MAP Pharmaceuticals, Inc.
Form 10-Q
November 13, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the quarterly period ended September 30, 2008

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

MAP PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-0507047**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2400 Bayshore Parkway, Suite 200, Mountain View, California	**94043**
(Address of principal executive offices)	**(Zip code)**

(650) 386-3100

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer x (do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of November 12, 2008, the registrant had outstanding 20,428,908 shares of Common Stock.

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PART I FINANCIAL INFORMATION

Item 1 Financial Statements

MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(Unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,279	$ 49,116
Short-term investments	24,742	45,874
Prepaid expenses and other current assets	525	1,079
Total current assets	63,546	96,069
Property and equipment, net	4,927	4,183
Other assets	27	122
Restricted investment	310	321
Total assets	$ 68,810	$ 100,695
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,343	$ 1,290
Accrued liabilities	13,017	7,622
Current portion of long-term debt	4,725	3,820
Total current liabilities	19,085	12,732
Long-term debt, net of current	15,827	6,357
Other liabilities	41	
Total liabilities	34,953	19,089
Commitments and contingencies (Note 4)		
Stockholders equity:		
Common stock	198	197
Additional paid-in capital	187,730	184,194
Accumulated other comprehensive income	15	181
Deficit accumulated during the development stage	(154,086)	(102,966)
Total stockholders equity	33,857	81,606
Total liabilities and stockholders equity	$ 68,810	$ 100,695

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from July 3, 2003 (Inception) to September 30,
	2008	2007	2008	2007	2008
Operating expenses:					
Research and development	$ 16,815	$ 7,510	$ 41,614	$ 18,343	$ 114,035
Sales, general and administrative	3,380	2,366	9,685	6,823	30,330
Total operating expenses	20,195	9,876	51,299	25,166	144,365
Loss from operations	(20,195)	(9,876)	(51,299)	(25,166)	(144,365)
Interest income	453	621	1,894	1,612	6,040
Interest expense	(621)	(336)	(1,437)	(1,017)	(3,013)
Other income (expense), net		(251)	(278)	(619)	(731)
Net loss	(20,363)	(9,842)	(51,120)	(25,190)	(142,069)
Cumulative stock dividend attributable to preferred stockholders		(1,902)		(5,575)	(13,925)
Net loss attributable to common stockholders	$ (20,363)	$ (11,744)	$ (51,120)	$ (30,765)	$ (155,994)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.00)	$ (14.07)	$ (2.52)	$ (39.27)	
Weighted-average common shares used in computing net loss per share attributable to common stockholders, basic and diluted	20,398,682	834,433	20,308,206	783,379	

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,		Cumulative Period from July 3, 2003 (Date of Inception) to September 30, 2008
	2008	2007	
Cash flows provided by (used for) operating activities:			
Net loss	$ (51,120)	$ (25,190)	$ (142,069)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	906	585	2,811
Accretion of investment discounts, net	(663)	(481)	(1,561)
Amortization of debt issuance costs	103	71	211
Accretion of debt payment premium	187		187
Change in carrying value of warrant liability		537	621
Share-based compensation	3,108	1,297	5,620
Loss on disposal of fixed and other assets	9	156	377
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	554	(119)	(750)
Other assets	67	(156)	65
Accounts payable	53	(1,267)	1,314
Accrued liabilities	5,395	3,168	12,986
Other liabilities	41		41
Net cash used in operating activities	(41,360)	(21,399)	(120,147)
Cash flows provided by (used for) investing activities:			
Purchase of intangible assets and in-process research and development			(412)
Purchase of property and equipment	(1,661)	(1,074)	(7,671)
Purchase of short-term investments	(48,648)	(44,033)	(162,503)
Sales and maturities of short-term investments	70,277	37,575	139,656
Maturity (purchase) of restricted investment	11	(121)	(310)
Net cash provided by (used in) investing activities	19,979	(7,653)	(31,240)
Cash flows provided by (used for) financing activities:			
Proceeds from issuance of convertible notes payable			4,300
Proceeds from issuance of debt	20,000		31,006
Proceeds from sales of shares through employee equity incentive plans	430	63	496
Repayment of debt	(9,886)	(378)	(10,741)
Proceeds from issuance of common stock in IPO, net of issuance costs			62,177
Proceeds from issuance of convertible preferred stock, net of issuance costs		50,179	102,428

Net cash provided by financing activities	10,544	49,864	189,666
Net increase (decrease) in cash and cash equivalents	(10,837)	20,812	38,279
Cash and cash equivalents at beginning of period	49,116	11,091	
Cash and cash equivalents at end of period	$ 38,279	$ 31,903	$ 38,279
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 1,152	$ 923	$ 2,516

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

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MAP PHARMACEUTICALS, INC.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. THE COMPANY AND BASIS OF PRESENTATION

MAP Pharmaceuticals, Inc., 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. We use 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 that address large market opportunities, including our 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 orally inhaled version of dihydroergotamine for the potential treatment of migraine. We are in the development stage and since inception have devoted substantially all of our efforts to research and development, raising capital and recruiting personnel.

In October 2007, we completed our initial public offering (IPO) of 5,750,000 shares of common stock at a public offering price of $12.00 per share. The aggregate net cash proceeds from the IPO were approximately $62.1 million, after deducting the underwriting discount and commissions and other offering expenses. In connection with the IPO, all outstanding redeemable convertible preferred stock converted into common stock, warrants to purchase convertible preferred stock converted into warrants to purchase common stock, and redeemable convertible preferred stock warrant liability was reclassified to equity.

We have incurred losses and negative cash flow since our inception in July 2003. We will continue to be in a loss position until sufficient revenue can be generated to offset our expenses. Prior to achieving profitable operations, we intend to continue to fund operations through public or private financings, strategic partnerships or other arrangements. We believe that we may need to raise additional capital in the next 12 months in order to continue with our clinical trial development efforts. Such funding, if needed, may not be available on favorable terms, if at all. In the event that we are unable to obtain additional capital, we may delay or reduce the scope of our current R&D programs and other expenses.

Basis of Presentation

We have 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. The financial statements include all adjustments (consisting of normal recurring adjustments) that management believes are necessary for the fair statement of the balances and results for the periods presented. These interim financial statement results are not necessarily indicative of the results to be expected for the full fiscal year or any future interim period.

The balance sheet at December 31, 2007 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 fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto contained in our Form 10-K for the year ended December 31, 2007.

Recent Accounting Pronouncements

We adopted Emerging Issues Task Force (EITF) Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities, on a prospective basis for new contracts entered into on or after January 1, 2008. EITF Issue No. 07-3 states that nonrefundable advance payments for future research and development activities should be deferred and recognized as an expense as the goods are delivered or the related services are performed. Entities should then continue to evaluate whether they expect the goods to be delivered or services to be rendered and, if an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. The adoption of EITF Issue No. 07-3 did not have a material impact on our financial position or results of operations

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157). SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods of those fiscal years. The adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our condensed consolidated financial position, results of operations or cash flows. Relative to SFAS 157, the FASB issued FSP FAS 157-1, FAS 157-2, and FAS 157-3. FSP FAS 157-1 amends SFAS 157 to exclude SFAS 13 and its

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related interpretive accounting pronouncements that address leasing transactions, while FSP FAS 157-2 delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. FSP FAS 157-3 clarifies the application of SFAS 157 as it relates to the valuation of financial assets in a market that is not active for those financial assets. This FSP is effective immediately and includes those periods for which financial statements have not been issued. We have considered FSP FAS 157-3 in its determination of estimated fair values as of September 30, 2008, and the impact was not material. We adopted SFAS 157 as of January 1, 2008, with the exception of the application of the statement to non-recurring nonfinancial assets and nonfinancial liabilities. We will adopt FAS 157 as it is applied to non-financial assets and non-financial liabilities at the beginning of 2009, and we do not expect the adoption of this pronouncement to have a material impact on our consolidated financial statements. Please see Note 2. Certain Balance Sheet Components.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159) effective for us January 1, 2008. SFAS 159 permits companies to choose to measure certain financial instruments and other items at fair value. We chose not to elect the fair value option for financial assets and liabilities existing at January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the nine months ended September 30, 2008. Therefore, the adoption of SFAS 159 had no impact on our financial position or results of operations.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). The standard expands the disclosure requirements of SFAS 133, Accounting for Derivative Instruments and Hedging Activities, and requires qualitative disclosures about the objectives and strategies for using derivatives, quantitative disclosures about the fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative agreements. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. We do not expect the adoption of this pronouncement to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51 (SFAS 160). The new standard changes the accounting and reporting of noncontrolling interests, which have historically been referred to as minority interests. SFAS 160 requires that noncontrolling interests be presented in the consolidated balance sheets within shareholders equity, but separate from the parent s equity, and that the amount of consolidated net income attributable to the parent and to the noncontrolling interest be clearly identified and presented in the consolidated statements of income. Any losses in excess of the noncontrolling interest s equity interest will continue to be allocated to the noncontrolling interest. Purchases or sales of equity interests that do not result in a change of control will be accounted for as equity transactions. Upon a loss of control, the interest sold, as well as any interest retained, will be measured at fair value, with any gain or loss recognized in earnings. In partial acquisitions, when control is obtained, the acquiring company will recognize, at fair value, 100% of the assets and liabilities, including goodwill, as if the entire target company had been acquired. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, with early adoption prohibited. The new standard will be applied prospectively, except for the presentation and disclosure requirements, which will be applied retrospectively for all periods presented. We do not expect the adoption of this pronouncement to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations (SFAS 141-R). The new standard changes the accounting for business combinations in a number of significant respects. The key changes include the expansion of transactions that will qualify as business combinations, the capitalization of in-process research and development as an indefinite-lived asset, the recognition of certain acquired contingent assets and liabilities at fair value, the expensing of acquisition costs, the expensing of costs associated with restructuring the acquired company, the recognition of contingent consideration at fair value on the acquisition date, and the recognition of post-acquisition date changes in deferred tax asset valuation allowances and acquired income tax uncertainties as income tax expense or benefit. SFAS 141-R is effective for business combinations that close in years beginning on or after December 15, 2008, with early adoption prohibited. This new standard will be adopted by the company at the beginning of 2009 and we do not expect the adoption of this pronouncement to have a material impact on our consolidated financial statements.

NOTE 2. CERTAIN BALANCE SHEET COMPONENTS

Short-term investments and Fair Value Measurements

Short-term investments, all of which have a term of less than one year, are summarized as follows (in thousands):

	Amortized Cost	Unrealized Gains/(Loss)	Estimated Fair Market Value

At September 30, 2008:			
Corporate debt securities	$ 6,157	$ 19	$ 6,176
U.S. government and agency securities	18,570	(4)	18,566
	$ 24,727	$ 15	$ 24,742
At December 31, 2007:			
Corporate debt securities	$ 36,336	$ 159	$ 36,495
U.S. government and agency securities	9,357	22	9,379
	$ 45,693	$ 181	$ 45,874

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SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, SFAS 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) significant unobservable inputs in which there is little or no market data, which require us to develop our own assumptions. This hierarchy requires us to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. On a recurring basis, we measure our marketable securities at fair value.

Our investment instruments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of instruments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The types of investments that are generally classified within Level 2 of the fair value hierarchy include U.S. government and agency securities, corporate securities and certificates of deposits.

Fair value hierarchy of our marketable securities at fair value in connection with the adoption of SFAS 157 are summarized as follows (in thousands):

Description	Total at September 30, 2008	Fair Value Measurements at Reporting Date using Quoted Prices in Active Markets for Identical Assets (Level 1)	Fair Value Measurements at Reporting Date using Significant Other Observable Inputs (Level 2)
Corporate debt securities	$ 6,176		$ 6,176
U.S. government and agency securities	$ 18,566		$ 18,566

As of September 30, 2008, we applied Level 2 measurements to our holdings of commercial paper with maturity dates less than three months classified under cash equivalents. Commercial paper with maturity dates less than three months are valued at the quoted market price from broker or dealer quotations.

We chose not to elect the fair value option as prescribed by SFAS 159 for our financial assets and liabilities that had not been previously carried at fair value. Therefore, financial assets and liabilities not carried at fair value, such as short- and long-term debt and accounts payable are still reported at their carrying values.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2008	December 31, 2007
Clinical trial related	$ 9,330	$ 5,440
Payroll and related expenses	2,599	1,619
Professional services and other	1,088	563
	$ 13,017	$ 7,622

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NOTE 3. LONG-TERM DEBT

In September 2006, we 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.

In September 2006, we entered into a $10.0 million loan facility agreement for the purpose of financing working capital (the 2006 Working Capital Loan) and borrowed all $10.0 million under the facility agreement during the year ended December 31, 2006. The 2006 Working Capital Loan bears interest at an annual interest rate of 11.9% and matures in 2010. In May 2008, we entered into a new loan agreement (the 2008 Working Capital Loan) for $20.0 million in order to repay the 2006 Working Capital Loan and to support general corporate purposes. The 2008 Working Capital Loan bears interest at an annual rate of 9.95%, with an effective rate of approximately 12% after factoring in a $1.0 million payment due at the termination of the agreement. The 2008 Working Capital Loan has interest-only payments up to and including January 2009, maturing in October 2011, and includes customary loan covenants. Expenses incurred in connection with the new loan agreement were not material.

The 2008 Working Capital Loan amounts are collateralized by all of our assets, excluding intellectual property, while Equipment Loan amounts are collateralized by our equipment purchased by such borrowed funds. Our long-term debt at September 30, 2008 consisted of the following (in thousands):

	September 30, 2008	December 31, 2007
Principal amount	$ 20,365	$ 10,177
Plus premium, based on imputed interest rate of 12%	187	
	20,552	10,177
Less current portion of long-term debt	4,725	3,820
Non-current portion	$ 15,827	$ 6,357

In connection with the loan facility agreements entered into in 2006, we issued warrants to purchase convertible preferred stock. The fair value of the warrants was estimated at an aggregate of approximately $300,000 using the Black-Scholes valuation model at the dates of issuance and recorded as debt issuance costs that are amortized to interest expense over the contractual life of seven years. The fair value of the warrants outstanding was recorded as a liability as of September 30, 2006 and revalued each subsequent reporting period with the resulting gains and losses recorded in other expense which is classified in other income (expense), net. We continued to adjust the liability for changes in fair value until the completion of our IPO, at which time all unexercised warrants converted into warrants to purchase common stock and the liability was reclassified to equity. In accordance with the revaluation through the date of the IPO, we recorded expense of approximately $0.5 million for the nine months ended September 30, 2007 and approximately $0.6 million for the cumulative period from July 3, 2003 (date of inception) to September 30, 2008.

NOTE 4. COMMITMENTS AND CONTINGENCIES

Operating Leases

In June 2004, we entered into a lease agreement for laboratory and office facilities in Mountain View, California and in August 2006 amended our lease agreement to include additional square footage within the same building, expiring in June 2008. In March 2008, we further amended our lease agreement to extend the term of the agreement until June 2012, and to include additional square footage and options to lease additional square footage. In September 2008, we amended and restated the March 2008 amendment to the lease agreement, providing for expanded square footage and certain renewal options. Rent is subject to an annual increase for the duration of the lease, which we recognize on a straight-line basis. The annual lease payments for this space under the amended and restated lease agreement, which was effective July 1, 2008, are approximately $0.5 million in 2008, $1.0 million in 2009, $1.3 million in 2010, $1.4 million in 2011, and $0.7 million 2012.

In accordance with the terms of the lease agreements we are obligated to maintain an irrevocable letter of credit from a bank as a security deposit. As collateral for the letter of credit, we are required to maintain a deposit account with the bank of $0.3 million at September 30, 2008 and December 31, 2007, which is shown as a restricted investment on our condensed consolidated balance sheets.

Contingencies

We are subject to claims and assessments from time to time in the ordinary course of business. We do not believe that any such matters, individually or in the aggregate, will have a material adverse effect on our financial condition or results of operation.

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Indemnification

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

In accordance with our certificate of incorporation and bylaws, we have indemnification obligations to our officers and directors for certain events or occurrences, subject to certain limits, while they are serving at our request in such capacity. There have been no claims to date and we have a director and officer insurance policy that may enable us to recover a portion of any amounts paid for future potential claims.

NOTE 5. LICENSE AND SUPPLY AGREEMENTS

Under the June 2004 agreement, as amended, with Nektar Therapeutics UK Limited (the Nektar Agreement), we were 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. We also agreed to pay royalties at specified rates based on net sales. As of September 30, 2008, we are 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. No amounts related to milestones were paid during the nine months ended September 30, 2008 and 2007, and we paid $2.6 million during the cumulative period from July 3, 2003 (date of inception) to September 30, 2008. Either party may terminate the Nektar Agreement upon a material, uncured default of the other party. We may terminate the agreement, with or without cause, at any time upon six months written notice.

Under the April 2004 agreement, as amended, with Elan Pharma International Limited (the Elan Agreement), Elan granted to us a worldwide, exclusive, sub-licensable license under Elan s intellectual property rights to use, market, distribute, sell, import and export ingredients for our UDB product candidate. We also agreed to pay royalties at specified rates based on net sales. As of September 30, 2008, we are required to make future nonrefundable milestone payments of up to $16.5 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. We paid $750,000 related to milestones during the nine months ended September 30, 2008 and $750,000 for the nine months ended September 30, 2007, and $4.0 million during the cumulative period from July 3, 2003 (date of inception) to September 30, 2008. Either party may terminate the Elan Agreement upon a material, uncured default of the other party. We may terminate the agreement, with or without cause, at any time upon 90 days written notice.

In June 2008, we entered into a Transfer and Assignment Agreement with Telesso Technologies Limited (the Telesso Agreement), formerly Eiffel Technologies Limited, which terminated our 2005 research and development, license and supply agreement with Eiffel Technologies Limited (Eiffel Agreement), including Eiffel s rights to royalty and milestone commitments under the Eiffel Agreement. Under the Telesso Agreement, Telesso is transferring and assigning all intellectual property and know-how owned by Telesso related to certain methods for manufacturing drug formulations previously licensed to us and will transfer to us certain capital equipment and other materials related to the technology. We are required to make future payments for the transfer of the technology and other transferred property, and for the achievement of specified clinical and regulatory milestones for the first product developed by us using the technology when and if certain regulatory milestones are met. These payments are considered to be immaterial in nature and no amounts related to milestones have been paid under the Telesso Agreement as of September 30, 2008.

NOTE 6. EMPLOYEE EQUITY INCENTIVE PLANS

Stock-based Compensation

We account for employee stock-based compensation under SFAS No. 123(R), Share-Based Payment (SFAS 123R), which requires compensation expense related to share-based transactions, including employee stock options, to be measured and recognized in the financial statements based on fair value. Employee stock-based compensation expense recognized is calculated based on awards ultimately expected to vest, and has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock-based compensation expense recognized under SFAS 123R related to stock options and awards under our employee stock purchase plan (ESPP) is as follows (in thousands):

	Three Months Ended September 30,		Nine months Ended September 30,	
	2008	2007	2008	2007
Research and development	$ 336	$ 232	$ 1,013	$ 481
Sales, general and administrative	520	312	1,582	641
	$ 856	$ 544	$ 2,595	$ 1,122

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Stock Option Awards

During the nine months ended September 30, 2008 and 2007, we granted 1,009,150 and 1,125,922 stock options, respectively, to employees with a weighted-average grant date fair value of $6.84 and $6.43 per share, respectively. The fair value of stock option grants was estimated at the grant date using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2008	2007
Weighted-average volatility	62.9%	56.0%
Weighted-average expected term (in years)	5.5	5.5
Risk-free interest rates	3.1%	4.7%
Expected dividend yield	0.0%	0.0%

Option activity under our plans is as follows:

		Outstanding Options	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
December 31, 2007	2,446,656	2,620,928	$ 3.32
Options granted	(1,009,150)	1,009,150	$ 12.04
Options exercised		(152,400)	$ 1.35
Options cancelled	272,886	(272,886)	$ 7.59
September 30, 2008	1,710,392	3,204,792	$ 5.79

As of September 30, 2008, there were unrecognized compensation costs of approximately $8.2 million 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 2.8 years.

Employee Stock Purchase Plan

We also estimated the fair value of employee stock purchase rights granted under the ESPP, which became effective in October 2007 upon the effectiveness of the IPO, using the Black-Scholes valuation model. For ESPP enrollment during the nine months ended September 30, 2008, the weighted-average fair value of each stock purchase right was $4.26 per share. The fair value of employee stock purchase rights is being recognized on a straight-line basis over the requisite service period of the purchase rights.

NOTE 7. 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. Our 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.

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A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine months Ended September 30,	
	2008	2007	2008	2007
Historical net loss per share:				
Numerator				
Net loss, as reported	$ (20,363)	$ (9,842)	$ (51,120)	$ (25,190)
Less: Cumulative stock dividend attributed to preferred stockholders		(1,902)		(5,575)
Net loss attributed to common stockholders	$ (20,363)	$ (11,744)	$ (51,120)	$ (30,765)
Denominator				
Weighted-average common shares outstanding	20,400,128	886,500	20,321,705	848,463
Less: Weighted average shares subject to repurchase	(1,446)	(52,067)	(13,499)	(65,084)
Denominator for basic and diluted net loss per share	20,398,682	834,433	20,308,206	783,379
Basic and diluted net loss per share	$ (1.00)	$ (14.07)	$ (2.52)	$ (39.27)

The following outstanding options, common stock subject to repurchase, convertible preferred stock and warrants 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:

	September 30,	
	2008	2007
	(Unaudited)	
Options to purchase common stock	3,204,792	2,573,004
Common stock subject to repurchase		47,729
Warrants	73,989	73,989
Convertible preferred stock (on an as if converted basis)		12,634,845

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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 and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2007.

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 pediatric asthma and MAP0004 for migraine. 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 orally 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.

We announced positive results from Phase 2 clinical studies of UDB and MAP0004 in early 2007 and initiated a Phase 3 clinical program for UDB in January 2008. For our MAP0004 migraine program we received a special protocol assessment, or SPA, from the U.S. Food and Drug Administration, or FDA, in January 2008 and initiated a Phase 3 clinical program in July 2008. We hold worldwide commercialization rights for each of our product candidates and intend to market UDB and MAP0004 in the United States through our own focused sales force targeting pediatricians for UDB and neurologists and headache specialists for MAP0004. Our program for UDB includes 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 includes 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.

Our product portfolio also includes two earlier stage product candidates, both of which highlight the broad applicability of our technologies to a diverse range of potential future products. MAP0005 is our proprietary combination of an inhaled corticosteroid and a long-acting beta-agonist for the potential treatment of asthma and chronic obstructive pulmonary disease, or COPD, and MAP0001 is our proprietary form of insulin for the potential treatment of Type 1 and Type 2 diabetes via pulmonary delivery using our proprietary Tempo® inhaler. We have no current intention to further develop either of these earlier stage product candidates independently.

We are a development stage company and have not generated any product revenues. Since our inception, we have incurred losses and have an accumulated deficit of $154.1 million as of September 30, 2008. We have financed our operations through equity financing, debt financing and the issuance of convertible notes. Prior to our initial public offering, or IPO, in October 2007, we had received net proceeds of $106.7 million from the issuance of convertible notes payable and convertible preferred stock. With the completion of our IPO we received net proceeds of $62.1 million after deducting expenses and underwriters discounts and commissions. 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, or the 2006 Working Capital Loan. In May 2008, we entered into an agreement to borrow $20.0 million, or the 2008 Working Capital Loan, in order to repay the 2006 Working Capital Loan and to support general corporate purposes.

We expect to continue to incur net losses for the next several years as we continue to develop our current product candidates, 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 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.

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Critical Accounting Policies

The accounting policies that we consider to be our most critical (those that are most important to the portrayal of our financial condition and results of operations and that require our most difficult, subjective or complex judgments), the effects of those accounting policies applied and the judgments made in their application are summarized in *Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

Financial Overview

Research and Development Expenses

Research and development expenses consist of: (i) 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; (ii) milestone payments paid to our collaborative partners who work on our processing and supply of clinical trial material ; (iii) the cost of manufacturing and supplying 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) stock-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. Through September 30, 2008, we had incurred approximately $114.0 million in research and development expenses since our inception in 2003. 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 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 earlier stage projects. 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,
	2008	2007	2008	2007	2008
Our most advanced product candidates:					
UDB	47%	34%	50%	37%	45%
MAP0004	45%	56%	42%	54%	46%
Other projects	8%	10%	8%	9%	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 advanced product candidates. However, we will need to raise substantial additional capital in the future in order to complete the development and potential commercialization of UDB, MAP0004 and other product candidates.

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Sales, General and Administrative Expenses

Sales, general and administrative expenses consist primarily of compensation for executive, finance, marketing, legal and administrative personnel, including share-based compensation. Other sales, general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, other professional services, the cost of market research activities and consulting fees. Through September 30, 2008, we had incurred approximately $30.3 million in sales, general and administrative expenses since our inception in 2003. 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, 2008 and 2007

	Three Months Ended September 30,				Nine months Ended September 30,			
	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)				(in thousands, except percentages)			
Research and development expenses	$ 16,815	$ 7,510	$ 9,305	124%	$ 41,614	$ 18,343	$ 23,271	127%
Sales, general and administrative expenses	3,380	2,366	1,014	43%	9,685	6,823	2,862	42%
Interest income	453	621	(168)	-27%	1,894	1,612	282	17%
Interest expense	(621)	(336)	(285)	85%	(1,437)	(1,017)	(420)	41%
Other expense, net		(251)	251	*	(278)	(619)	341	-55%

* Percentage removed as it is not meaningful.

Research and Development Expenses. The increase in research and development expenses for the three and nine months ended September 30, 2008 as compared to the same periods in 2007 was primarily driven by an increase of $7.4 million and $17.3 million, respectively, related to clinical expenses to support Phase 3 clinical programs initiated in 2008 for our two lead program candidates, UDB and MAP0004, and an increase of $1.3 million and $4.1 million, respectively, in personnel related expenses and stock-based compensation in support of these Phase 3 clinical programs.

Sales, General and Administrative Expenses. The increase in sales, general and administrative expenses for the three months ended September 30, 2008 as compared to the same period in 2007 was primarily related to increases of $0.4 million in personnel related expenses and stock-based compensation, as well as an increase of $0.5 million due to professional fees, outside services and other administrative related costs. The increase in sales, general and administrative expenses for the nine months ended September 30, 2008 as compared to the same period in 2007 was primarily related to increases of $2.0 million in personnel related expenses and stock-based compensation, as well as an increase of $0.9 million due to professional fees, outside services and other administrative related costs, partially offset by a decrease in non-recurring IPO expenses incurred in the prior year.

Interest Income. The decrease in interest income for the three months ended September 30, 2008 as compared to 2007 was due primarily to a decrease in market interest rates. The increase in interest income for the nine months ended September 30, 2008 as compared to 2007 was due primarily to higher average cash balances during that period resulting from proceeds raised from the completion of our IPO in October 2007, partially offset by the decrease in market interest rates. We expect our interest income to fluctuate in the future with changes in average investment balances and market interest rates.

Interest Expense. Interest expense increased for the three months and nine months ended September 30, 2008 as compared to the same periods in 2007 as a result of an increase in long-term debt related to the 2008 Working Capital Loan. We expect our interest expense to fluctuate in the future with average debt balances.

Other Income (Expense), Net. Other income (expense), net for the three and nine months ended September 30, 2007 primarily consisted of the change in carrying value of warrants to purchase redeemable convertible preferred stock. At the time of our IPO, the warrants to purchase preferred stock converted into warrants to purchase common stock with the carrying value included in equity and no further expense was incurred. Other income (expense), net, for the nine months ended September 30, 2008 primarily consisted of expenses related to the 2008 Working Capital Loan and the debt extinguishment related to the 2006 Working Capital Loan and gains of $91,000 due to the sale of investments.

Liquidity and Capital Resources

We have incurred losses and negative cash flow since our inception in July 2003 and, as of September 30, 2008, we had an accumulated deficit of $154.1 million. We will continue to be in a loss position until sufficient revenue can be generated to offset our expenses, and we anticipate that we will continue to incur net losses for the next several years. We expect that our research and development, and sales, general, and administrative expenses may 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. Prior to our IPO in October 2007, we had received net proceeds of $106.7 million from the issuance of convertible notes payable and convertible preferred stock. Through our IPO we received net proceeds of $62.1 million after deducting expenses and underwriters discounts and commissions. In 2006,

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we entered into the 2006 Working Capital Loan and borrowed $10.0 million to finance working capital and $1.0 million to finance equipment purchases. In May 2008, we entered into the 2008 Working Capital Loan and borrowed $20.0 million in order to repay the 2006 Working Capital Loan and to support general corporate purposes.

As of September 30, 2008, we had approximately $63.0 million in cash, cash equivalents and short-term investments. Our cash and short-term investment balances are held in a variety of interest bearing instruments, including commercial paper, corporate debt, U.S. government and agency securities and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to capital preservation and liquidity.

We believe that we may need to raise additional capital in the next 12 months in order to continue with our clinical trial development efforts. In addition, 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 future 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. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current R&D programs and other expenses.

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

	Nine months Ended September 30,	
	2008	2007
	(In thousands)	
Cash provided by (used in):		
Operating activities	$ (41,360)	$ (21,399)
Investing activities	$ 19,979	$ (7,653)
Financing activities	$ 10,544	$ 49,864

Net cash used in operating activities. Net cash used in operating activities primarily reflects the net loss for those periods as we continue as a development stage company. The net loss in each period was reduced in part by non-cash depreciation and amortization, stock-based compensation and changes in operating assets and liabilities. The increase for the nine months ended September 30, 2008 as compared to the same period of 2007 was primarily driven by an increase in operating expenses related to our clinical development programs and an increase in headcount across all departments.

Net cash used in investing activities. Net cash used in investing activities was primarily related to investment activity, with more maturities than purchases of investments in 2008 as compared to 2007. Purchase of property and equipment also increased over the prior year period due to our company s growth.

Net cash provided by financing activities. Net cash provided by financing activities for the nine months ended September 30, 2008 was primarily attributable to the issuance of $20.0 million in debt in May 2008, offset by the repayment of $8.3 million for the 2006 Working Capital Loan. Issuance of Series D convertible preferred stock in the nine months ended September 30, 2007 provided $50.2 million in financing.

Contractual Obligations

As of September 30, 2008, future minimum payments under lease obligations and debt obligations were as follows (in thousands).

		Payments due by period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
		(in thousands)			
Contractual Obligations:					
Debt [(1)]	$ 24,990	$ 6,609	$ 18,381	$	$

Operating lease obligation [2]	4,631	1,019	3,612		
Total	$ 29,621	$ 7,628	$ 21,993	$	$

(1) Represents principal maturities, net of premium, including interest. In May 2008, we entered into the 2008 Working Capital Loan and borrowed $20.0 million in order to repay the 2006 Working Capital Loan and to support general corporate purposes. Please see Note 3. Long-Term Debt in the notes to the condensed consolidated financial statements in this Form 10-Q for additional information relating to debt.

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(2) In September 2008, we amended and restated the March 2008 amendment to our lease agreement which provides for expanded square footage and certain renewal options. Please see Note 4. Commitments and Contingencies in the notes to the condensed consolidated financial statements in this Form 10-Q for additional information.

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. Please see Note 5. License and Supply Agreements in the notes to the condensed consolidated financial statement in this Form 10-Q for additional information.

Recent Accounting Pronouncements

We adopted Emerging Issues Task Force (EITF) Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities, on a prospective basis for new contracts entered into on or after January 1, 2008. EITF Issue No. 07-3 states that nonrefundable advance payments for future research and development activities should be deferred and recognized as an expense as the goods are delivered or the related services are performed. Entities should then continue to evaluate whether they expect the goods to be delivered or services to be rendered and, if an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. The adoption of EITF Issue No. 07-3 did not have a material impact on our financial position or results of operations

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157). SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods of those fiscal years. The adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our condensed consolidated financial position, results of operations or cash flows. Relative to SFAS 157, the FASB issued FSP FAS 157-1, FAS 157-2, and FAS 157-3. FSP FAS 157-1 amends SFAS 157 to exclude SFAS 13 and its related interpretive accounting pronouncements that address leasing transactions, while FSP FAS 157-2 delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. FSP FAS 157-3 clarifies the application of SFAS 157 as it relates to the valuation of financial assets in a market that is not active for those financial assets. This FSP is effective immediately and includes those periods for which financial statements have not been issued. We have considered FSP FAS 157-3 in its determination of estimated fair values as of September 30, 2008, and the impact was not material. We adopted SFAS 157 as of January 1, 2008, with the exception of the application of the statement to non-recurring nonfinancial assets and nonfinancial liabilities. We will adopt FAS 157 as it is applied to non-financial assets and non-financial liabilities at the beginning of 2009, and we do not expect the adoption of this pronouncement to have a material impact on our consolidated financial statements. Please see Note 2. Certain Balance Sheet Components.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159) effective for us January 1, 2008. SFAS 159 permits companies to choose to measure certain financial instruments and other items at fair value. We chose not to elect the fair value option for financial assets and liabilities existing at January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the nine months ended September 30, 2008. Therefore, the adoption of SFAS 159 had no impact on our financial position or results of operations.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). The standard expands the disclosure requirements of SFAS 133, Accounting for Derivative Instruments and Hedging Activities, and requires qualitative disclosures about the objectives and strategies for using derivatives, quantitative disclosures about the fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative agreements. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. We do not expect the adoption of this pronouncement to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51 (SFAS 160). The new standard changes the accounting and reporting of noncontrolling interests, which have historically been referred to as minority interests. SFAS 160 requires that noncontrolling interests be presented in the consolidated balance sheets within shareholders equity, but separate from the parent s equity, and that the amount of consolidated net income attributable to the parent and to the noncontrolling interest be clearly identified and presented in the consolidated statements of income. Any losses in excess of the noncontrolling interest s equity interest will continue to be allocated to the noncontrolling interest. Purchases or sales of equity interests that do not result in a change of control will be accounted for as equity transactions. Upon a loss of control, the interest sold, as well as any interest retained, will be measured at fair value, with any gain or loss recognized in earnings. In partial acquisitions, when control is obtained, the acquiring company will recognize, at fair value, 100% of the assets and liabilities, including goodwill, as if the entire target company had been acquired. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, with early adoption prohibited. The new standard will be

applied prospectively, except for the presentation and disclosure requirements, which will be applied retrospectively for all periods presented. We do not expect the adoption of this pronouncement to have a material impact on our consolidated financial statements.

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In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations (SFAS 141-R). The new standard changes the accounting for business combinations in a number of significant respects. The key changes include the expansion of transactions that will qualify as business combinations, the capitalization of in-process research and development as an indefinite-lived asset, the recognition of certain acquired contingent assets and liabilities at fair value, the expensing of acquisition costs, the expensing of costs associated with restructuring the acquired company, the recognition of contingent consideration at fair value on the acquisition date, and the recognition of post-acquisition date changes in deferred tax asset valuation allowances and acquired income tax uncertainties as income tax expense or benefit. SFAS 141-R is effective for business combinations that close in years beginning on or after December 15, 2008, with early adoption prohibited. This new standard will be adopted by the company at the beginning of 2009 and we do not expect the adoption of this pronouncement to have a material impact on our consolidated 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 DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents and short-term investments which have maturities not to exceed one year. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and capturing a market rate of return based on our investment policy parameters and market conditions. 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 very 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.

In the United States, recent market and economic conditions have been unprecedented and challenging with tighter credit conditions and slower growth through the third quarter of 2008. For the nine-month period ended September 30, 2008, continued concerns about the systemic impact of inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining real estate market in the United States have contributed to increased market volatility and diminished expectations for the U.S. economy. In the third quarter, added concerns fueled by the federal government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of Lehman Brothers Holdings Inc., the U.S. government-provided loan to American International Group Inc. and other federal government interventions in the U.S. credit markets have led to increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment have recently contributed to substantial market volatility.

As a result of these market conditions, the cost and availability of credit and investments has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may adversely affect our liquidity and financial condition. If these market conditions continue, they may limit our ability to timely replace maturing liabilities, and access the capital markets to meet liquidity needs, resulting in adverse effects on our financial condition and results of operations.

ITEM 4T. 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.

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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, 2008 at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the third quarter of 2008, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceeding.

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, 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 and negative cash flow in each year since our inception, including net losses of approximately $16.2 million, $25.8 million and $40.1 million, for the years ended December 31, 2005, 2006 and 2007, respectively. As of September 30, 2008, we had a deficit accumulated during development stage of approximately $154.1 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 continue with 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 and with preparing for commercialization and we expect to continue to incur costs 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 completion of, clinical testing, as well as the analysis and reporting of results from such clinical testing;

our ability to manage our supply chain for study drug, other clinical materials and potentially approved products;

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

the FDA s determination of the special protocol assessment, or SPA, we entered into concerning MAP0004;

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

our ability to receive regulatory approval or commercialize our product candidates;

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

our ability to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act to seek FDA marketing approval of our product candidates;

market acceptance of our product candidates for which we obtain regulatory approval;

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;

the ability to receive regulatory approval or commercialize our products outside of the United States;

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

guidelines and recommendations of therapies published by various organizations;

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;

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, many of whom 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.

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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 proceed with 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 we may need to raise additional capital in the next 12 months in order to continue with our clinical trial development efforts. In addition, 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 future 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. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current R&D programs and other expenses.

In the third quarter, the federal government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of Lehman Brothers Holdings Inc., the U.S. government-provided loan to American International Group Inc. and other federal government interventions in the U.S. credit markets led to increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment have recently contributed to substantial market volatility. As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may limit our ability to access the capital markets to meet our funding requirements. 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.

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 clinical and 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. We have initiated Phase 3 clinical trials for UDB and MAP0004. 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.

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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.

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 our 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 contract 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;
- 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;
- maintaining and supplying clinical trial material on a timely basis;
- complying with design protocols of any applicable SPAs; and
- collecting, analyzing and reporting final data from the clinical trials.

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. We have initiated Phase 3 clinical trials for UDB and MAP0004. 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.

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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 studies 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 initiated a Phase 3 clinical program for UDB in January 2008 and initiated a Phase 3 clinical program for MAP0004 in July 2008. We anticipate conducting additional Phase 2 clinical studies for UDB and MAP0004. Specifically, our programs include 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. In our Phase 3 clinical trial for UDB, patients will be randomized and given 0.25 mg UDB, 0.135 mg UDB or placebo to evaluate changes in Nighttime and Daytime Composite Symptom Score. We may not demonstrate statistically significant efficacy for the 0.25 mg dose or the 0.135 mg dose, which could make it difficult to receive regulatory approval for either dose.

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. In our Phase 3 clinical trial for UDB, patients will be randomized and given 0.25 mg UDB, 0.135 mg UDB or placebo to evaluate changes 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 product candidates in development require regulatory review and approval prior to commercialization. Any delay in the regulatory review or approval of any of our product candidates in development will harm our business.

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All of our product candidates in development require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our product candidates 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 product candidates, 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 product candidates 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 studies and clinical trials 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 interaction 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.

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.

While we have negotiated a SPA with the FDA for our first Phase 3 clinical trial of MAP0004 for the potential treatment of migraine, the achievement of pre-specified trial results under the SPA does not guarantee any particular outcome from regulatory review of the study or the product candidate.

The FDA s SPA process creates a written agreement between the sponsoring company and the FDA regarding clinical trial design and other clinical trial issues that can be used to support approval of a product candidate. The SPA is intended to provide assurance that if pre-specified trial results are achieved, they may serve as the primary basis for an efficacy claim in support of a NDA. However, the SPA agreement is not a guarantee of an approval of a product or any permissible claims about the product. In particular, the SPA is not binding on the FDA if public health concerns unrecognized at the time of the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if the sponsor company fails to comply with the agreed upon trial protocols. In January 2008, we announced that we reached agreement with the FDA on a SPA for the first Phase 3 clinical trial of our MAP0004 product candidate for the potential treatment of migraine. We cannot assure you that the Phase 3 clinical trial will be successful. In addition, we do not know how the FDA will interpret the commitments under the SPA agreement, how it will interpret the data and results or whether it will approve our MAP0004 product candidate for the treatment of migraine. As a result, we cannot guarantee any particular outcome from regulatory review of the first MAP0004 Phase 3 trial.

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 FFDCA. Section 505(b)(2), if applicable to us, would allow an 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.

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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:

- a product s FDA-approved labeling as well as limitations or warnings contained in the 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 medical 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 or lower 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 notice to us that any of our product candidates has been approved. 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.

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.

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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;
- research and 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 resources and 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 $880 million in the United States and approximately $1.1 billion worldwide in 2007 according to data published by IMS Health. Leukotriene antagonists are an alternative to inhaled corticosteroids for asthmatic children. Prescriptions of Merck & Co., Inc. s Singulair, the leading leukotriene antagonist, for children under the age of six generated approximately $500 million in sales in 2007. 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.

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 2007 sales of approximately $1.2

billion in the United States and $1.6 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.

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.

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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 pre-clinical studies and clinical trials and additional administrative review periods. For example, European regulatory authorities generally require clinical testing 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;
- regulatory authorities may withdraw their approval of the product and require us to take our approved drug off the market;
- 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;

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.

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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.

We will need to obtain FDA approval of our proposed product names and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. If the FDA objects to our product names, we may be required to adopt an alternative name for our initial product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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 we do not own or operate a 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 drug substance and drug packaging, including the components of the device used to administer certain of our drug candidates. 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 all necessary 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 all third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements or, for those agreements that we have already entered into, 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 are 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 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, sales and distribution collaborations with third parties, we may not be able to commercialize our products successfully.

We plan to establish marketing, sales and distribution 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 potential of the commercialization opportunity. Outside the United States, we may establish commercial partnerships for all of our product candidates in order to effectively reach target markets 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, sales and distribution collaborations to target primary care physicians, specialists and other large groups of prescribing physicians within and outside the United States, 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 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.

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.

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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 unforceable, 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.

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 and Trademark 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 and Trademark Office or during litigation under the revised criteria which make it more difficult to obtain patents.

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

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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.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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, 2008, we had 91 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 for UDB and MAP0004 and other additional trials effectively, which we anticipate will be conducted at numerous clinical sites; and

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

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 area of California. 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 previously 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.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock together control approximately 75% 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;

status and/or 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;

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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;

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. In the third quarter, the federal government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of Lehman Brothers Holdings Inc., the U.S. government-provided loan to American International Group Inc. and other federal government interventions in the U.S. credit markets have led to increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment have recently contributed to substantial market volatility, and if such market conditions continue, the market price of shares of our common stock may fluctuate or decline.

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 IPO continue to hold a substantial number of shares of our common stock that they are now able to sell in the public market. 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 establish programmed selling plans under Rule 10b5-1 of the 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.

We will continue to incur significant increased costs as a result of operating as a public company.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we must use additional internal controls and disclosure controls and procedures, as required by Section 404 of the Sarbanes-Oxley Act of 2002. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. In addition, we will continue to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

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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 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 will continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of 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.

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.

We have never paid dividends on our common stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our stock.

We have never paid cash dividends on our common stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may become involved in securities class action litigation that could divert management s attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business.

ITEM 6. EXHIBITS

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to the Registrant s Registration Statement on Form S-1-A (File No. 333-143823), filed on September 20, 2007, and incorporated herein by reference).

10.1*	Amended and Restated Fourth Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated July 15, 2008.
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.
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.

* Certain portions have been omitted pursuant to a confidential treatment request. Omitted information has been filed separately with the Securities and Exchange Commission.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 13, 2008

MAP PHARMACEUTICALS, INC.

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

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
4.1	Specimen Stock Certificate (filed as Exhibit 4.1 to the Registrant s Registration Statement on Form S-1-A (File No. 333-143823), filed on September 20, 2007, and incorporated herein by reference).
10.1*	Amended and Restated Fourth Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated July 15, 2008.
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