

MAP Pharmaceuticals, Inc.  
Form 10-Q  
November 19, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-Q**

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(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 001-33719

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**MAP PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

**2834**  
(Primary Standard Industrial  
Classification Code Number)  
**2400 Bayshore Parkway, Suite 200**

**20-0507047**  
(I.R.S. Employer  
Identification No.)

**Mountain View, CA 94043**

**(650) 386-3100**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Indicate by check mark whether the Registrant 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.

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

Indicate the number of shares outstanding of each of the issuer's classes of Common Stock, as of the latest practicable date.

As of November 15, 2007, there were 20,228,361 shares of the registrant's common stock, \$0.01 par value, outstanding.

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****MAP PHARMACEUTICALS, INC.****(a development stage enterprise)****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)**

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 31,902,612	\$ 11,090,800
Short-term investments	13,612,360	6,655,370
Prepaid expenses and other current assets	562,536	443,149
Total current assets	46,077,508	18,189,319
Property and equipment, net	3,392,439	2,852,008
Other assets	1,984,568	383,019
Restricted investment	320,926	200,370
Total assets	\$ 51,775,441	\$ 21,624,716
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 542,966	\$ 1,762,348
Accrued liabilities	7,285,857	2,328,568
Current portion of long-term debt	3,349,192	840,369
Total current liabilities	11,178,015	4,931,285
Long-term debt, net of current	7,059,598	10,061,034
Redeemable convertible preferred stock warrant liability	947,775	410,988
Total liabilities	19,185,388	15,403,307
Commitments and contingencies (Note 3)		
Redeemable convertible preferred stock	120,652,596	64,898,089
Stockholders' deficit:		
Common stock	3,539	3,307
Accumulated other comprehensive income	24,579	6,063
Deficit accumulated during the development stage	(88,090,661)	(58,686,050)
Total stockholders' deficit	(88,062,543)	(58,676,680)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 51,775,441	\$ 21,624,716

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See Notes to the Condensed Consolidated Financial Statements.

**Table of Contents****MAP PHARMACEUTICALS, INC.****(a development stage enterprise)****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from July 3, 2003 (Date of Inception) to September 30,
	2007	2006	2007	2006	2007
Operating expenses:					
Research and development	\$ 7,510,102	\$ 5,908,490	\$ 18,342,904	\$ 15,097,494	\$ 59,401,989
Sales and marketing	507,987	45,773	1,308,891	136,164	1,993,101
General and administrative	1,857,647	1,019,177	5,513,982	2,730,833	15,907,323
<b>Total operating expenses</b>	<b>9,875,736</b>	<b>6,973,440</b>	<b>25,165,777</b>	<b>17,964,491</b>	<b>77,302,413</b>
Loss from operations	(9,875,736)	(6,973,440)	(25,165,777)	(17,964,491)	(77,302,413)
Interest income	621,181	202,252	1,611,986	699,665	2,983,377
Interest expense	(335,595)	(11,241)	(1,017,427)	(11,241)	(1,252,452)
Other expense, net	(251,761)	(3,254)	(618,505)	(7,719)	(506,739)
<b>Net loss</b>	<b>(9,841,911)</b>	<b>(6,785,683)</b>	<b>(25,189,723)</b>	<b>(17,283,786)</b>	<b>(76,078,226)</b>
Cumulative stock dividend attributed to preferred stockholders	(1,902,346)	(1,215,065)	(5,575,402)	(3,488,265)	
<b>Net loss attributed to common stockholders</b>	<b>\$ (11,744,257)</b>	<b>\$ (8,000,748)</b>	<b>\$ (30,765,125)</b>	<b>\$ (20,772,051)</b>	
<b>Net loss per share basic and diluted</b>	<b>\$ (14.07)</b>	<b>\$ (11.20)</b>	<b>\$ (39.27)</b>	<b>\$ (29.61)</b>	
Weighted average shares outstanding used in calculating net loss per share basic and diluted	834,433	714,581	783,379	701,505	

See Notes to the Condensed Consolidated Financial Statements.

**Table of Contents****MAP PHARMACEUTICALS, INC.****(a development stage enterprise)****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

	Nine Months Ended		Cumulative Period from July 3, 2003 (Date of Inception) to September 30 2007
	2007	September 30, 2006	
Cash flows from operating activities:			
Net loss	\$ (25,189,723)	\$ (17,283,786)	\$ (76,078,226)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	585,320	410,247	1,609,152
Amortization of debt issuance costs	70,497	5,952	84,435
Change in carrying value of warrant liability	536,787		620,578
Issuance of common stock in exchange for services			51,200
Share-based compensation	1,297,740	306,363	1,799,121
Loss on disposal and other non-cash items	156,422	11,683	370,387
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(600,035)	(339,835)	(1,268,073)
Other assets	(156,660)	(102,522)	(166,876)
Accounts payable	(1,267,439)	(520,130)	494,909
Accrued liabilities	3,168,223	(294,838)	5,496,791
<b>Net cash used in operating activities</b>	<b>(21,398,868)</b>	<b>(17,806,866)</b>	<b>(66,986,602)</b>
Cash flows from investing activities:			
Purchase of intangible assets and in-process research and development			(412,000)
Purchase of property and equipment	(1,080,590)	(962,658)	(4,911,935)
Proceeds from sale of property and equipment	5,600	3,114	5,600
Purchase of short-term investments	(44,032,826)	(22,036,416)	(71,217,522)
Sales and maturities of short-term investments	37,575,000	18,700,000	58,429,274
Purchase of restricted investment	(120,556)		(320,926)
<b>Net cash used in investing activities</b>	<b>(7,653,372)</b>	<b>(4,295,960)</b>	<b>(18,427,509)</b>
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable			4,300,000
Proceeds from issuance of long-term debt		7,006,025	11,006,025
Proceeds from issuance of common stock	63,005	181	65,745
Repayment of long-term debt	(378,058)		(482,680)
Proceeds from issuance of convertible preferred stock, net of issuance costs	50,179,105	25,099,988	102,427,633
<b>Net cash provided by financing activities</b>	<b>49,864,052</b>	<b>32,106,194</b>	<b>117,316,723</b>
<b>Net increase in cash and cash equivalents</b>	<b>20,811,812</b>	<b>10,003,368</b>	<b>31,902,612</b>
Cash and cash equivalents at beginning of period	11,090,800	7,158,101	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 31,902,612</b>	<b>\$ 17,161,469</b>	<b>\$ 31,902,612</b>

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**Supplemental disclosures of cash flow information**

Cash paid for interest	\$ 923,301	\$ 5,289	\$ 1,065,742
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**Supplemental non-cash information**

Conversion of notes payable to convertible preferred stock	\$	\$	\$ 4,300,000
Issuance of convertible preferred stock warrants	\$	\$ 327,197	\$ 327,197
Accretion of cumulative dividends on redeemable convertible preferred stock	\$ 5,575,402	\$ 3,488,265	\$ 13,924,963

See Notes to the Condensed Consolidated Financial Statements.



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**MAP PHARMACEUTICALS, INC.**

**(a development stage enterprise)**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**NOTE 1. THE COMPANY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***The Company***

MAP Pharmaceuticals, Inc. (the Company), incorporated in the state of Delaware, was originally formed as a limited liability company on July 3, 2003 and converted to a corporation on December 11, 2003. The Company uses proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. The Company has several proprietary product candidates in clinical development that address large market opportunities, including its two most advanced product candidates: a proprietary formulation of nebulized budesonide for the potential treatment of pediatric asthma in children from 12 months to eight years of age, and a proprietary formulation of inhaled dihydroergotamine for the potential treatment of migraine. The Company is in the development stage and since inception has devoted substantially all of its efforts to research and development, raising capital and recruiting personnel.

In October 2007, the Company completed its initial public offering (IPO) of 5,750,000 shares of its common stock at a public offering price of \$12.00 per share, including the underwriters' exercise of their option to purchase 750,000 shares to cover over-allotments. The aggregate net cash proceeds from the IPO, including the shares issued upon exercise of the over-allotment option, were approximately \$64.2 million, after deducting the underwriting discount and commissions. All of our outstanding redeemable convertible preferred stock converted into common stock in connection with the completion of the IPO.

The Company has incurred losses since its inception in July 2003. Prior to achieving profitable operations, the Company intends to continue to fund operations through public or private financings, strategic partnerships or other arrangements.

***Reverse Stock Split***

The Company initiated a 1-for-1.77 reverse stock split effective October 4, 2007. All shares and per share amounts in these condensed consolidated financial statements and notes thereto have been retroactively adjusted to give effect to the reverse stock split.

***Basis of Presentation***

The Company has prepared the accompanying interim condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements and accompanying notes do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of the Company, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007 or any future interim period.

The interim financial information is unaudited, but reflects all normal adjustments that are, in the Company's opinion, necessary to provide a fair statement of results for the interim periods presented. The balance sheet at December 31, 2006 has been derived from the audited financial statements at that date. The financial statements and related disclosures have been prepared with the presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Registration Statement on Form S-1, as amended, which was filed with the Securities and Exchange Commission (SEC) in connection with the IPO and declared effective by the SEC on October 4, 2007.

***Use of Estimates***

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The preparation of the accompanying condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

**Table of Contents*****Concentration of Credit Risk and Other Risks and Uncertainties***

Financial instruments that may potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and short-term investments. Substantially all the Company's cash and cash equivalents are held by two financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits.

The Company's product candidates require approval from the U.S. Food and Drug Administration or other international regulatory agencies prior to commencing commercial sales. There can be no assurance that the Company's product candidates will receive any of these required approvals. If the Company is denied such approvals or such approvals are delayed, the Company's results of operations, financial position and future cash flows may be materially adversely affected.

***Share-Based Compensation***

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS No. 123(R)), using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards granted, modified and settled to the Company's employees and directors after January 1, 2006. The Company's financial statements reflect the impact of SFAS No. 123(R). The Company chose the straight-line attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123, Accounting for Stock-Based Compensation and Emerging Issues Task Force (EITF) No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

***Comprehensive Income***

Comprehensive income represents all changes in stockholders' deficit except those resulting from investments or contributions by stockholders. For the three and nine months ended September 30, 2007 and 2006, the difference between comprehensive loss and net loss represented unrealized gains on available-for-sale securities.

***Net Loss Per Share***

Basic net loss per share is computed by dividing net loss attributed to common stockholders by the weighted-average number of common shares outstanding during the period. The Company's potential dilutive shares, which include outstanding common stock options, unvested common shares subject to repurchase, convertible preferred stock and warrants, have not been included in the computation of diluted net loss per share for all the periods as the result would be anti-dilutive. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Historical net loss per share:</b>				
Numerator				
Net loss, as reported	\$ (9,841,911)	\$ (6,785,683)	\$ (25,189,723)	\$ (17,283,786)
Less: Cumulative stock dividend attributed to preferred stockholders	(1,902,346)	(1,215,065)	(5,575,402)	(3,488,265)
Net loss attributed to common stockholders	\$ (11,744,257)	\$ (8,000,748)	\$ (30,765,125)	\$ (20,772,051)
Denominator				
Weighted-average common shares outstanding	886,500	818,716	848,463	818,657

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Less: Weighted average shares subject to repurchase	(52,067)	(104,135)	(65,084)	(117,152)
Denominator for basic and diluted net loss per share	834,433	714,581	783,379	701,505
Basic and diluted net loss per share	\$ (14.07)	\$ (11.20)	\$ (39.27)	\$ (29.61)

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The following outstanding options, common stock subject to repurchase, convertible preferred stock and warrants to purchase convertible preferred stock were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	As of September 30,	
	2007	2006
Options to purchase common stock	2,573,004	1,341,720
Common stock subject to repurchase	47,729	99,796
Warrants to purchase convertible preferred stock	73,989	73,989
Convertible preferred stock (on an as if converted basis)	12,634,845	8,685,934

**Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value and enhances fair value measurement disclosure. The measurement and disclosure requirements are effective for the Company beginning in the first quarter of fiscal 2008. The Company is currently evaluating the requirements of SFAS No. 157 and has not yet determined the impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS No. 159). SFAS No. 159 permits companies to choose to measure certain financial instruments and other items at fair value. The standard requires that unrealized gains and losses are reported in earnings for items measured using the fair value option. SFAS No. 159 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of adopting SFAS No. 159 on its consolidated financial statements.

In June 2007, the FASB ratified EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development activities to be recorded as an asset and the payments to be expensed when the research and development activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into beginning in the first quarter of fiscal year 2008. The Company currently recognizes these non-refundable advanced payments as an expense upon payment. The Company is currently evaluating the impact of adopting EITF Issue No. 07-3 on its consolidated financial statements.

**NOTE 2. CERTAIN BALANCE SHEET COMPONENTS****Accrued Liabilities**

Accrued liabilities consist of the following:

	September 30, 2007	December 31, 2006
Clinical trials	\$ 3,938,190	\$ 1,409,461
Payroll and related expenses	1,363,168	847,278
Professional services	1,721,739	31,979
Other	268,759	39,850
	\$ 7,285,857	\$ 2,328,568

**NOTE 3. COMMITMENTS AND CONTINGENCIES****Long-term Debt**

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In September 2006, the Company entered into a \$10.0 million loan facility agreement for the purpose of financing working capital (the Working Capital Loan) and borrowed all \$10.0 million under the facility agreement during the year ended December 31, 2006. The Working Capital Loan bears interest at an annual interest rate of 11.9% and matures in 2010. Additionally, in September 2006, the Company entered into a \$3.0 million loan facility agreement for the purpose of financing equipment purchases (the Equipment Loan) and borrowed \$1.0 million under this facility. The Equipment Loan bears interest at an annual interest rate of 9.5% and matures in 2009.

All Working Capital Loan amounts are collateralized by all of the Company's assets, excluding intellectual property, while all Equipment Loan amounts are collateralized by equipment of the Company purchased by such borrowed funds. As of September 30, 2007, the remaining balance under the Working Capital Loan and the Equipment Loan was \$9.7 million and \$0.7 million, respectively.

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In connection with these loan facility agreements, the Company issued warrants to purchase convertible preferred stock. The fair value of the warrants was estimated at an aggregate of \$327,197 using the Black-Scholes valuation model at the dates of issuance and recorded as debt issuance costs and amortized to interest expense over the contractual life of 7 years. The fair value of the warrants outstanding was recorded as a liability on the condensed consolidated balance sheet as of September 30, 2006. The warrants are revalued at each reporting period with the resulting gains and losses recorded in other expense, net on the condensed consolidated statements of operations. The Company recorded expense of \$131,193 as a result of the revaluation for the three months ended September 30, 2007, and \$536,787 for the nine months ended September 30, 2007. For the cumulative period from July 3, 2003 (date of inception) to September 30, 2007, \$620,578 was recorded as expense as a result of the revaluation. In connection with the completion of the IPO, all warrants were converted into warrants to purchase common stock.

### ***Operating Leases***

Our lease agreement for laboratory and office facilities in Mountain View, California expires in June 2008, after which the Company has two options to extend the term of the lease, each for three to five years, subject to certain conditions. The rent is subject to a 3.5% increase on May 15 of each year for the duration of the lease.

The Company has an irrevocable letter of credit from a bank in the amount of \$320,926 as of September 30, 2007 as required by the operating lease. This letter of credit was increased from \$200,370 as of December 31, 2006. If the Company defaults under the terms of the lease, the lessor will be entitled to borrow upon the letter of credit in the amount necessary to cure the default. The letter of credit is renewed annually and will expire on the lease termination date, June 30, 2008. As collateral for the letter of credit, the Company is required to maintain a deposit account with the bank. The amount is shown as a restricted investment on the condensed consolidated balance sheets at September 30, 2007 and December 31, 2006.

### ***Contingencies***

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business financial condition or results of operation.

### ***Indemnification***

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves potential claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its certificate of incorporation and bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future potential claims.

## **NOTE 4. LICENSE AND SUPPLY AGREEMENTS**

Under the Company's June 2004 agreement, as amended in October 2007, with Nektar Therapeutics UK Limited (the Nektar Agreement), the Company was granted a worldwide, exclusive license, with a right to sublicense, under Nektar patents and know-how, to develop and commercialize any formulation of a form of dihydroergotamine for administration by inhalation using a device. As of September 30, 2007, the Company is required to make future nonrefundable milestone payments of up to \$5.0 million related to products currently being developed under this agreement, when and if certain regulatory and commercial milestones are met. The Company did not make any milestone payments in the three months ended September 30, 2007 and September 30, 2006. The Company paid \$1.0 million and \$500,000 related to milestones for the nine months ended September 30, 2007 and September 30, 2006, respectively, and \$2.6 million during the cumulative period from July 3, 2003 (date of inception) to September 30, 2007. The Company also agreed to pay royalties at specified rates based on net sales as noted in the Nektar Agreement. No royalty expense has been recognized through September 30, 2007. Either party may terminate the Nektar Agreement upon a material, uncured default of the other party. The Company may terminate the agreement, with or without cause, at any time upon six months written notice.

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Under the Company's April 2004 agreement, as amended in February 2005 and July 2007, with Elan Pharma International Limited (the EPIL Agreement). EPIL granted to the Company a worldwide, exclusive, sub-licensable license under EPIL's intellectual property rights to use, market, distribute, sell, import and export ingredients for the Company's UDB product candidate. As of September 30, 2007, the Company is required to make future nonrefundable milestone payments of up to \$17.3 million related to products currently being developed under this agreement, when and if certain regulatory and commercial milestones are met with respect to our UDB product candidate. The Company paid \$750,000 and \$1.0 million related to milestones for the three months ended September 30, 2007 and September 30, 2006, respectively. The Company paid \$750,000 and \$2.0 million related to milestones for the nine months ended September 30, 2007 and September 30, 2006, respectively, and \$3.3 million during the cumulative period from July 3, 2003 (date of inception) to September 30, 2007. The Company also agreed to pay royalties at specified rates based on net sales as noted in



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the EPIL Agreement. No royalty expense has been recognized through September 30, 2007. Either party may terminate the EPIL Agreement upon a material, uncured default of the other party. The Company may terminate the agreement, with or without cause, at any time upon 90 days written notice.

Under the Company's September 2005 agreement with Eiffel Technologies Limited (the Eiffel Agreement), Eiffel agreed to research and develop certain methods for manufacturing formulations for steroids, steroid beta-agonist combinations or insulin. Eiffel agreed to manufacture pre-clinical and clinical supplies of such formulations and granted to the Company an exclusive, worldwide, sub-licensable license under certain of its intellectual property rights to develop, use, make, sell, export and import the formulations it develops under the Eiffel Agreement. As of September 30, 2007, the Eiffel Agreement requires the Company to make future nonrefundable milestone payments to Eiffel of up to \$11.0 million related to products currently being developed under this agreement, upon achievement of certain development milestones related to clinical development and regulatory progress. The Company also agreed to pay royalties at specified rates based on net sales and a percentage of sublicense fees. Through September 30, 2007 no expenses related to milestones, royalties, or sublicense revenue sharing have been recognized. Either party may terminate the Eiffel Agreement upon a material, uncured default of the other party or if the other party becomes insolvent. The Company may terminate the Eiffel Agreement, with or without cause, at any time upon three months' written notice.

In April 2006, the Company entered into a manufacturing and supply agreement with Xemplar Pharmaceuticals, LLC (the Xemplar Agreement) to manufacture and supply the final packaged MAP0004 product candidate. The Company has agreed that from the date the first new drug application is submitted for a product and for a period of five years thereafter the Company will purchase the fully assembled Tempo inhalers only from Xemplar. In addition, Xemplar will manufacture and supply from its manufacturing facility all such final packaged devices as required to support development and commercialization of those devices. All payments made to Xemplar were expensed to research and development. Either party may terminate the Xemplar Agreement upon a material, uncured breach or default by the other party. The Company may terminate the Xemplar Agreement upon 60 days' written notice upon the Company's reasonable determination that Xemplar does not have the capability to manufacture the product in accordance with the warranty described in the Xemplar Agreement or in sufficient quantities.

**NOTE 5. REDEEMABLE CONVERTIBLE PREFERRED STOCK**

The holders of our convertible preferred stock are entitled to receive cumulative dividends at an annual rate of 8% from the date of issuance of each such share. As of September 30, 2007, \$13,924,963 in dividends was payable to our preferred stockholders. Convertible preferred stock at September 30, 2007 consists of the following:

Series	Shares		Proceeds Net of Issuance Costs	Accrued Dividends	Carrying Amount	Liquidation Amount
	Authorized	Outstanding				
A	610,169	610,168	\$ 1,498,800	\$ 470,192	\$ 1,968,992	\$ 1,970,200
B	4,679,222	4,679,216	29,949,740	8,060,053	38,009,793	38,059,882
C	3,470,548	3,396,550	25,099,988	3,450,155	28,550,143	28,700,108
D	4,124,293	3,948,911	50,179,105	1,944,563	52,123,668	52,269,485
	12,884,232	12,634,845	\$ 106,727,633	\$ 13,924,963	\$ 120,652,596	\$ 120,999,675

**NOTE 6. EQUITY INCENTIVE PLAN**

In 2005, the Company adopted the 2005 Equity Incentive Plan (the 2005 Plan), amended in February 2006, which provides for the grant of stock options to employees and consultants of the Company. Options granted under the 2005 Plan may be either incentive stock options (ISOs) or nonqualified stock options (NSOs). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees, consultants and directors. Options under the 2005 Plan may be granted with a term of up to ten years. To date, options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the vesting commencement date and 1/48th per month thereafter.

At September 30, 2007, a total of 394,580 shares of common stock remain available for issuance under the 2005 Plan. In September 2007, the Company adopted the 2007 Equity Award Plan (the 2007 Plan) which became effective upon the completion of the IPO and the common stock available for issuance under the 2005 Plan will be available for future grant under the 2007 Plan. Outstanding options under the 2005 Plan that expire or are canceled without having been exercised in full or are repurchased or forfeited following the effective date of the 2007 Plan will be available for future issuance under the 2007 Plan.



**Table of Contents****Share-Based Compensation**

The Company's financial statements as of and for the three and nine months ended September 30, 2007 and September 30, 2006 reflect the impact of SFAS No. 123(R). The Company estimates the fair value of stock options using the Black-Scholes option valuation model, and amortizes the fair value on a straight-line basis over the requisite service period of the awards. Share-based compensation expense recorded under SFAS No. 123(R) related to options granted to employees was allocated to the following departments:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Research and development	\$ 232,248	\$ 25,575	\$ 480,781	\$ 66,458
Sales and marketing	64,722	13,427	146,597	34,891
General and administrative	247,021	24,936	494,568	64,797
	\$ 543,991	\$ 63,938	\$ 1,121,946	\$ 166,145

The fair value of share-based awards was estimated using the Black-Scholes option pricing model using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Risk-free interest rate	4.50%	4.84%	4.64%	4.79%
Volatility	56%	53%	56%	58%
Expected term (in years)	5.5	5.5	5.5	5.5
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

A summary of the Company's stock option activity under the 2005 Plan and related information are as follows:

	Shares Available for Grant	Outstanding Options Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Additional shares reserved	847,457			
Options granted	(1,125,922)	1,125,922	\$ 6.43	
Options exercised		(94,369)	\$ 0.67	
Options canceled	85,931	(85,931)	\$ 3.85	
<b>Balance, September 30, 2007</b>	394,580	2,573,004	\$ 3.10	

Options vested and expected to vest at September 30, 2007	2,540,944	\$ 3.05	\$ 5,477,450
Options vested at September 30, 2007	675,994	\$ 0.68	\$ 481,513

The total fair value of options that vested during the nine month periods ended September 30, 2007 and September 30, 2006 was \$223,128 and \$239,080, respectively. The Company granted options to purchase 171,741 shares of common stock during the three months ended September 30, 2007 with a weighted average Black-Scholes fair value of \$6.84 per share.

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A summary of the Company's stock options outstanding and exercisable as at September 30, 2007 are as follows:

Exercise Price	Options Outstanding and		Options Vested at	
	Exercisable at September 30, 2007	Weighted Average Remaining Contractual Life (Years)	September 30, 2007	Weighted Average Exercise Price
	Number of Options		Number of Options	
\$0.64	683,476	7.62	422,103	\$ 0.64
\$0.74	813,654	8.66	253,891	\$ 0.74
\$3.36	308,057	9.42		\$ 3.36
\$6.39	601,725	9.58		\$ 6.39
\$12.37	166,092	9.80		\$ 12.37
	2,573,004	8.76	675,994	\$ 0.68

As of September 30, 2007, there were \$7.2 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested stock option awards granted after January 1, 2006 that will be recognized on a straight-line basis over the weighted average remaining period of 3.3 years.

**NOTE 7. SUBSEQUENT EVENTS**

The Company's Board of Directors approved the authorization of 100,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock effective in connection with the closing of the IPO in October 2007.

In addition, effective upon the closing of the IPO in October 2007, the Company adopted the 2007 Plan and the Employee Stock Purchase Plan. Under the terms of the 2007 Plan, 2,100,000 shares of common stock are reserved for issuance, in addition to the shares of common stock that remain available for future grants under the 2005 Plan as of the closing of the IPO.

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as may, will, should, could, would, expect, plans, anticipates, believes, estimates, projects, predicts, potential and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the implications of interim or final results of our clinical trials, the progress of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, and the sufficiency of our cash resources. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this quarterly report on Form 10-Q and our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this quarterly report on Form 10-Q. You should read this quarterly report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.*

*The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this quarterly report on Form 10-Q.*

**Overview**

We use our proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. We have several proprietary product candidates in clinical development which address large market opportunities, including our two most advanced product candidates, Unit Dose Budesonide, or UDB, for the potential treatment of pediatric asthma and MAP0004 for the potential treatment of migraine. We announced positive results from Phase 2 clinical studies of UDB and MAP0004 in early 2007, and anticipate initiating Phase 3 clinical programs of both product candidates by early 2008. Our program for UDB will include Phase 3 pivotal efficacy clinical trials as well as trials of the uptake of UDB by the body, known as pharmacokinetic trials, and with respect to MAP0004, our program will include Phase 3 pivotal efficacy clinical trials as well as a pharmacokinetic trial and a trial of the effect of MAP0004 on the body, known as a pharmacodynamic trial. UDB is our proprietary nebulized version of budesonide intended to treat pediatric asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide, which is the current leading treatment for pediatric asthma. MAP0004 is our proprietary inhaled version of dihydroergotamine intended to treat migraine. MAP0004 is designed to provide faster onset and longer lasting pain relief than triptans, the class of drugs most often prescribed for treating migraine.

In addition to our product candidates in late-stage development, our development pipeline consists of MAP0005, our proprietary combination of an inhaled corticosteroid and a long-acting beta-agonist for the treatment of asthma and chronic obstructive pulmonary disease, or COPD, and MAP0001, our proprietary form of insulin for the treatment of Type 1 and Type 2 diabetes via pulmonary delivery using our proprietary Tempo inhaler. We initiated a Phase 2a clinical trial with MAP0005 for the treatment of asthma and COPD in October 2007. We have no current intention to further develop either of these earlier stage product candidates independently. We hold worldwide commercialization rights for each of our product candidates, and intend to market our two most advanced product candidates in the United States through our own focused sales force targeting pediatricians for UDB and neurologists and headache specialists for MAP0004.

We are a development stage company. We were formed in the State of Delaware in July 2003 as a limited liability company and converted to a corporation in December 2003. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates. From inception through September 30, 2007, we have received net proceeds of \$106.7 million from the issuance of convertible notes payable and convertible preferred stock. In 2006, we entered into loan facility agreements and borrowed \$10.0 million to finance working capital and borrowed \$1.0 million to finance equipment purchases.

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Since our inception, we have incurred significant net losses, and we expect to continue to incur net losses for the next several years as we develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential U.S. Food and Drug Administration, or the FDA, approval of our product candidates. We will need to expand our commercial organization to launch any products. Significant capital is required to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

In October 2007, we completed our initial public offering, or IPO, whereby we sold 5,000,000 shares of common stock at \$12.00 per share and our underwriters exercised an over-allotment option to purchase an additional 750,000 shares of our common stock in connection with the IPO. The offering, including the over-allotment shares, generated net proceeds to the Company of approximately \$64.2 million (after deducting underwriting discounts and commissions). All of our outstanding redeemable convertible preferred stock converted into common stock in connection with the completion of the IPO. We believe that the net proceeds from the IPO, existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operating requirements for at least 12 months.

We also initiated a 1-for-1.77 reverse stock split effective upon the IPO. All shares and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

### **Critical Accounting Policies and Significant Judgments and Estimates**

We believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements. Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

#### ***Pre-clinical Study and Clinical Trial Accruals***

We estimate our pre-clinical study and clinical trial expenses based on the services received pursuant to contracts with several research institutions and clinical research organizations that conduct and manage pre-clinical studies and clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payments. Pre-clinical study and clinical trial expenses include the following:

fees paid to contract research organizations in connection with pre-clinical studies;

fees paid to contract research organizations, clinical investigators and clinical research organizations in connection with clinical trials; and

fees paid to contract manufacturers and service providers in connection with the production and testing of clinical trial materials for pre-clinical studies and clinical trials.

Payments under some of these contracts depend on factors such as the milestones achieved, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

#### ***Share-Based Compensation***

Prior to January 1, 2006, we accounted for share-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25), and related interpretations and complied

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with the disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of our stock and the exercise price.

Effective January 1, 2006, we adopted the fair value provision of SFAS No. 123(R) which supersedes previous accounting under APB No. 25. SFAS No. 123(R) requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. SFAS No. 123(R) requires companies to estimate the fair value of the share-based payment awards on the date of grant using an option-pricing model. We adopted SFAS No. 123(R) using the prospective transition method, which requires that entities that used the minimum value method for either pro forma or financial statement recognition purposes, shall apply SFAS No. 123(R) to options grants or modifications after the effective date of this standard. For options granted prior to the SFAS No. 123(R) effective date, for which

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the requisite service period has not been performed as of January 1, 2006, we will continue to recognize compensation expense on the remaining unvested awards under the intrinsic-value method of APB No. 25. All options grants valued after January 1, 2006 will be expensed on a straight-line basis over the vesting period.

The fair values of the common stock underlying stock options granted during 2005, 2006 and the first and second quarters of 2007 were estimated by our board of directors, which intended all options granted to be exercisable at a price per share not less than the per share fair market value of our common stock underlying those options on the date of grant. In the absence of a public trading market, our board of directors considered numerous objective and subjective factors to determine its best estimate of the fair market value of our common stock as of the date of each option grant, including but not limited to, the following factors: (i) prices of our Series A, Series B, Series C and Series D convertible preferred stock issued by us primarily to outside investors in arm's-length transactions, and the rights, preferences and privileges of the preferred stock relative to the common stock; (ii) our performance and the status of research and product development efforts; (iii) our stage of development and business strategy, including our regulatory review status with regulatory authorities; (iv) valuations of our common stock; and (v) the likelihood of achieving a liquidity event for the shares of common stock underlying these stock options, such as an initial public offering or sale, given prevailing market conditions.

Our management conducted a contemporaneous valuation for accounting purposes in connection with stock option grants during the third quarter of 2007.

**Common Stock Valuations**

We granted stock options with an exercise price of \$3.36 per share in March 2007, \$6.39 per share in May 2007, and \$12.37 per share in July 2007. The valuations conducted resulted in estimated fair value of our common stock of \$8.92, \$10.23, and \$12.37 per share at March 31, 2007, April 30, 2007 and July 24, 2007, respectively. A brief narrative of estimated fair value as of the date of each grant and the option exercise price are set forth below:

*March 2007:* During this period, we announced positive Phase 2 data from our MAP0004 clinical trials. In February 2007, we had previously announced positive Phase 2 data from our UDB clinical trial. In addition, in March 2007, we raised approximately \$50.2 million through a Series D convertible preferred stock financing priced at \$12.74 per share. The option awards granted during this period had an exercise price of \$3.36 per share. Since there were material changes in our business related to our two most advanced product candidates and the completion of our preferred stock financing, and a significant amount of option awards was granted during this period, we conducted a retrospective valuation analysis for accounting purposes. As a result of this analysis, the fair value of our common stock as of March 31, 2007 was estimated at \$8.92 per share.

*May 2007:* During this period, we continued to make progress on the design of and preparations for our clinical trials for our most advanced clinical programs, UDB and MAP0004. In addition, we undertook preparations for our proposed initial public offering, including interviewing numerous investment banks and drafting a preliminary registration statement on Form S-1. The option awards granted during this period had an exercise price of \$6.39 per share. In anticipation of a proposed initial public offering, and because the Company granted a significant amount of option awards during this period, we conducted a retrospective valuation analysis for accounting purposes. As a result of this analysis, the fair value of our common stock as of April 30, 2007 was estimated at \$10.23 per share.

*July 2007:* During this period, Phase 2 clinical data from our two most advanced clinical programs, MAP0004 and UDB, were presented at scientific conferences. These conferences were attended by leading clinicians in the headache and asthma fields, who may be potential prescribers of our product candidates, if approved. We also made further progress on the design of and preparation for our clinical trials for UDB and MAP0004. We also selected underwriters and filed our Form S-1 with the SEC in June 2007. For accounting purposes, we conducted a contemporaneous valuation analysis whereby the fair value of our common stock was estimated at \$12.37 per share. We granted option awards during this period at this price.

Under SFAS No. 123(R), we calculated the fair value of the stock option grants using the Black-Scholes option pricing model. The fair value of the stock options was based on the following assumptions:

Three Months Ended	March 31, 2007	June 30, 2007	September 30, 2007
Expected term (in years)	5.5 years	5.5 years	5.5 years
Risk-free interest rate	4.65%	4.77%	4.50%
Expected volatility	56%	56%	56%



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Expected dividend yield

0%

0%

0%

The estimated average expected term, as well as the estimated volatility rate, were calculated based on selected companies in similar markets, due to a lack of historical information regarding the volatility and expected term of our stock. We will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for our common stock becomes available. The risk-free rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of our stock options. The expected dividend assumption was based on our history and expectation of dividend payouts.

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Using the Black-Scholes option pricing model, we recorded non-cash share-based compensation expenses related to employee stock options granted of approximately \$544,000 and \$64,000 for the three months ended September 30, 2007 and September 30, 2006, respectively, and approximately \$1,122,000 and \$166,000 for the nine months ended September 30, 2007 and September 30, 2006, respectively, in accordance with the requirements of SFAS No. 123(R).

**Financial Overview****Research and Development Expenses**

Research and development expenses consist of: (i) milestone payments paid to our collaborative partners who work on our processing and supply of clinical trial material; (ii) expenses incurred under agreements with contract research organizations and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (iii) the cost of manufacturing clinical trial materials; (iv) payments to contract service organizations, as well as consultants; (v) employee-related expenses, which include salaries and benefits; (vi) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies; and (vii) share-based compensation expense. All research and development expenses are expensed as incurred.

Conducting a significant amount of research and development is central to our business model. From our inception through September 30, 2007, we had incurred approximately \$59.4 million in research and development expenses. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our research and development expenses for the foreseeable future in order to complete development of our two most advanced product candidates, UDB and MAP0004, and our earlier-stage research and development projects.

The following table summarizes the percentages of our research and development expenses related to our two most advanced product candidates and other projects including MAP0005 and MAP0001. The percentages summarized in the following table reflect costs directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management's estimate.

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 3, 2003  (Date of Inception)  Through September 30, 2007
	2007	2006	2007	2006	September 30, 2007
Our most advanced product candidates:					
UDB	34%	51%	37%	39%	42%
MAP0004	56%	40%	54%	51%	49%
Other projects	10%	9%	9%	10%	9%
Total	100%	100%	100%	100%	100%

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are currently focused on developing our two most

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advanced product candidates. However, we will need to raise substantial additional capital in the future in order to complete the development and commercialization of UDB and MAP0004, or NDAs, and to fund the development and commercialization of our other product candidates.

**Sales and Marketing Expenses**

Sales and marketing expenses consist principally of personnel costs and business development expenses within our marketing and business development functions. Sales and marketing expenses also consist of share-based compensation expense. We expect these expenses to increase as we continue to grow our business.

**General and Administrative Expenses**

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, accounting, legal, information technology and human resources functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, professional fees for legal, consulting and auditing and tax services. General and administrative expenses also consist of share-based compensation expense. We expect these expenses to increase as we continue to grow our business.

**Results of Operations****Comparison of Three and Nine Months Ended September 30, 2007 and 2006**

	Three Months Ended				Nine Months Ended			
	September 30, 2007	September 30, 2006	Increase/ (Decrease)	% Increase/ (Decrease)	September 30, 2007	September 30, 2006	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)				(in thousands, except percentages)			
Research and development expenses	\$ 7,510	\$ 5,908	\$ 1,602	27%	\$ 18,343	\$ 15,097	\$ 3,246	22%
Sales and marketing expenses	508	46	462	*	1,309	136	1,173	*
General and administrative expenses	1,858	1,019	839	82%	5,514	2,731	2,783	102%
Interest income	621	202	419	207%	1,612	700	912	130%
Interest expense	(336)	(11)	(325)	*	(1,017)	(11)	(1,006)	*
Other expense, net	(252)	(3)	(249)	*	(619)	(8)	(611)	*

\* Percentage removed as it is not meaningful.

**Research and Development Expenses.** The increase in research and development expenses in the three months ended September 30, 2007 as compared to the same period in 2006 was due primarily to an increase of \$1.2 million in personnel costs resulting from increased headcount and share-based compensation expense and an increase of \$1.2 million in program costs primarily resulting from an increase in third-party expenses to support our growth in preparation for our Phase 3 clinical programs related to our two most advanced product candidates, partially offset by a \$1.0 million milestone payment related to the UDB program paid in 2006.

The increase in research and development expenses in the nine months ended September 30, 2007 as compared to the same period in 2006 was due primarily to an increase of \$2.4 million in personnel costs resulting from increased headcount and share-based compensation expense, an increase of \$1.1 million in program costs primarily resulting from an increase in third-party expenses to support our growth in preparation for our Phase 3 clinical programs related to our two most advanced product candidates and an increase of \$320,000 related to facility and information technology expenses. These increases were partially offset by a \$1.0 million milestone payment related to the UDB program paid in 2006.

**Sales and Marketing Expenses.** The increase in sales and marketing expenses in the three months ended September 30, 2007 as compared to the same period in 2006 was due to an increase of \$210,000 in personnel costs related to increased headcount and share-based compensation expense and an increase of \$250,000 primarily due to an increase in professional services and market research activities. The increase in sales and marketing expenses in the nine months ended September 30, 2007 as compared to the same period in 2006 was due to an increase of \$550,000 in personnel costs resulting from increased headcount and share-based compensation expense and an increase of \$620,000 primarily due to an increase in professional services and market research activities.

**General and Administrative Expenses.** The increase in general and administrative expenses in the three months ended September 30, 2007 as compared to the same periods in 2006 was due to an increase of \$600,000 in personnel costs related to increased headcount and share-based

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compensation expense and an increase of \$240,000 primarily due to an increase in professional services. The increase for the nine months ended September 30, 2007 as compared to the same period in 2006 was due to an increase of \$1.3 million in personnel cost related to increase headcount and share-based compensation expense and an increase of \$1.5 million primarily due to an increase in professional services.

*Interest Income.* The increase in interest income in the three and nine months ended September 30, 2007 as compared to the same periods in 2006 was due primarily to higher cash balances related to the closing of our \$50.2 million Series D convertible preferred stock financing in March 2007.

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*Interest Expense.* The increase in interest expense in the three and nine months ended September 30, 2007 as compared to the same periods in 2006 was primarily due to the outstanding debt related to the loan facility agreements entered into in September and December 2006.

*Other Expense, Net.* The decrease in other expense, net is primarily due to the non-cash expense associated with redeemable convertible preferred stock warrants issued in September 2006 in conjunction with loan facility agreements.

**Liquidity and Capital Resources**

We have incurred losses since our inception in July 2003 and, as of September 30, 2007, we had an accumulated deficit of \$88.1 million. We anticipate that we will continue to incur net losses for the next several years. We expect that our development, selling, marketing and general and administrative expenses will continue to increase and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

We have financed our operations through equity financing, debt financing and issuance of convertible notes. Through September 30, 2007, we have received net proceeds of \$106.7 million from the issuance of convertible notes payable and convertible preferred stock as follows: \$4.3 million from the issuance of convertible notes payable in 2004 which were converted into Series A convertible preferred stock and a portion of Series B convertible preferred stock, \$27.1 million for Series B convertible preferred stock in August 2004, \$25.1 million for Series C convertible preferred stock in January 2006 and \$50.2 million for Series D convertible preferred stock in March 2007. In 2006, we entered into loan facility agreements and borrowed \$10.0 million to finance working capital and \$1.0 million to finance equipment purchases. As of September 30, 2007, we had \$45.5 million in cash, cash equivalents and short-term investments. Our short-term investment balances of \$13.6 million are primarily held in commercial paper securities. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation.

The holders of our convertible preferred stock were entitled to receive cumulative dividends at an annual rate of 8% from the date of issuance of each share. As of September 30, 2007, an aggregate of approximately \$13.9 million in dividends was payable to our preferred stockholders. Upon the completion of our IPO in October 2007, this amount was converted into 928,314 shares of common stock to our preferred stockholders in connection with the dividend.

The following table shows a summary of our cash flows for the periods indicated:

	<b>Nine Months Ended September 30, 2007      2006 (in millions)</b>	
Cash, cash equivalents and short-term investments	\$ 45.5	\$ 20.8
Cash provided by (used in):		
Operating activities	(21.4)	(17.8)
Investing activities	(7.7)	(4.3)
Financing activities	49.9	32.1

*Net cash used in operating activities.* Net cash used in operating activities during the nine months ended September 30, 2007 primarily reflected the net loss, offset in part by changes in operating assets and liabilities, depreciation and amortization, share-based compensation and the change in the carrying value of the warrant liability. Net cash used in operating activities during the nine months ended September 30, 2006 primarily reflected the net loss, offset in part by changes in operating assets and liabilities, depreciation and amortization and share-based compensation. Changes in operating assets and liabilities for both periods were primarily a result of third party research and development expenses, pre-clinical and clinical trial costs, professional fees and personnel-related costs.

*Net cash used in investing activities.* Net cash used in investing activities was primarily related to purchase of investments and, to a lesser extent, purchase of property and equipment offset partially by the proceeds from the sales and maturities of short-term investments.

*Net cash provided by financing activities.* Net cash provided by financing activities was primarily attributable to the issuance of Series C convertible preferred stock and the proceeds from debt financing in the year ended December 31, 2006 and issuance of Series D convertible preferred stock in March 2007. Net cash used in financing activities in the nine months ended September 30, 2007 was attributable to repayments made on outstanding loan amounts.

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We believe that our existing cash, cash equivalents and short-term investments, including the net proceeds from our IPO completed in October 2007, will be sufficient to meet our projected operations requirements through at least 12 months. However, we may be required to raise substantial additional capital to complete the development and commercialization of UDB and MAP0004 given the cost of developing and commercializing two product candidates in parallel. Our capital requirements are likely to increase. As a result, we will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds

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through public or private financings, strategic partnerships or other arrangements. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. We will need substantial additional funding, and if we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs.

**Contractual Obligations**

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2006.

	Total	Payments due by period			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
(in thousands)					
<b>Contractual Obligations:</b>					
Debt <sup>(1)</sup>	\$ 13,646	\$ 2,092	\$ 11,554	\$	\$
Operating lease obligation <sup>(2)</sup>	1,381	916	465		
Total	\$ 15,027	\$ 3,008	\$ 12,019	\$	\$

(1) During 2006, we entered into loan facility agreements and borrowed \$11.0 million for the purpose of financing working capital and purchasing equipment. The working capital loans of \$10.0 million allow for interest only payments through July 1, 2007 on \$3.0 million of the debt and through January 1, 2008 on \$7.0 million of the debt, and bear interest at an annual rate of 11.9%. The equipment loan of \$1.0 million is repayable in equal monthly payments and bears interest at an annual interest rate of 9.5%. The amounts in the table above include interest and principal repayments on these notes. See Note 3 of the Notes to the Condensed Consolidated Financial Statements in this Form 10-Q for additional information.

(2) Includes the minimum rental payments for our laboratory and office facilities in Mountain View, California expiring on June 30, 2008. The rent is subject to a 3.5% increase on May 15 of each year for the duration of the lease. We have two options to extend the term of the lease, each for three to five years, subject to certain conditions.

The table above reflects only payment obligations for development products that are fixed and determinable. Milestone payments and royalty payments under our license and supply agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur. See Note 4 of the Notes to the Condensed Consolidated Financial Statements in this Form 10-Q for additional information.

**Recent Accounting Pronouncements**

See Note 1 of the Notes to the Condensed Consolidated Financial Statements for recent accounting pronouncements, including the expected dates of adoption and estimated effects on our financial statements.

**Off-Balance Sheet Arrangements**

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE OF MARKET RISKS**

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Our exposure to market risk is confined to our cash, cash equivalents and short-term investments which have maturities of less than one year. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio.



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**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures and internal controls that are designed to provide reasonable assurance that information required to be disclosed in our 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 our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures and internal controls, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost benefit relationship of possible controls and procedures and internal controls.

Management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as required by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended. Based on this review, our Chief Executive Officer and Chief Financial Officer concluded that these disclosure controls and procedures were effective as of September 30, 2007 at the reasonable assurance level.

**Changes in Internal Control Over Financial Reporting**

During our third quarter of 2007, there were no changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

We are not a party to any legal proceeding.

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### **ITEM 1A. RISK FACTORS**

*Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, which has been updated since the filing of our registration statement on Form S-1, as amended, in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.*

#### **Risks Relating to Our Financial Position and Need for Additional Capital**

**We have a history of net losses. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. As a result, we expect to continue to incur substantial and increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.**

We are not profitable and do not expect to be profitable in the foreseeable future. We have incurred significant net losses in each year since our inception, including net losses of approximately \$8.8 million, \$16.2 million and \$25.8 million for the years ended December 31, 2004, 2005 and 2006, respectively. As of September 30, 2007, we had a deficit accumulated during development stage of approximately \$88.1 million. We have devoted most of our financial resources to research and development, including our pre-clinical development activities and clinical trials. We have not completed development of any product candidate and have therefore not generated any product revenues. In that regard, we expect our expenses to increase as we initiate our Phase 3 clinical programs for our two most advanced product candidates and conduct our other clinical trials. In addition, if we are required by the U.S. Food and Drug Administration, or the FDA, to perform studies in addition to those we currently anticipate, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We also expect an increase in our expenses associated with our manufacturing work, with preparing for commercialization and with creating additional infrastructure to support operations as a public company. As a result, we expect to incur substantial and increasing net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders equity (deficit) and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to those that we currently anticipate. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities and debt financings. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth, if any, of our revenues. Revenues from potential strategic partnerships are uncertain because we may not enter into any strategic partnerships. If we are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

**We have a limited operating history, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.**

Our operations to date have been primarily limited to organizing and staffing our company, developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, among others:

our ability to obtain additional funding to develop our product candidates;

the need to obtain regulatory approval of our two most advanced product candidates, Unit Dose Budesonide, or UDB, for pediatric asthma, and MAP0004 for migraine;

delays in the commencement, enrollment, and the timing of, clinical testing;

the success of our clinical trials through all phases of clinical development;

the success of clinical trials of our UDB and MAP0004 product candidates or future product candidates;

any delays in regulatory review and approval of product candidates in clinical development;

our ability to receive regulatory approval or commercialize our products;

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potential side effects of our future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;

regulatory difficulties relating to products that have already received regulatory approval;

market acceptance of our product candidates;

our ability to establish an effective sales and marketing infrastructure;

competition from existing products or new products that may emerge;

the impact of competition in the pediatric asthma market on our ability to commercialize UDB;

the impact of competition in the migraine market on the commercialization of MAP0004;

guidelines and recommendations of therapies published by various organizations;

the ability of patients to obtain coverage of or sufficient reimbursement for our products;

potential product liability claims;

potential liabilities associated with hazardous materials;

our ability to maintain adequate insurance policies;

our dependency on third-party manufacturers to supply or manufacture our products;

our ability to establish or maintain collaborations, licensing or other arrangements;

our ability and third parties' abilities to protect intellectual property rights;

costs related to and outcomes of potential intellectual property litigation;

compliance with obligations under intellectual property licenses with third parties;

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our ability to adequately support future growth;

our ability to attract and retain key personnel to manage our business effectively; and

the level of experience in running a public company of our senior management who are new to their current roles.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

**We will need substantial additional funding, and if we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs.**

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we initiate our Phase 3 clinical programs and conduct our other clinical trials of our two most advanced product candidates. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies to those that we currently anticipate, and the timing of any potential product approval may be delayed. We currently have no commitments or arrangements for any additional financing to fund the research and development of our product candidates. We believe that the net proceeds from our initial public offering completed in October 2007, together with existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operating requirements for at least 12 months. However, we will need to raise substantial additional capital in the future in order to complete the development and commercialization of UDB and MAP0004 given the cost of developing and commercializing two product candidates in parallel, and to fund the development and commercialization of our other product candidates.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

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Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this Risk Factors section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

the scope, rate of progress and cost of our clinical trials and other research and development activities;

the costs and timing of regulatory approval;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the effect of competing technological and market developments;

the terms and timing of any collaboration, licensing or other arrangements that we may establish;

the cost and timing of completion of commercial-scale outsourced manufacturing activities; and

the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

### **Risks Relating to the Development, Regulatory Approval and**

#### **Commercialization of Our Product Candidates**

**We are largely dependent on the success of our two most advanced product candidates, UDB and MAP0004, and we cannot be certain that either of these product candidates will receive regulatory approval.**

We have invested a significant portion of our efforts and financial resources in the development of our two most advanced product candidates, UDB and MAP0004. Our ability to generate product revenue, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and regulatory approval of these product candidates. We may have inadequate financial or other resources to advance these product candidates through the clinical trial process, depending on the requirements of the FDA. In addition, our clinical development programs for UDB and MAP0004 may not lead to regulatory approval from the FDA and similar foreign regulatory agencies if we fail to demonstrate that the product candidates are safe and effective in our planned clinical trials, and we may therefore fail to commercialize any product candidates. Any failure to obtain regulatory approval of UDB and MAP0004 would have a material and adverse impact on our business.

We currently have no approved drug products for sale and we cannot guarantee that we will ever have marketable drug products. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a new drug application, or an NDA, from the FDA. We have not submitted an NDA or received marketing approval for any of our product candidates. Obtaining approval of an NDA is a lengthy, expensive and uncertain process.

**Delays in the commencement, enrollment and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.**

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Delays in the commencement, enrollment and completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials for UDB and MAP0004 will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may be required to withdraw from a clinical trial as a result of changing standards of care or may become ineligible to participate in clinical studies. The commencement, enrollment and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining regulatory approval to commence a clinical trial;

obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;

recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates; and

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retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues or side effects from the therapy or who are lost to further follow-up.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that a trial presents unacceptable health risks; or

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, particularly for our UDB and MAP0004 product candidates, we may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. Based upon our discussions with the FDA, we intend to conduct Phase 3 clinical programs for each of our most advanced product candidates. Our programs for UDB and MAP0004 will include Phase 3 pivotal efficacy clinical trials as well as additional trials of the uptake of UDB by the body, known as pharmacokinetic trials, and with respect to MAP0004, a pharmacokinetic trial and a trial of the effect of MAP0004 on the body, known as a pharmacodynamic trial. Furthermore, we may not be able to obtain approval for indications that are as broad as intended or entirely different than those indications for which we sought approval.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage.

**Because the results of earlier clinical trials are not necessarily predictive of future results, UDB, MAP0004 or any other product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.**

Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of the investigational drug. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

We expect to initiate Phase 3 clinical programs for UDB and MAP0004 by early 2008. We anticipate conducting additional Phase 2 clinical studies for UDB and MAP0004. Specifically, we intend to conduct two pharmacokinetic trials for UDB and a pharmacokinetic trial and a separate pharmacodynamic trial for MAP0004. The data collected from our clinical trials may not be adequate to support regulatory approval of UDB, MAP0004 or any of our other product candidates. Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase 3 or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. For instance, the Phase 2 clinical trial of UDB compared two doses of UDB, at 0.135 mg and 0.25 mg administered twice a day. The study showed that 0.135 mg of UDB produced a statistically significant reduction in Nighttime and Daytime Composite Symptom Score, a measure of asthma severity, when compared to placebo, but the 0.25 mg dose was not significantly better than placebo in Nighttime and Daytime Composite Symptom Score. We are planning to clinically evaluate the 0.25 mg dose further, but we may not demonstrate statistically significant efficacy for this dose, which could make it difficult to receive regulatory approval for this dose.





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**If clinical trials of our UDB or MAP0004 product candidates or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere or show undesirable side effects, we will be unable to commercialize these products.**

To receive regulatory approval for the commercial sale of UDB, MAP0004 or any other product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. In addition, the results of our clinical trials may show that our product candidates may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Our failure to adequately demonstrate the efficacy and safety of UDB, MAP0004 or any other product candidates would prevent regulatory approval and, ultimately, the commercialization of that product candidate. For example, the Phase 2 clinical trial of UDB compared two doses of UDB, at 0.135 mg and 0.25 mg administered twice a day. The study showed that 0.135 mg of UDB produced a statistically significant reduction in Nighttime and Daytime Composite Symptom Score when compared with placebo, but the 0.25 mg dose was not significantly better than placebo in Nighttime and Daytime Composite Symptom Score. If we are unable to show a statistically significant reduction in Nighttime and Daytime Composite Symptom Score at the 0.25 mg dose, we may only obtain approval for our UDB product candidate at the single 0.135 mg dose, thereby potentially limiting our sales opportunities.

**All of our products in development require regulatory review and approval prior to commercialization. Any delay in the regulatory review or approval of any of our products in development will harm our business.**

All of our products in development require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our products in development would delay market launch, increase our cash requirements and result in additional operating losses.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We may not be able to maintain our proposed schedules for the submission of any NDA in the United States or any marketing approval application or other foreign applications for any of our products. If we submit any NDA, including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our products, the FDA must decide whether to either accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that our marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner without delaying potential regulatory action. We also cannot be certain that any of our products will receive favorable recommendation from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and/or studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and/or the emergence of new information regarding our products or other products.

Data obtained from pre-clinical and clinical studies are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our products. In addition, as a routine part of the evaluation of any potential drug, clinical studies are generally conducted to assess the potential for drug-to-drug interactions that could impact potential product safety. At this point in time, we have not been requested to perform drug-to-drug studies, but any such request may delay any potential product approval and will increase our expenses associated with our clinical programs. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

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In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

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**We may not be able to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which could result in a longer development program and more costly trials than we anticipate.**

We may not be able to seek FDA marketing approval of our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2), if applicable to us, would allow any NDA we file with the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the overall scope of work we must do ourselves. If we are unable to rely on Section 505(b)(2), the development program for our product candidates would be longer than we expect, and we would also have to conduct more costly trials than we anticipate.

**If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.**

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products among physicians, the medical community, patients, and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

limitations or warnings contained in a product's FDA-approved labeling;

changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;

limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;

lower demonstrated clinical safety and efficacy compared to other products;

prevalence and severity of adverse effects;

ineffective marketing and distribution efforts;

lack of availability of reimbursement from managed care plans and other third-party payors;

lack of cost-effectiveness;

timing of market introduction and perceived effectiveness of competitive products;

availability of alternative therapies at similar costs;

patients potential preferences to take oral medications over inhaled medications; and

potential product liability claims.

Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

**We have never marketed a drug before, and if we are unable to establish an effective and focused sales force and marketing infrastructure, we will not be able to commercialize our product candidates successfully.**

We plan to market or co-promote our products where appropriate and build our own focused sales force in the United States. We currently do not have significant internal sales, distribution and marketing capabilities. In order to commercialize our most advanced product candidates, we intend to develop a focused sales force and marketing capabilities in the United States. The development of a focused sales and marketing infrastructure for our domestic operations will require substantial resources, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay of any product launch. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to hire a focused sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target, including pediatrics and neurology. If we are unable to establish our focused sales force and marketing capability for our most advanced product candidates, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

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### **We expect intense competition with respect to our existing and future product candidates.**

The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these companies have greater financial resources, marketing capabilities and experience in obtaining regulatory approvals for product candidates. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than us, obtain approvals for such products from the FDA more rapidly than us or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us.

Competitors may seek to develop alternative formulations of our product candidates that address our targeted indications. The commercial opportunity for our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our products. Compared to us, many of our potential competitors have substantially greater:

capital resources;

development resources, including personnel and technology;

clinical trial experience;

regulatory experience;

expertise in prosecution of intellectual property rights;

manufacturing and distribution experience; and

sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than us in manufacturing and marketing their products.

### **The pediatric asthma market is extremely competitive which may adversely affect our ability to commercialize UDB.**

If approved for the treatment of pediatric asthma, we anticipate that UDB would compete with other marketed asthma therapeutics, including inhaled corticosteroids and leukotriene antagonists, and may compete with products currently under development by both large and small companies. Conventional nebulized budesonide is the only inhaled corticosteroid approved by the FDA for treating asthma in children under four years old and is available from AstraZeneca plc as Pulmicort Respules. Pulmicort Respules was introduced in the United States in 2000, and annual sales have grown to approximately \$700 million in the United States and approximately \$900 million worldwide in 2006 according to data published by IMS Health. Leukotriene antagonists are an alternative to inhaled corticosteroids for asthmatic children. Prescriptions of Singulair, the leading leukotriene antagonist, for children under the age of six generated approximately \$400 million in sales in 2006. In addition to the marketed asthma therapies, there are several inhaled corticosteroid product candidates under development by large pharmaceutical companies, such as GlaxoSmithKline plc, or GlaxoSmithKline, and other smaller companies, that could potentially be used to treat pediatric asthma.

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We may also face competition from potential generic entry of conventional nebulized budesonide. For example, Teva Pharmaceuticals Industries Ltd. has filed a generic or abbreviated new drug application, or ANDA, for conventional nebulized budesonide based on Pulmicort Respules. Although we believe a generic product could not be substituted for UDB, if approved, a generic version of conventional nebulized budesonide may be more quickly adopted by health insurers and patients than UDB. Financial pressure to use generic products and uncertainty of reimbursement for single source alternatives, such as UDB, may encourage the use of a generic product over UDB.

### **The migraine market is extremely competitive which may negatively impact the commercialization of MAP0004.**

If approved for the treatment of acute migraine, we anticipate that MAP0004 would compete against other marketed migraine therapeutics and may compete with products currently under development by both large and small companies. The majority of marketed prescription products for treatment of migraine are in the triptan class. The largest selling triptan is Imitrex from GlaxoSmithKline, with 2006 sales of approximately \$1.2 billion in the United States and \$1.5 billion worldwide, according to data published by IMS Health. There are at least six other branded triptan therapies being sold by pharmaceutical companies. Alternative formulations of triptans are available which may have faster onset of action than solid oral dosage forms. Alternative formulations of DHE include Migranal, which is nasally delivered. In addition to the marketed migraine therapeutics, there are several product candidates under development by large pharmaceutical companies, such as GlaxoSmithKline and Merck & Co., Inc., and other smaller companies, that could potentially be used to treat migraines and compete with MAP0004.

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In addition, we may face competition from generic sumatriptan, the active ingredient in Imitrex. Although we believe generic sumatriptan could not be substituted for MAP0004, if approved, a generic version of sumatriptan may be more quickly adopted by health insurers and patients than MAP0004. Financial pressure to use generic products and uncertainty of reimbursement for single source alternatives, such as MAP0004, may encourage the use of a generic product over MAP0004.

### **If our patients are unable to obtain coverage of or sufficient reimbursement for our products, it is unlikely that our products will be widely used.**

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

In addition, the market for our future products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies. Third-party payors may refuse to include a particular branded drug in their formularies when a generic equivalent is available.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, limiting our ability to sell our products on a profitable basis.

### **Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.**

In order to market and commercialize any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. For example, European regulatory authorities generally require a trial comparing the efficacy of the new drug to an existing drug prior to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

### **Our product candidates may have undesirable side effects and cause our approved drugs to be taken off the market.**

If either or both of our most advanced product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products:

regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;



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regulatory authorities may withdraw their approval of the product;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

we may have limitations on how we promote our drugs;

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regulatory authorities may require us to take our approved drug off the market;

sales of products may decrease significantly;

we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

### **Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.**

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for UDB, MAP0004 or any other product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications. The FDA historically has required that labeling for products containing DHE include a contraindication for use in women who are, or who may become, pregnant. Although we believe that this contraindication is not applicable to our formulation of DHE, the FDA may disagree and require the MAP0004 labeling to carry this contraindication.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as current Good Manufacturing Practices, or cGMPs, a regulatory agency may:

issue warning letters;

require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

impose other civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications filed by us;

impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products or require a product recall.

**Guidelines and recommendations published by various organizations may affect the use of our products.**

Government agencies issue regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health/science foundations, and organizations involved in various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage, dosage, route of administration and use of related or competing therapies. For example, organizations like Global Initiative for Asthma, or GINA, and the National Asthma Education and Prevention Program, or NAEPP, have made recommendations about therapies in the pediatric asthma market. GINA guidelines issued in 2006 and NAEPP guidelines issued in 2007 recommend the use of inhaled corticosteroids as the preferred treatment to reduce inflammation and maintain long-term control of asthma in children aged five years and younger. Changes to this recommendation or other guidelines advocating alternative therapies could result in decreased use of our products, which may adversely affect our results of operations.

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### **We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.**

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

withdrawal of clinical trial participants;

termination of clinical trial sites or entire trial programs;

costs of related litigation;

substantial monetary awards to patients or other claimants;

decreased demand for our product candidates;

impairment of our business reputation;

loss of revenues; and

the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials domestically and in selected foreign countries where we are conducting clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

### **Our operations involve hazardous materials, which could subject us to significant liabilities.**

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals, including employees, to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use of these materials and our liability may exceed our total assets. We maintain insurance for the use of hazardous materials which may not be adequate to cover any claims. Compliance with environmental and other laws and regulations may be expensive and current or future regulations may impair our research, development or production efforts.

**Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.**

We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss. Some of the policies we currently maintain include general liability, property, auto, workers' compensation, products liability and directors' and officers' insurance policies. Our insurance is expensive and we do not know if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

#### **Risks Related to Our Dependence on Third Parties**

**We have no experience manufacturing large clinical-scale or commercial-scale pharmaceutical products and have no manufacturing facility. As a result, we are dependent on numerous third parties for the manufacture of our product candidates and our supply chain, and if we experience problems with any of these suppliers the manufacturing of our products could be delayed.**

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We do not own or operate manufacturing facilities for clinical or commercial manufacture of our product candidates, which includes the drug substance and the components of the device used to administer the drug. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently outsource all manufacturing and packaging of our pre-clinical and clinical product candidates to third parties. In addition, we do not currently have any agreements with third-party manufacturers for the long-term commercial supply of many of our product candidates. We may be unable to enter agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time. We may not be able to establish additional sources of supply for our products prior to commercialization. Such suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier who meets all regulatory requirements.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

reliance on the third parties for regulatory compliance and quality assurance;

the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and

the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

Any of these factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions, required approvals or commercialization of our products, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of or finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. It may take a significant period of time to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA.

### **If we are unable to establish marketing collaborations with third parties, we may not be able to commercialize our products successfully.**

We plan to establish marketing collaborations with third parties where appropriate. For example, if we choose to expand the marketing and sales of MAP0004 to primary care physicians, we may establish partnerships with other companies to maximize the breadth of the commercialization opportunity. Outside the United States, we may establish commercial partnerships for all of our product candidates in order to maximize their commercial opportunities. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial areas. If we are unable to establish adequate marketing collaborations to target primary care physicians and other large groups of prescribing physicians or to establish worldwide marketing collaborations for our other current product candidates, then we may not be able to achieve the full commercial opportunity for these product candidates.

### **We may not be successful in maintaining or establishing development collaborations, which could adversely affect our ability to develop certain of our product candidates.**

Our earlier stage product portfolio includes MAP0005 and MAP0001. We initiated a Phase 2a clinical trial with MAP0005 for the treatment of asthma and chronic obstructive pulmonary disease in October 2007. We have no current intention to further develop either of these earlier stage product candidates independently. Developing pharmaceutical products, conducting clinical trials, establishing manufacturing capabilities and marketing approved products is expensive. Consequently, we may establish partnerships for further development and commercialization of these two product candidates. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, if any. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may not be successful. If we seek collaborators to help develop MAP0005 and MAP0001, but are unable to reach agreements with suitable collaborators, we may fail to

commercialize the affected product or program.

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**Risks Relating to Our Intellectual Property**

**It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.**

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We license certain intellectual property from third parties that covers our product candidates. We rely on certain of these third parties to file, prosecute and maintain patent applications and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents. Further, if any of our patents are deemed invalid and unenforceable, it could impact our ability to commercialize or license our technology.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

we might not have been the first to make the inventions covered by our pending issued patents or patent applications;

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that our pending patent applications will not result in issued patents;

our issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

we may not develop additional proprietary technologies that are patentable; or

the patents of others may have an adverse effect on our business.



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We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

**We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.**

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents. In addition, the U.S. Supreme Court has recently invalidated some tests used by the U.S. Patent Office in granting patents over the past 20 years. As a consequence, several issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a re-examination proceeding before the U.S. Patent Office or during litigation under the revised criteria which make it more difficult to obtain patents.

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Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

### **If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.**

We are a party to a number of license agreements, including with Elan Pharma International Limited and with Nektar Therapeutics UK Limited, pursuant to which we license key intellectual property, including intellectual property relating to our most advanced product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensors may have the right to terminate the license, in which event we might not be able to develop or market any product that is covered by the licensed patents. If we lose such license rights that are important to our product candidates, our business may be materially adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

### **Risks Related to Employee Matters and Managing Growth**

#### **We will need to increase the size of our company, and we may experience difficulties in managing growth.**

As of September 30, 2007, we had 69 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. To support this growth, we expect to hire additional employees within the next 12 months. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

manage our Phase 3 clinical programs and other additional trials effectively, which we anticipate being conducted at numerous clinical sites; and

continue to improve our operational, financial and management controls, reporting systems and procedures.

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We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

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### **We may not be able to manage our business effectively if we are unable to attract and retain key personnel.**

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Silicon Valley, California area. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and product acquisition expertise of our senior management, particularly Timothy S. Nelson, our President and Chief Executive Officer, and Thomas A. Armer, our co-founder and Chief Scientific Officer. If we lose one or more of these key employees, our ability to implement our business strategy successfully could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, obtain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel.

In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. Because our business depends on certain key personnel and advisors, the loss of such personnel and advisors could weaken our management team and we may experience difficulty in attracting and retaining qualified personnel and advisors.

### **Our executive officers and certain key personnel are critical to our business and have limited experience in running a public company and are new to their current roles.**

As a public company, we are highly dependent on the expertise of our senior management, particularly our Chief Executive Officer and Chief Financial Officer. Many members of our senior management have not acted in their current capacities for a public company. In addition, certain key members of our management team were hired recently. Therefore, they will not have been involved with our business and have not worked together as a team for a significant period of time. Consequently, their focus and attention may be diverted while they familiarize themselves with our business.

## **Risks Relating to Owning Our Common Stock**

### **Our executive officers, directors and principal stockholders have the ability to control all matters submitted to our stockholders for approval.**

Immediately following the completion of our initial public offering in October 2007, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock together controlled approximately 71% of our outstanding common stock. If these persons were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, will control the election of directors and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including obtaining a premium value for their common stock, and might affect the prevailing market price for our common stock.

### **Our share price may be volatile which may cause the value of our common stock to decline and subject us to securities class action litigation.**

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

actual or anticipated fluctuations in our financial condition and operating results;

results of our clinical trials;

results of clinical trials of our competitors' products;

regulatory actions with respect to our products or our competitors' products;

actual or anticipated changes in our growth rate relative to our competitors;

actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;

competition from existing product or new products that may emerge;

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issuance of new or updated research or reports by securities analysts;

fluctuations in the valuation of companies perceived by investors to be comparable to us;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

market conditions for biopharmaceutical stocks in general; and

general economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock. If the market price of shares of our common stock decline in value, stockholders may lose some or all of their investment. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

### **If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.**

The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

### **Future sales of our common stock may cause our stock price to decline.**

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock. Future sales of these shares is restricted from immediate resale, but will be able to be sold in the public market in the near future, after the 180-day lock up period following the date of the final prospectus for our initial public offering. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

### **Being a public company increases our expenses and administrative burden.**

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. For example, we must use additional internal controls and disclosure controls and procedures, and bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and related regulations implemented by the Securities and Exchange Commission and the Nasdaq Global Market, are creating

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uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We are currently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are investing resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of

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management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. We also expect that these new rules and regulations may make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

### **Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.**

Provisions in our amended and restated certificate of incorporation and our bylaws may delay or prevent an acquisition of us. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management team. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits, with some exceptions, stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Finally, our charter documents establish advanced notice requirements for nominations for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

## **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

### **Recent Sales of Unregistered Securities**

From July 1, 2007 to September 30, 2007, we granted stock options to purchase 171,741 shares of our common stock at an exercise price of \$12.37 per share to our employees under our 2005 Equity Incentive Plan. From July 1, 2007 to September 30, 2007, we issued and sold an aggregate of 79,132 shares of our common stock to our employees at a price ranging from \$0.64 to \$0.74 per share for an aggregate of \$52,998 pursuant to exercises of options granted under our 2005 Equity Incentive Plan.

The sales and issuances of securities in the transactions described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Rule 701 promulgated under Section 3(b) of the Securities Act of 1933, as amended, as transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of securities in each transaction represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. All recipients had adequate access, through employment or other relationships, to information about us. All certificates representing the shares of common stock issued in these transactions included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth above.

### **Use of Proceeds**

Our initial public offering of common stock was effected through a Registration Statement on Form S-1/A (File No. 333-143823) that was declared effective by the Securities and Exchange Commission on October 4, 2007, which registered an aggregate of 5,750,000 shares of our common stock. On October 4, 2007, we sold 5,000,000 shares of common stock at an initial public offering price of \$12.00 per share, for aggregate gross proceeds of \$60.0 million, managed by Merrill Lynch & Co., Morgan Stanley & Co. and Deutsche Bank Securities. On October 8, 2007, in connection with the exercise of the underwriters' over-allotment option, 750,000 additional shares of common stock were sold on our behalf at the initial public offering price of \$12.00 per share, for aggregate gross proceeds of \$9.0 million.



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We paid to the underwriters underwriting discounts totaling approximately \$4.8 million in connection with the offering. In addition, we incurred expenses of approximately \$1.8 million in connection with the offering, which when added to the underwriting discounts paid by us, amount to total expenses of approximately \$6.6 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately \$62.4 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

In September 2007, our stockholders acted by written consent to approve the following actions in connection with our initial public offering.

The approval and adoption of an Amendment to our Amended and Restated Certificate of Incorporation to be filed prior to the effectiveness of our initial public offering to implement a 1-for-1.77 reverse stock split of our outstanding capital stock;

The approval and adoption of our Amended and Restated Certificate of Incorporation, which, among other things, authorized 100,000,000 shares of common stock and eliminated certain series of existing preferred stock and implemented certain stockholder protection measures, including the authorization of up to 5,000,000 shares of undesignated preferred stock to become effective upon the closing of our initial public offering;

The approval and adoption of our Amended and Restated Bylaws containing various stockholder protection measures customary for bylaws of publicly traded companies, to become effective upon the closing of our initial public offering;

The approval and adoption of the form of indemnity agreement between us and each of our directors and executive officers to become effective upon the closing of our initial public offering;

The approval and adoption of our 2007 Equity Award Plan to become effective upon the completion of our initial public offering;

The approval and adoption of our Employee Stock Purchase Plan to become effective upon the completion of our initial public offering;

The approval of effectiveness of our Registration Statement on Form S-1; and

The conversion of each outstanding share of Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock into shares of our common stock at a ratio of one to 1.000, 1.000, 1.000 and 1.000, respectively. Stockholders holding an aggregate of 21,421,844 shares of our common stock (on an as-converted basis) approved each of the above matters and stockholders holding approximately 2,561,803 shares of our common stock (on an as-converted basis) did not vote with respect to such matters as of the record date of such written consents. The share numbers reported above do not reflect the 1-for-1.77 reverse stock split of our outstanding common stock effected in October 2007.

### **ITEM 6. EXHIBITS**

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<b>Exhibit No.</b>	<b>Description</b>
3.1*	Amended and Restated Certificate of Incorporation of MAP Pharmaceuticals, Inc. filed with the Secretary of the State of the State of Delaware on October 10, 2007 and effective as of October 11, 2007
3.2*	Amended and Restated Bylaws of MAP Pharmaceuticals, Inc. effective as of October 11, 2007
4.1#	Specimen Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A No. 333-143823, filed on September 30, 2007 )
10.1*	Amendment to Restated and Amended License Agreement between Nektar Therapeutics UK Limited and MAP Pharmaceuticals, Inc. dated as of October 8, 2007
31.1*	Certification of Principal Executive Officer Required Under Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.

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<b>Exhibit No.</b>	<b>Description</b>
31.2*	Certification of Principal Financial Officer Required Under Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.

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# Previously filed.

\* Filed herewith.

Confidential treatment requested for certain portions.

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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.

**MAP PHARMACEUTICALS, INC.**

Date: November 15, 2007

By: /s/ TIMOTHY S. NELSON  
Timothy S. Nelson  
*President and Chief Executive Officer*  
(Duly Authorized Officer and Principal Financial Officer)

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**EXHIBIT INDEX**

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