of our stock. We require substantial external funding to finance our research and development programs and may seek such funding through the issuance and sale of our common stock. We have filed a shelf registration statement to permit the sale by us of up to 4.0 million shares of our common stock, pursuant to which we sold 2.6 million shares on September 25, 2007. We have filed additional shelf registration statements to permit the public reoffer and sale from time to time of up to 286,000 shares of our common stock by certain stockholders. Sales of our common stock pursuant to these registration statements could cause the market price of our stock to decline. In addition, some of our other stockholders are entitled to require us to register their shares of common stock for offer or sale to the public. Also, we have filed Form S-8 registration statements registering shares issuable pursuant to our equity compensation plans. Any sales by existing stockholders or holders of options may have an adverse effect on our ability to raise capital and may adversely affect the market price of our common stock.

**Item 6. Exhibits**

(a) Exhibits

31.1 Certification of Paul J. Maddon, M.D., Ph.D., Chief Executive Officer of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended

31.2 Certification of Robert A. McKinney, Chief Financial Officer and Senior Vice President, Finance and Operations (Principal Financial and Accounting Officer) of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended

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

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**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.

Date: November 8, 2007

**PROGENICS PHARMACEUTICALS, INC.**

By:

/s/ Robert A. McKinney

Robert A. McKinney

Chief Financial Officer

Senior Vice President, Finance & Operations and  
Treasurer

(Duly authorized officer of the Registrant and  
Principal Financial and Accounting Officer)