

MAP Pharmaceuticals, Inc.  
Form 10-K/A  
March 09, 2010  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**Form 10-K/A**

**Amendment No. 2**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 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)

Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

**Delaware**  
(State or Other Jurisdiction of

**20-0507047**  
(I.R.S. Employer

Incorporation or Organization)

Identification No.)

**2400 Bayshore Parkway, Suite 200, Mountain View, California, 94043**

(Address of principal executive offices and zip code)

**Registrant's telephone number, including area code: (650) 386-3100**

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
<b>Common Stock par share \$0.01 par value</b>	<b>The Nasdaq Global Market</b>

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity stock held by non-affiliates of the registrant was \$90,342,802 as of June 30, 2008, the last day of the registrant's second fiscal quarter during its fiscal year ended December 31, 2008, based upon the closing sale price on The NASDAQ Global Market reported for such date. Shares of Common Stock held by each officer and director and by each person who may be deemed to be an affiliate have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2009, the registrant had outstanding 20,602,870 shares of Common Stock.



**Table of Contents**

**Explanatory Note**

MAP Pharmaceuticals, Inc. (the Company) is filing this Amendment No. 2 to its Annual Report on Form 10-K for the year ended December 31, 2008 (the Annual Report), as filed with the Securities and Exchange Commission on March 12, 2009 and as amended on April 9, 2009, to include in one document the Annual Report and the amended certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended.

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
PART I	
Item 1. <u>Business</u>	4
Item 1A. <u>Risk Factors</u>	28
Item 2. <u>Properties</u>	51
Item 3. <u>Legal Proceedings</u>	51
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	51
PART II	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	52
Item 6. <u>Selected Financial Data</u>	55
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	56
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	66
Item 8. <u>Financial Statements and Supplementary Data</u>	67
Item 9A. <u>Controls and Procedures</u>	93
Item 9B. <u>Other Information</u>	93
PART III	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	94
Item 11. <u>Executive Compensation</u>	94
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	94
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	94
Item 14. <u>Principal Accountant Fees and Services</u>	94
PART IV	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	95
<u>Signatures</u>	96

---

**Table of Contents**

**PART I**

**ITEM 1. BUSINESS**

**Overview**

We use our proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. We have several proprietary product candidates in clinical development which address large market opportunities, including our two most advanced product candidates, Unit Dose Budesonide, or UDB, for the potential treatment of asthma in children and MAP0004 for the potential treatment of migraine.

In December 2008, MAP Pharmaceuticals and AstraZeneca AB, or AstraZeneca, entered into a worldwide collaboration to develop and commercialize UDB, our proprietary nebulized formulation of budesonide. This collaboration became effective in February 2009. We are jointly developing UDB with AstraZeneca in the United States. AstraZeneca has rights to commercialize UDB in the United States, and to develop and commercialize UDB outside of the United States. AstraZeneca will reimburse us for our costs of future UDB development in the United States, and will provide funding for up to a 60-person sales force for the company to co-promote UDB with AstraZeneca in the United States after product launch. In February 2009, AstraZeneca paid us a nonrefundable upfront cash payment of \$40 million. Under the terms of the agreement, the company is eligible to receive up to \$240 million in development and regulatory milestones. The agreement also provides for additional progressively demanding sales performance-related milestone payments of up to \$585 million in the event the product is a considerable commercial success. We are eligible to receive significant and escalating double-digit royalty payments on worldwide sales.

In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in the two doses evaluated when compared to placebo. We and our partner AstraZeneca are conducting further analyses of these data to determine appropriate next steps for the UDB program.

We initiated our first Phase 3 clinical trial of MAP0004 in July 2008 and completed enrollment in the efficacy portion of this trial in January 2009. This clinical trial is being conducted pursuant to a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA.

We hold worldwide commercialization rights for MAP0004 and our goal is to market MAP0004 in the United States through our own focused sales force targeting neurologists and headache specialists. We may establish partnerships with pharmaceutical companies to market and sell to primary care physicians and outside of the United States.

Our proprietary technologies enable us to develop proprietary drug candidates for administration via the respiratory tract to more effectively treat both local respiratory and systemically treatable diseases. We develop inhalable drug particles with the specific physical and chemical characteristics to facilitate efficient pulmonary delivery. We believe this will result in medicines that are most appropriate for the intended indication. We believe that our product candidates potentially offer several benefits to patients compared to alternative therapies, including: quicker symptom relief, longer-lasting therapeutic benefit at lower doses, shorter administration time, enhanced safety profile and convenient, non-invasive delivery.

The following are our two product candidates in Phase 3 clinical development:

*Unit Dose Budesonide* is our proprietary nebulized version of budesonide intended to treat 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, currently marketed by our partner, AstraZeneca, under the brand name Pulmicort® Respules®. Conventional nebulized budesonide is an inhaled corticosteroid approved by the FDA, for treating asthma in children from 12 months up to eight years of age in the United States. In 2007, sales of conventional nebulized budesonide generated revenues

## Table of Contents

of approximately \$900 million in the United States and approximately \$1.2 billion worldwide, according to data published by IMS Health. Our UDB product candidate has been designed to achieve a particle size smaller than previously possible with budesonide. We believe this smaller particle size may allow for faster delivery and efficacy at a lower dose, which together may offer improved safety, compliance and convenience. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in the two doses evaluated when compared to placebo. Median nebulization times were less than four minutes for both doses in the study. Initial review of the data has not identified any serious adverse events attributed to the study drug. We and our partner AstraZeneca are conducting further analyses of these data to determine appropriate next steps for the UDB program.

**MAP0004** is our proprietary orally inhaled version of dihydroergotamine, or DHE, intended to treat migraine. Migraine is a syndrome characterized by four symptoms: pain, nausea, phonophobia, or abnormal sensitivity to sound, and photophobia, or abnormal sensitivity to light. MAP0004 is designed to provide faster onset and longer-lasting migraine relief than triptans, the class of drugs most often prescribed for treating migraine. In 2007, triptans generated revenues of approximately \$2.2 billion in the United States, according to data published by IMS Health. MAP0004 is an easy to use, non-invasive, at-home therapy in development that patients self-administer using our proprietary hand-held Tempo<sup>®</sup> inhaler. DHE is available as an intravenous, or IV, therapy which has been used in clinical settings for over 50 years for the safe and effective treatment of migraine, particularly forms of migraine that are severe or do not respond to triptans or other therapies. We believe MAP0004 has the potential to be suitable as a first-line therapy for some migraine patients. We announced positive results from our Phase 2 clinical trials for MAP0004 in March 2007. In a Phase 2 clinical trial, MAP0004 retained the rapid onset and long-lasting effectiveness of IV DHE while avoiding the nausea that IV administration can cause. We initiated a Phase 3 clinical trial in July 2008 pursuant to an SPA and completed enrollment in the efficacy portion of the trial in January 2009.

Our product portfolio also includes the two earlier stage product candidates listed below, both of which highlight the broad applicability of our technologies to a diverse range of potential future products. While we do not plan to make further significant direct investment in these two product candidates, we plan to evaluate other potential product candidates which may utilize these technologies, as well as partnership opportunities for further development and commercialization of these two product candidates.

*Combination Particle Technology:* We are applying our proprietary particle formulation technologies to deliver the optimal ratio of multiple drugs in a reproducible and consistent manner. We combine two or more drugs together into a single micron sized particle at consistent and reproducible ratios, which may improve the delivery profile and stability of the resultant combination therapy. We believe our proprietary technologies in this area have potential broad applicability for a number of small molecule combination product candidates in diverse indications via inhalation and other routes of delivery.

**MAP0005:** We are demonstrating this combination particle capability with MAP0005, our proprietary single particle combination of an inhaled corticosteroid and a long-acting beta-agonist, or LABA, for the potential treatment of asthma and chronic obstructive pulmonary disease, or COPD, using our proprietary Tempo inhaler. In April 2008, we announced positive results from a Phase 2a clinical trial evaluating MAP0005 in adult asthmatics.

*Stable Protein & Peptide Technology:* We have also demonstrated our ability to apply our proprietary technologies to formulate and stabilize biologically-active proteins and peptides. We design and incorporate our protein formulations without the need for excipients or other additives, to be stored for months at room temperature and to provide multiple doses of medicine delivered accurately without the need for needle injections.

**MAP0001:** We are demonstrating this stable protein and peptide capability with MAP0001, our proprietary formulation of insulin for the potential treatment of Type 1 and Type 2 diabetes via

**Table of Contents**

pulmonary delivery using our proprietary Tempo inhaler. This approach may overcome many of the issues currently associated with the invasive delivery of proteins by injection or infusion in general, and with inhalable insulin therapies in particular.

We have not filed an investigational new drug application, or IND, with the FDA for MAP0005 or MAP0001 because our clinical trials were not conducted in the United States.

A core part of our strategy is to reduce the risk of drug development by focusing on the development of proven drugs with established safety and efficacy profiles. The compounds underlying our product candidates are well characterized and have been previously approved by the FDA for other sponsors and in other dosage forms and formulations. As a result, we may seek FDA marketing approval of our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDC, which, if available to us, would allow any new drug application, or 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. This may expedite the development program for our product candidates by potentially decreasing the overall scope of work we must do ourselves.

**Our Product Candidates**

The following table summarizes our product candidates, each developed using our proprietary technologies:

<b>Product Candidate</b>	<b>Potential Indication</b>	<b>Status of Clinical Programs</b>	<b>Commercial Rights</b>
Unit Dose Budesonide (UDB)	Asthma in children from 12 months to eight years of age	Phase 3	AstraZeneca worldwide, MAP Pharmaceuticals co-promotion in US
MAP0004	Acute treatment of migraine	Phase 3	Worldwide
MAP0005	Adult asthma and chronic obstructive pulmonary disease	Phase 2a	Worldwide
MAP0001	Type 1 and Type 2 diabetes	Phase 1a	Worldwide

In the table, under the heading Status of Clinical Programs, generally Phase 3 indicates evaluation of clinical efficacy and safety within an expanded patient population, at geographically dispersed clinical trial sites; Phase 2 indicates clinical safety testing, dosage testing and initial efficacy testing in a limited patient population; Phase 1 indicates initial clinical safety testing in healthy volunteers or a limited patient population, or trials directed toward understanding the mechanisms or metabolism of the drug. For purposes of the table, Status indicates the most advanced stage of development that has been completed or is on-going.

***Unit Dose Budesonide (UDB) for the Treatment of Asthma in Children***

UDB is our proprietary nebulized version of budesonide under development for treating asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at doses lower than those approved for conventional nebulized budesonide, which is the current leading nebulized treatment for asthma in children. Conventional nebulized budesonide is an inhaled corticosteroid, or ICS, approved by the FDA for treating asthma in children from 12 months up to eight years of age in the United States. Conventional nebulized budesonide was first introduced as Pulmicort Respules by our partner,



---

## **Table of Contents**

AstraZeneca, in Europe in 1990 and in the United States in 2000. Our version of nebulized budesonide, UDB, has been designed to have a particle size smaller than previously possible. This potentially allows a higher percentage of drug to be delivered into the lung in a shorter period of time. We believe this may reduce the amount of drug deposited in the back of the mouth and throat where it may result in local and systemic side effects. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in the two doses evaluated when compared to placebo. We and our partner AstraZeneca are conducting further analyses of these data to determine appropriate next steps for the UDB program.

### ***Asthma in Children***

According to the Centers for Disease Control and Prevention, or CDC, asthma is the most common chronic childhood disease in the United States, and is a major global public health problem. Asthma is a chronic respiratory disorder that is characterized by inflammation and narrowing of the airways, leading to limitation or obstruction of airflow and resulting in symptoms such as episodes of wheezing, chest tightness, breathlessness and coughing. In children, these symptoms are often seen at night, leading to disturbed sleep for both the parents and the child.

According to the CDC, of the estimated 23 million patients diagnosed with asthma in the United States, approximately 6.8 million are children under 18 years of age and approximately 3 million are children up to eight years of age. In the United States, rates of asthma diagnosis in children under five years old are approximately 5.8%, compared to approximately 11.5% for children between five and 11 years old. The number of very young children with asthma may be underestimated because diagnosis in young children is difficult and physicians are often reluctant to make a formal diagnosis of asthma at such a young age.

Guidelines from both the Global Initiative for Asthma, or GINA, issued in 2006 and from the National Asthma Education and Prevention Program, or NAEPP, issued in 2007 recommend the use of ICSs, as the preferred initial treatment to reduce inflammation and maintain long-term control of asthma in children of all ages. According to data published by IMS Health, prescriptions of Pulmicort Respules, marketed by our partner AstraZeneca, which was introduced in the United States in 2000, exceeded three million in the United States in 2007. Since its introduction, annual sales of Pulmicort Respules have grown to approximately \$900 million in the United States and approximately \$1.2 billion worldwide in 2007. In the United States, children under the age of five often use a nebulizer to administer inhaled asthma therapies. A nebulizer is a vaporizing device which is used to administer medication to patients in the form of a mist. Children under the age of five are generally unable to master the coordination required to use other inhalation technologies. These include metered dose inhalers, or MDIs, which use pressurized propellants to expel a specific amount of drug from a canister, and dry powder inhalers, or DPIs, which are unpressurized devices that dispense specific amounts of dry drug particles powered by the patients' own inhalation. In some cases, and more often outside the United States, physicians may prescribe an MDI plus a holding chamber or spacer, because, like nebulizers, these do not require patients to time their breaths to dispense the drug. Many physicians prefer to prescribe nebulizer therapy because it requires little training or coordination and has less dose-to-dose drug variability.

As an alternative to ICS therapy for asthmatic children up to eight years of age, physicians sometimes prescribe leukotriene modifiers since they can be given orally and avoid concerns about possible adverse effects associated with high doses of ICS, such as suppression of growth. Leukotriene modifiers, however, are not the preferred treatment according to the NAEPP and GINA guidelines, and are often used as additive therapy with an ICS. We estimate that prescriptions of the leading leukotriene modifier, Singulair, for children up to eight years of age generated approximately \$900 million in sales in 2007, out of a total of approximately \$3.5 billion in the United States.

### ***Limitations of Current Nebulized Therapies***

Due to the well established safety of the compound, budesonide has been widely adopted for use in children with asthma. GINA and NAEPP guidelines indicate ICS therapy should be used as the first line of treatment.

---

## **Table of Contents**

Conventional nebulized budesonide has three major limitations:

*Lengthy administration time for delivery of therapeutic dose:* Administration of an effective dose of conventional nebulized budesonide is relatively slow, with a published nebulization time in clinical use of five to ten minutes. However, our own market research indicates that nebulization times can often be between ten and fifteen minutes. We believe the lengthy administration process limits compliance to the prescribed therapy, especially for restless toddlers, reducing the effectiveness of the treatment. In addition, conventional nebulized budesonide is only compatible with a narrow range of nebulizers, and cannot be administered effectively using next generation nebulizers, which are designed to be smaller, quieter, more convenient and to have potentially faster drug administration times.

*Delivery of therapeutic dose late in the administration cycle:* We believe that much of the conventional nebulized budesonide dose is delivered late in the administration cycle, because a smaller percentage of drug is nebulized in the first few minutes of administration. This late, or delayed, delivery in an already lengthy administration cycle can exacerbate poor patient compliance, particularly for young children who may be unlikely to complete a full administration cycle, and reduces the likelihood of a restless toddler receiving a therapeutic dose.

*Potential side effects associated with local and systemic exposure:* During administration, conventional nebulized budesonide is often deposited in the back of the mouth and throat, never reaching the lungs where the drug is effective. If drug adheres to the back of the mouth and throat, it can lead to local side effects, such as cough, hoarseness and oral yeast infections, known as thrush. High doses of ICS can also lead to excessive systemic exposure to the drug, which may potentially cause impaired growth in children, reduction in bone density and skin thinning and bruising.

### ***Our Potential Solution: Unit Dose Budesonide***

We use our proprietary technologies to develop UDB as a smaller, consistently reproducible budesonide particle. The small size and stability of these drug particles allows for many more drug particles to be collected and transported into the lung by the small droplets generated by the nebulizer. The result is a formulation that exhibits a consistent, linear delivery of therapy over the entire administration time. By creating stable, small drug particles with consistent delivery over time, we believe we may overcome many limitations of current asthma therapies for children.

Based on our Phase 2 clinical trial, we believe UDB may provide patients with the following therapeutic benefits when compared to conventional nebulized budesonide:

*Faster delivery:* UDB has been shown to enable complete administration of an effective dose in approximately half the time of conventional nebulized budesonide. In addition, we may elect in the future to perform the required clinical trials to market UDB with next generation nebulizers. According to our *in vitro* research, UDB is compatible with next generation nebulizers and may therefore have additional benefits such as an even faster administration time.

*Higher percentage of drug delivered earlier:* UDB's smaller particle size allows for more consistent and linear dosing throughout a shorter administration cycle, rather than drug being delivered later in the cycle. According to our *in vitro* research, the small size of our UDB particles resulted in approximately three times as much Fine Particle Dose, or FPD, of UDB being nebulized in the first minute when compared to conventional budesonide. FPD is a measure of the amount of drug that may reach the lungs. Therefore, restless toddlers may be more likely to receive a therapeutic dose of UDB more often compared to conventional budesonide, potentially resulting in better asthma control, and reduction of emergency room visits.

*Efficient delivery at a lower dose:* Our Phase 2 clinical trials have shown that our low dose of UDB has the potential to treat asthma effectively with approximately half of the lowest dose of conventional nebulized budesonide, further reducing potential local and systemic side effects including cortisol suppression. UDB is efficiently delivered to the surface of the lung, reducing the amount of drug



## **Table of Contents**

deposited in the back of the mouth and throat. This may lead to a reduction in oral thrush and systemic cortisol suppression, which is a marker of potential systemic adverse effects including decreased bone density and impaired growth. No clinically significant cortisol suppression has been observed in our clinical trials with UDB to date.

### ***UDB Clinical Development Program***

In a Phase 2 clinical trial, UDB was effective in improving asthma symptoms and was well tolerated when compared to placebo. Nebulization time was three to five minutes. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in the two doses evaluated when compared to placebo. We and our partner AstraZeneca are conducting further analyses of these data to determine appropriate next steps for the UDB program.

*Phase 2 Clinical Trial Results.* In February 2007, we announced positive results from a Phase 2 clinical trial of UDB as a potential treatment for asthma in children. The clinical trial included 205 asthmatic children aged one to 18 years old across multiple sites in the United States. The objective of the clinical trial was to evaluate the efficacy, tolerability and pharmacokinetics of UDB. The clinical trial compared two different doses of UDB, 0.135 mg and 0.25 mg, administered twice a day, in a randomized, double-blind, placebo-controlled trial. The co-primary endpoints of the clinical trial were the change from baseline in Nighttime Composite Symptom Score, which is a composite of the three symptoms of coughing, wheezing and shortness of breath, and the change from baseline in Daytime Composite Symptom Score in the same three symptoms. Secondary endpoints included changes from baseline in morning and evening peak expiratory flow, a measure of lung function. In addition, we evaluated trends in Forced Expiratory Volume in one second, or FEV<sub>1</sub>, which indirectly measures airway narrowing.

This Phase 2 clinical trial demonstrated that after six weeks of dosing, UDB produced a statistically significant reduction in Nighttime and Daytime Composite Symptom Scores versus placebo for the 0.135 mg dose of UDB ( $p = 0.002$  for the nighttime score and  $p = 0.003$  for the daytime score). A  $p$ -value of 0.05 or less generally represents statistical significance. Positive trends in FEV<sub>1</sub> were seen in those patients old enough to take this test. The higher 0.25 mg twice a day dose was not significantly better than placebo in the co-primary endpoints of Nighttime and Daytime Composite Symptom Score. However, we observed consistent trends with respect to secondary endpoints and similar magnitude of FEV<sub>1</sub> improvements in both doses compared to placebo, which we believe is sufficient to support future clinical evaluation of the 0.25 mg dose.

The clinical trial showed both doses of UDB to be well tolerated, with no serious adverse events reported. There were no incidences of oral thrush. Also, there was no reduction in cortisol levels as compared to placebo over the duration of the clinical trial. Suppression of cortisol, a natural steroid hormone produced by the body, correlates with the occurrence of systemic side effects from the administration of high dose ICSs. Therefore, cortisol levels are often measured as an indication of systemic side effects from the administration of ICSs. Patients experienced average nebulization times of three to five minutes, which steadily decreased over the course of the clinical trial period.

*Phase 3 Clinical Trial Results.* In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints, asthma control as assessed by changes from baseline in nighttime and daytime composite symptom scores, in the two doses evaluated, when compared to placebo.

In this randomized, double-blind, placebo-controlled study, 360 steroid naïve children with asthma, 12-months to eight years of age, were randomized to receive 0.25 mg UDB, 0.135 mg UDB or placebo twice a day over a 12-week period. The co-primary endpoints evaluated asthma control as assessed by changes from baseline as compared to placebo in nighttime composite symptom scores, and daytime composite symptom scores, both comprised of cough, wheeze and shortness of breath. Based on our initial review of these data, both

---

## **Table of Contents**

the placebo and study groups experienced improvements in asthma symptoms, but the differences between placebo and active were not statistically significant. We observed a higher than expected response in the placebo group, starting as early as one week after randomization and continuing throughout the 12-week treatment period. Median nebulization times were less than four minutes for both doses in the study. Initial review of the data has not identified any serious adverse events attributed to the study drug. Patients continue to be treated in a long-term safety study to collect long-term safety data on the two doses under investigation.

*Remaining Development Program.* We and our partner AstraZeneca are conducting further analyses of data from our first Phase 3 clinical trial of UDB to determine appropriate next steps for the program.

Because budesonide is well characterized and previously approved, we may seek FDA marketing approval of UDB under Section 505(b)(2) of the FDCA. Section 505(b)(2) of the FDCA provides an alternate path to FDA approval for modifications to formulations of products previously approved by the FDA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This may expedite the development program for UDB by potentially decreasing the overall scope of work we must do ourselves.

### ***MAP0004 for the Acute Treatment of Migraine***

MAP0004 is our proprietary orally inhaled version of DHE intended to treat migraine. In a Phase 2 clinical trial, MAP0004 provided pain relief in as fast as ten minutes after dosing and this relief lasted at least 24 hours. Based on these results, we believe MAP0004 has the potential to be suitable as a first-line therapy for some migraine patients. Historically, estimated onset of significant pain relief with oral triptans, the class of drugs most often prescribed for treating migraine, occurs between 45 and 90 minutes after dosing. Migraine is a syndrome characterized by four symptoms: pain, nausea, phonophobia, or abnormal sensitivity to sound, and photophobia, or abnormal sensitivity to light. MAP0004 is an easy to use, non-invasive, at-home therapy in development that patients self-administer using our proprietary hand-held Tempo inhaler. DHE is available as an IV therapy which has been used in clinical settings for over 50 years for the safe and effective treatment of migraine, particularly forms of migraine that are severe or do not respond to triptans or other therapies. We believe DHE's adoption as a first-line therapy has been limited by its invasive mode of administration and high incidence of nausea. In a Phase 2 clinical trial, MAP0004 retained the rapid onset and long-lasting effectiveness of IV DHE while avoiding the nausea that IV administration can cause. We announced positive results from our Phase 2 clinical trials in March 2007. In January 2008, we completed the SPA process with the FDA for the first Phase 3 clinical trial of our MAP0004 product candidate, and reached agreement with the FDA on the design of the protocol. The clinical trial if successful could support the potential approval of MAP0004 as an acute treatment for migraine. We initiated the Phase 3 clinical program in July 2008 and completed enrollment in the efficacy portion of our first Phase 3 clinical trial in January 2009. We expect to announce clinical data from the efficacy portion of this trial during the first half of 2009.

### ***Migraine***

Migraine is a chronic and debilitating neurological disorder characterized by episodic attacks. Migraine attacks typically manifest themselves as moderate to severe headache pain, with associated symptoms that often include nausea and vomiting, photophobia, phonophobia, and visual disturbances or aura. They usually involve pounding or throbbing pain on one side of the head, although pain may occur on both sides. Migraines limit the normal functioning of patients, who often seek dark, quiet surroundings until the episode has passed. Most migraines last between four and 24 hours, but some last as long as three days. According to published studies, the median frequency of attack is 1.5 times per month, although approximately 25% of migraine sufferers experience one or more attacks every week.

Migraine is a major public health problem that affects up to approximately 12% of the population in the United States and Europe. According to the National Headache Foundation, approximately 30 million people in

## **Table of Contents**

the United States suffer from migraine. According to data published by IMS Health, the total sales revenue for prescription drugs used to treat migraine is approximately \$3.7 billion worldwide. Within this market, triptans are the major class of migraine-specific drugs used for the treatment of acute migraines, with 2007 sales totaling approximately \$2.2 billion in the United States and approximately \$3.3 billion worldwide. Approximately 90% of triptan prescriptions are for oral formulations, with the remaining 10% split between injectable and nasal formulations. Of the approximately \$2.2 billion triptan market in the United States, oral, injectable and nasal formulations accounted for approximately \$1.9 billion, \$200 million and \$100 million in sales in 2007, respectively. Of the seven triptan products, Imitrex, generically referred to as sumatriptan, from GlaxoSmithKline plc, or GlaxoSmithKline, is the market leader, with sales of approximately \$1.2 billion in the United States and approximately \$1.6 billion worldwide in 2007.

There are two general categories of migraine therapies: acute and preventive. Acute therapies dominate the migraine market and are used during infrequent attacks, typically characterized as one to three attacks per month, and are designed to relieve the pain, nausea, phonophobia and photophobia symptoms of migraine. The goals of acute therapy are to stop the attack quickly and consistently, while preventing recurrence, to maintain the patient's ability to function, to use the least amount of medication and to limit adverse side effects. Although triptans are the predominant class of drugs used to specifically target migraine, DHE is another class of acute, migraine-specific therapy.

### ***Limitations of Current Migraine Therapies***

The type of migraine treatment pursued depends on the frequency and severity of the headache, speed of onset and previous response to medication. In published studies, migraine sufferers often cite faster onset of pain relief and lower incidence of migraine recurrence as two key therapeutic attributes they would like from their medication. Treatment typically involves patients self-medicating with over-the-counter drugs when pain is mild and attacks are infrequent. Patients with more frequent or severe migraine or those who do not respond to simple analgesics may seek medical attention with a primary care physician initially and then with a headache clinic or neurology specialist, if needed. Once a physician has diagnosed migraine, triptans are generally prescribed. If a patient does not respond to one triptan, the physician may switch to another, as the response to various triptans is unpredictable.

Triptans have three major limitations:

*Slow onset:* While triptans have improved the treatment of migraine, their onset of pain relief is relatively slow. Historically, estimated onset of significant pain relief with oral triptans occurs between 45 and 90 minutes after dosing.

*Not broadly efficacious:* Approximately 30% to 40% of migraine patients do not fully respond to the first triptan prescribed. Migraine patients who do not respond to any triptan therapy have few satisfactory alternatives.

*Side effects:* Triptans may constrict arteries, which may raise blood pressure.

DHE is an acute therapy and alternative to triptans that has been used for more than 50 years to safely treat migraine. Many headache specialists consider DHE to be the standard of care in treatment of *status migrainosus*, which is a condition characterized by debilitating migraines that last more than 72 hours. Although DHE overcomes many of the limitations of triptans, historically it has also had its own limitations, including the following:

*Inconvenient and inconsistent dosing:* DHE has been available predominantly for administration nasally and intravenously. Intravenous administration of DHE requires the supervision of a healthcare provider and is typically performed in a headache clinic or hospital setting, which is expensive and requires the patient to travel to one of these locations while suffering with the migraine. Absorption of DHE via the nasal pathway may lead to inconsistent dosing, and generally takes 30 to 60 minutes to provide

## **Table of Contents**

significant pain relief. Nasal administration of DHE may result in unpleasant taste, and can cause inflammation of the nasal membrane.

*Side effects:* One of the common side effects of conventional DHE administered intravenously is nausea. Patients who receive DHE intravenously are often given an anti-nausea medication at the same time.

### ***Our Potential Solution: MAP0004***

Based on our Phase 2 clinical trials, we believe that MAP0004 may provide patients with the following benefits when compared to existing migraine therapeutics:

*Rapid onset:* The inhalation of DHE via our Tempo inhaler offered fast onset of pain relief similar to IV DHE and faster onset of pain relief than oral and nasal triptans. In a Phase 2 clinical trial, MAP0004 provided pain relief as early as within ten minutes of dosing.

*Long-lasting:* In a Phase 2 clinical trial, MAP0004 provided long-lasting pain relief with low incidence of recurrence. Our clinical trial supports sustained pain relief through 24 hours.

*Broadly efficacious:* Based on historical DHE use, MAP0004 may provide a higher response rate and has the potential to treat patients who have not previously responded to other therapies, such as triptans. We also believe that MAP0004 has the potential to treat additional indications, including chronic migraine, migraine with sensitization, migraine headaches lasting over 72 hours, medication overuse headache, cluster headache, menstrual migraine, adolescent migraine and migraine prophylaxis.

*Convenient and consistent delivery:* MAP0004 is non-injectable and designed to be easy to use, which may result in increased patient comfort and compliance. Our clinical trials were performed in the home, without clinical supervision and with minimal training. Dose-to-dose variability was comparable to solid oral dosage forms.

*Low incidence of side effects:* Drug-induced nausea was very low in our Phase 2 clinical trials, in which migraine-associated nausea also decreased with treatment. In addition, there were no indications of arterial constriction in our clinical trials. There were no reports of bitter taste or local inflammation associated with the dose of MAP0004 selected for further development.

### ***MAP0004 Clinical Development Program***

In a Phase 2 clinical trial, MAP0004 was effective in providing pain relief to migraine sufferers within ten minutes of dosing and was well tolerated when compared to placebo. We announced positive results from our Phase 2 clinical trials in March 2007. In January 2008, we completed the SPA process with the FDA for the first Phase 3 clinical trial of our MAP0004 product candidate, and reached agreement with the FDA on the design of the protocol. The clinical trial if successful could support the potential approval of MAP0004 as an acute treatment for migraine. We initiated the Phase 3 clinical program in July 2008 and completed enrollment in the efficacy portion of our first Phase 3 clinical trial in January 2009.

*Phase 2 Clinical Trial Results.* In March 2007, we announced positive results from two Phase 2 clinical trials with MAP0004 for the acute treatment for migraine.

The objective of the first Phase 2 clinical trial was to evaluate the efficacy and tolerability of three different doses of MAP0004 in adult migraine patients when self-administered at home. This Phase 2 clinical trial was a randomized, double blind, placebo-controlled trial of three doses of MAP0004 in 86 patients. The clinical trial consisted of two treatment periods. The first treatment period evaluated two doses of MAP0004, 1.0 mg and 0.5 mg versus placebo and the second treatment period re-randomized responders in the first treatment period to evaluate a lower dose, 0.25 mg versus placebo. In the first treatment period, the 0.5 mg dose of MAP0004 showed pain relief in 32% of the patients at ten minutes ( $p = 0.019$ ), pain relief in 72% of the patients at two hours, the clinical trial's primary endpoint ( $p = 0.019$ ), and sustained pain relief in 43% of the patients at 24





## Table of Contents

hours ( $p = 0.066$ ) in a treatment received population. A number of secondary endpoints were also examined, including sustained pain relief and total migraine relief at multiple time points over 24 hours. The clinical trial also showed clinically significant trends in the resolution of phonophobia, photophobia and nausea (reaching  $p < 0.05$ ) at certain time points. Unlike conventional IV DHE, which is generally administered with an anti-nausea medication, MAP0004 was administered by itself and showed no statistically significant drug related increase in nausea. MAP0004 was also shown in the clinical trial to be well tolerated, with no serious adverse events reported, including cardiovascular or respiratory adverse events. In the second treatment period, 35 subjects were randomized to treat a second subsequent migraine with a 0.25 mg dose versus placebo. No significant benefit was seen with this lowest dose when compared to placebo.

The objective of the second Phase 2 clinical trial was to evaluate the safety and tolerability of MAP0004 in subjects with asthma and to demonstrate that the blood levels of the drug achieved by the therapy were similar to those seen after inhalation by subjects with healthy lungs. This second Phase 2 clinical trial was a randomized, double blind, placebo-controlled trial in 19 adult asthmatics. Each patient received three doses, one every week in randomized order over a 15-day period, including two 1.0 mg doses of MAP0004 and one dose of placebo. The clinical trial indicated that MAP0004 was well tolerated by subjects with compromised lung function, and that the pharmacokinetics of MAP0004, or distribution of the drug in the body, was similar to that experienced by adults with healthy lungs as shown in an earlier Phase 1 clinical trial. No serious or significant drug related adverse events were reported. In addition, no clinically significant changes were observed in pulmonary function tests, heart rate, blood pressure, respiratory rate or mean IgE levels, a measure of systemic immune response, or the body's defenses reacting to a foreign substance.

*Phase 3 Clinical Program.* We are evaluating the safety and efficacy of MAP0004 as a potential acute treatment for migraine in a Phase 3 multi-center, randomized, double-blind, placebo-controlled trial in approximately 850 migraine sufferers followed by a 12-month open-label safety assessment. In January 2009, we completed enrollment in the efficacy portion of this trial. In this trial, patients were randomized to either 0.5 mg MAP0004 or placebo during the efficacy portion of the trial. The primary efficacy endpoints will be pain relief at two hours, and freedom from nausea, photophobia and phonophobia at two hours. This clinical trial is being conducted pursuant to an SPA with the FDA. We anticipate that the second Phase 3 clinical trial will be a confirmatory efficacy trial with a similar design to the efficacy portion of the first Phase 3 clinical trial. We also plan to conduct the following additional two Phase 2 pharmacokinetic and pharmacodynamic trials with MAP0004: a pharmacokinetic trial in approximately 24 adult smokers comparing them to non-smokers; and a pharmacodynamic trial in approximately 24 healthy adults compared to placebo, studying echocardiographic effects.

We believe that, based on our pharmacokinetic and receptor binding research, MAP0004's administration via the lung may provide an opportunity to retain the efficacy attributes seen with IV DHE while minimizing the potential side effects seen during IV DHE administration. Pharmacokinetic data suggest that MAP0004 closely mimics the blood levels and the time to maximum drug concentration seen with effective doses of DHE administered intravenously. However, unlike IV administration of DHE, we do not expect MAP0004 to cause significant treatment related nausea which may be a factor that has limited the usage of IV DHE outside the headache clinic or hospital. In our Phase 1 trial comparing IV DHE to MAP0004, the blood levels of drug were similar. However, the maximum drug concentration for inhaled DHE administered with our Tempo inhaler was approximately 11 to 13 fold lower than that for IV DHE, which we believe in part accounts for the absence of drug-induced nausea observed in our clinical trials to date.

In addition, we have conducted pre-clinical animal studies to evaluate lung toxicity and coronary vascular effects of our proprietary formulation of DHE. In our six month chronic inhalation toxicity assessment of DHE, where test subjects were exposed to up to 1.08 mg/kg (more than 29 times the maximum safe daily IV human dose) of DHE per day for six months, there was no significant respiratory tract toxicity observed. In our pre-clinical study designed to evaluate cardiovascular parameters, we observed no significant differences in coronary vascular effects comparing inhaled DHE to IV DHE.

## **Table of Contents**

Because DHE is well characterized and previously approved, we may seek FDA marketing approval of MAP0004 under Section 505(b)(2) of the FDCA. Section 505(b)(2) of the FDCA provides an alternate path to FDA approval for modifications to formulations of products previously approved by the FDA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This may expedite the development program for MAP0004 by potentially decreasing the overall scope of work we must do ourselves.

### ***MAP0005 Combination Particle Technology***

We believe MAP0005 serves as a proof of concept for the robust, specific delivery of two therapeutic agents that could benefit from targeted receptor delivery in a fixed ratio within a single particle. We intend to opportunistically evaluate the application of this technology to additional product candidates because we believe our proprietary technologies in this area have potential broad applicability for a number of small molecule combination product candidates in diverse indications via inhalation and other routes of delivery. MAP0005, our proprietary combination of an inhaled corticosteroid and a long-acting beta-agonist, or LABA, for the potential treatment of asthma and chronic obstructive pulmonary disease, or COPD, utilizes our proprietary particle formulation technologies to administer the optimal ratio of multiple drugs in a reproducible and consistent manner. We combine two or more drugs together into a single micron sized particle at a pre-defined consistent and reproducible ratio, which may improve the delivery profile and stability of the resultant combination therapy. In April 2008, we announced positive results from a Phase 2a clinical trial evaluating MAP0005 for the potential treatment of asthma and COPD. We believe this approach, as compared to current ICS/LABA combinations, may allow the optimal ratio of each drug to the lung to reach the relevant receptors at the cellular level in the lung in a more reproducible and consistent manner, reducing the amount of drug delivered systemically and potentially improving the side effect profile, while improving therapeutic efficacy.

### ***MAP0001 Stable Protein Particle Technology***

We believe MAP0001 serves as proof of concept for the ability to formulate and stabilize biologically-active proteins and peptides and deliver them to the lung. We design and incorporate our protein formulations without the need for excipients or other additives, to be stored for months at room temperature and to provide multiple doses of medicine delivered accurately without the need for invasive needle injections. We intend to opportunistically evaluate the application of this technology to additional product candidates. We are demonstrating this capability with MAP0001, our proprietary formulation of insulin for the potential treatment of Type 1 and Type 2 diabetes via pulmonary delivery using our proprietary Tempo inhaler. In a Phase 1a clinical study conducted in Australia, MAP0001 was biologically active and achieved maximum therapeutic blood levels as quickly as Novorapid subcutaneous injection, a widely used injectable insulin.

We have not filed an IND with the FDA for MAP0005 or MAP0001 because our clinical trials were not conducted in the United States.

While we do not plan to make further significant direct investment in MAP0005 and MAP0001, we plan to evaluate other potential product candidates which may utilize these technologies, as well as partnership opportunities for further development and commercialization of these two product candidates.

### ***Our Technology***

Our aerosol delivery and pharmacological profiling technology combines our knowledge of aerosol science and medicine, and enables us to create inhaled drug products with potentially enhanced pharmacological profiles relative to the parent drugs, thereby improving their efficacy and safety. Starting with bulk drug substance, we develop particles with the physical and chemical characteristics that are well suited for the aerosol delivery of the product candidate. The particle engineering allows more of our drug to reach the areas of the respiratory tract to

## **Table of Contents**

treat disease and reduces the amount of drug that is deposited in the back of the throat where it can cause local and systemic side effects. We then formulate the drug particles into a delivery medium and package them into the aerosol delivery system that is best suited for the formulation and dosing regimen in order to maximize patient compliance. Our expertise in aerosol formulation science and pulmonary medicine allows us to select excipients, already in wide use and regarded as safe, that result in favorable safety characteristics and allow flexibility in delivery format. The resulting drug products can be as consistent and efficient as alternative, often more invasive dosing formats, such as injection, but with the advantages of fast onset, high degree of intake at the target organs, and lower or controlled systemic exposure. The convenience, consistency and efficiency of inhaled administration in combination with the characteristics of our product candidates can offer meaningful therapeutic benefits when compared to existing drugs, increasing the probability of the successful adoption of our product candidates.

We apply our proprietary technologies to optimize drugs for two general types of therapeutic applications:

*Delivery of drugs to treat respiratory diseases locally.* Diseases such as asthma, COPD and some respiratory tract infections have been treated by pulmonary drug delivery for many years in order to target therapeutic effect to the lung and reduce systemic drug exposure and related side effects. Our technology is designed to improve the therapeutic efficacy and safety of known drugs for these applications, by efficiently delivering customized drug particles to those areas in the lung where drug is required and minimizing the drug exposure to other areas of the respiratory tract and body. In addition, our technologies have the potential to broaden the types of respiratory illnesses that can effectively be targeted and treated safely via pulmonary delivery.

*Pulmonary delivery as a non-invasive method of quickly and safely administering systemic drugs.* Administration of drugs via the respiratory tract is a non-invasive method of delivering drugs efficiently to the systemic circulation, with rapid onset of action, bypassing the gastrointestinal tract where many drugs are extensively metabolized after oral administration, and with rapid onset of action. The drug, or combination of drugs can reach the intended site of action as quickly as intravenously administered drugs and more quickly than oral, dermal, sublingual or even alternative injection routes, such as subcutaneous or intramuscular. We can apply our technology to small or large molecules, including peptides and proteins.

### ***Aerosol Delivery and Pharmacological Profiling Technology***

Our proprietary technologies include particle creation and formulation technologies, which can be applied to small or large molecules, including peptides and proteins. Our technologies also include the development and manufacturing of aerosol delivery devices, including our current Tempo inhaler. Tempo is a proprietary, next generation pressurized MDI that dispenses drug automatically when the patient inhales and has high consistency and efficiency compared to other inhalers. Our technologies are covered by over 22 issued U.S. patents and over 30 U.S. patent applications that we own or have licensed, as well as their foreign counterparts.

### ***Particle Creation and Formulation***

We control the characteristics of our drug particles by using technology and expertise in aerosol physics, particle science and formulation, and in safety toxicology and pharmacology. We can consistently generate drug-containing aerosols with the optimal particle or droplet sizes for the therapeutic indication. Particles that are too large tend to be deposited in the throat, while medium sized particles are more efficiently delivered to the large bronchial tubes and small particles are more efficiently delivered to the alveoli, the small sacks that make up most of the absorptive surface area of the lung. We can formulate product candidates in propellants without additional excipients, or with small amounts of excipients previously shown to be safe. We can also combine drugs by producing small, inhalable particles composed of one drug which is reproducibly intermingled or coated with multiple drugs in fixed ratios.

## **Table of Contents**

One of our key technologies is the generation of particles by supercritical fluid, or SCF, precipitation. SCF gives us the ability to create very small particles ranging from 100 nanometers to ten microns in diameter with highly precise particle size distributions. The particles have uniform surfaces with few discontinuities or irregularities that provide enhanced aerosol performance. They are also stable for long storage periods without refrigeration, and require minimal or no excipients that can increase the potential for local toxicity or inflammatory response.

In addition to particle generation, we have extensive expertise in formulating aerosol drugs, especially for nebulized and MDI delivery formats. A key feature of this expertise is our know-how in formulating aerosolized drugs with appropriate excipients. We have expertise in formulation screening, assay development, aerosol performance testing and clinical performance simulation, long-term stability testing, large volume non-clinical testing and generation and release of pre-clinical and clinical supplies through to human clinical proof of concept.

We believe that the combination of these various particle creation and formulation technologies is a key component of our competitive advantage.

### ***Tempo Inhaler Platform***

We designed our proprietary Tempo inhaler to enable accurate and reproducible pulmonary delivery of the drug particles we develop. Our Tempo inhaler is an innovative next generation MDI. The Tempo inhaler incorporates the size, ease of use and convenience advantages associated with standard MDIs, and is designed to overcome their greatest limitations: inconsistent dosing, drug delivery inefficiency and the need for patients to synchronize a breath with manual triggering of the device, which is particularly difficult for certain patient populations such as children and elderly patients. Even the more recently introduced breath-actuated MDIs exhibit the inconsistent dosing and drug delivery inefficiency of older MDIs.

The Tempo inhaler is designed to offer a number of key competitive advantages compared to standard MDIs. These advantages include:

*Automatic, optimal release of therapy:* Our triggering technology is tuned for each particular drug so that drug release is synchronized to the optimal point in the breathing cycle to allow the released drug to reach the targeted area of the respiratory tract. For example, data from a clinical trial showed that the Tempo inhaler deposited 75% less of a corticosteroid in the mouth and throat and delivered three times as much drug to the lungs as a conventional MDI.

*Plume speed control:* Conventional MDIs spray plumes of drug at speeds of up to 50 miles per hour, causing much of the drug to hit the back of the throat. By contrast, our Tempo inhaler controls and slows down the drug plume to match the speed of the patient's inhaled breath, so more of the drug is entrained in the inhaled air and carried into the lungs.

*Dose consistency:* Our clinical trials indicate that the Tempo inhaler's dose-to-dose consistency is comparable to oral dosing. Tempo inhaler also includes a dose counter to display how many doses have been administered so patients can track their medication use and remaining supply. The dose counter can lock out after a maximum number of doses have been delivered to prevent overdosing.

*Convenient, multiple dose use:* The Tempo inhaler does not use electronics or batteries, can conveniently contain multiple doses and is relatively efficient to manufacture. It can include up to a month's supply depending on the drug, in a small, handheld package approximately the same size as a conventional MDI and it may be used with small molecule drugs and biologics.

The FDA issued draft guidelines in 1998 covering the MDI performance that the FDA would like MDI manufacturers to achieve. However, the FDA has not implemented the new guidelines to date, in part because conventional MDIs may not be capable of meeting them. We believe that our Tempo inhaler may meet the FDA's draft guidelines should the FDA elect to implement them.

## **Table of Contents**

We have conducted clinical trials with three clinical product candidates which utilize our Tempo inhaler: MAP0004 for the potential treatment of migraine, MAP0005 for the potential treatment of asthma and COPD and MAP0001 for the potential treatment of diabetes.

### **Our Strategy**

Key elements of our strategy include:

*Obtain regulatory approval for our two most advanced product candidates, UDB and MAP0004:* UDB and MAP0004 are being evaluated in Phase 3 clinical programs. We believe the risk of clinical trial failure may be lower than traditional new chemical entities because we are evaluating drugs that have been previously reviewed and approved by the FDA and have a known safety and efficacy profile.

*Advance and expand our product pipeline in our target commercial areas, leveraging our extensive expertise in pulmonary delivery and respiratory science and medicine in a lower risk manner:* We intend to focus our pipeline development initially on products with established safety and efficacy records, but whose market potential has been limited by safety, relative efficacy and patient compliance. We believe that we can overcome these limitations by leveraging our technologies. These technologies underpin our competitive advantage in developing multiple, high-value products with clearly defined patient benefits.

*Build a focused sales force to commercialize UDB and MAP0004:* Our goal is to build a focused sales force in the United States to market and sell our products, once approved, to pediatricians for UDB, and neurologists and headache specialists for MAP0004. Our collaboration with AstraZeneca will allow us to establish a commercial infrastructure for UDB. We plan to develop or in-license additional product candidates for this sales force and any other sales forces we may develop.

*Expand the market opportunity for our most advanced product candidates:* In order to expand the commercial opportunity for MAP0004, we may establish partnerships with pharmaceutical companies to market and sell to primary care physicians. Outside the United States, we may establish commercial partnerships for all of our product candidates in order to accelerate development and regulatory approvals in those countries and further broaden their commercial potential. In December 2008, we entered into an agreement with AstraZeneca in which we licensed to AstraZeneca global rights to develop and commercialize our proprietary nebulized formulation of budesonide.

### **Collaborations and License Agreements**

#### ***AstraZeneca***

In December 2008, we entered into a license agreement with AstraZeneca, which became effective in February 2009. Pursuant to the terms of the agreement, we licensed to AstraZeneca global rights to develop and commercialize our proprietary nebulized formulation of UDB, our next generation UDB therapy and certain combination nebulization therapies for the potential treatment of asthma in children.

We are jointly developing UDB in the United States with AstraZeneca, and we are responsible for executing the development plan. AstraZeneca reimburses us for the costs of future UDB development activities beginning on the effective date, and has the right to develop follow-on products using different nebulizers and certain products combining nebulized budesonide with other drugs. AstraZeneca has rights to commercialize UDB in the United States and to develop and commercialize UDB outside of the United States.

AstraZeneca will pay for up to a 60-person sales force for the company to co-promote UDB with AstraZeneca in the United States after product launch. AstraZeneca will provide funding for this sales force for up to five years after product launch.

In February 2009, under the terms of this agreement, AstraZeneca paid us a nonrefundable upfront cash payment of \$40 million. The agreement also provided for a \$35 million milestone payment payable upon the



## **Table of Contents**

successful achievement of co-primary endpoints and safety results in our initial Phase 3 clinical trial. In addition, we are eligible to receive up to \$240 million in other development and regulatory milestones. The agreement also provides for additional progressively demanding sales performance-related milestone payments of up to \$585 million in the event the product is a considerable commercial success.

We are also eligible to receive significant and escalating double-digit royalty payments on worldwide sales, as well as reimbursement for all royalties payable to Elan Pharma International Limited or Elan under our license agreement with Elan. These payments will begin following the date of the first commercial sale of UDB or any other licensed product. We are also eligible to receive reimbursement for a portion of certain milestone payments payable to Elan. Under the terms of the agreement, both companies agree, under certain circumstances, for a period until three years after the first commercial sale of a licensed product in the United States, not to commercialize or assist any third party in commercializing certain competing products. We also have the right to terminate the agreement in relation to licensed products developed for administration solely using jet nebulizers if AstraZeneca commercializes certain competing products for use in jet nebulizers.

Either party may terminate the agreement upon a material, uncured default of the other party. AstraZeneca may terminate the agreement, with or without cause, at any time upon 90 days' written notice. If AstraZeneca terminates the agreement under certain circumstances, AstraZeneca will be obligated to reimburse our remaining development costs under the development plan. Our failure to meet co-primary endpoints in our initial Phase 3 clinical trial gives AstraZeneca the right to terminate the agreement or continue with the collaboration without paying the \$35 million milestone. AstraZeneca has 60 days from deemed receipt of the complete data package from our initial Phase 3 clinical trial to decide whether to terminate the agreement. If AstraZeneca proceeds with the collaboration, AstraZeneca will be responsible for reimbursing the remaining development costs we incur under the development plan.

### ***Elan Pharma International***

In April 2004 we entered into a license agreement with Elan Pharma International Limited, or Elan, which was superseded in February 2005 by an agreement that clarified the rights previously granted in 2004, and amended in June 2007. We also entered into a services agreement with Elan Drug Delivery International in February 2005.

Under the terms of this license agreement, Elan granted to us a worldwide, exclusive, sublicensable license under Elan's intellectual property rights to use, market, distribute, sell, have sold, offer for sale, import and export aqueous formulations of budesonide (alone or with certain other active ingredients) for pulmonary delivery using certain devices for therapeutic use in humans.

Elan also granted to us, subject to the execution of a manufacturing process transfer agreement, or manufacturing agreement, a non-exclusive sublicensable license in the same field as the exclusive license under its intellectual property rights to make and have made a bulk intermediate form of budesonide in certain countries including Canada, the United States, Ireland, certain countries in Europe, Japan, Australia and New Zealand.

Elan granted to us a worldwide non-exclusive, sublicensable license to all improvements to its intellectual property rights arising as a direct result of the performance under the license agreement, the services agreement, and/or the manufacturing agreement.

In connection with the execution of the AstraZeneca agreement, we amended the Elan agreements, so that we and AstraZeneca will have certain rights under the Elan agreements during the term of the AstraZeneca agreement.

Under the license agreement, we are required to make payments to Elan based upon achievement of certain development and sales milestones. As of December 31, 2008, when and if certain milestones are met we may be

## **Table of Contents**

obligated to pay Elan up to \$16.5 million in total future development and sale milestone payments with respect to our UDB product candidate. In addition, we are also required to make payments to Elan with respect to other product candidates we may develop pursuant to the license agreement. We are also required to pay royalties based on net sales of the product for an initial royalty term, calculated on a country-by-country basis, equal to either the expiration of Elan's patents covering the product in such country, or 15 years after commercial launch in such country, if Elan does not have patents covering the product in such country. After the initial royalty term, we continue to pay royalties on product sales to Elan at reduced rates.

Either party may terminate the 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.

### ***Nektar Therapeutics***

We entered into a license agreement with Nektar Therapeutics UK Limited, or Nektar, in June 2004, and amended the agreement in August 2006 and October 2007. Under the agreement, Nektar granted us 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. The Nektar patents licensed to us include two types of patent claims: compound-limited claims and compound-inclusive claims. Compound-limited claims are Nektar patent claims that claim a form of dihydroergotamine, or formulations or methods of manufacture or methods of use of dihydroergotamine, and our license to these claims is fully-paid up and royalty free and will survive expiration or any termination of the agreement. Compound-inclusive claims are Nektar patent claims that are not compound-limited claims and our license to these claims is royalty-bearing.

Our obligation to pay royalties to Nektar is based on net sales of products, and will continue, on a country-by-country basis, until the longer of expiration of Nektar patents covering the product, ten years after the first commercial sale of the product, or the date that Nektar's know-how becomes known to the general public. In addition, we are required to make future payments based upon achievement of certain product development milestones. As of December 31, 2008, when and if certain milestones are achieved we may be obligated to pay Nektar up to \$5.0 million in total future development milestone payments with respect to our MAP0004 product candidate.

Under the agreement, we granted Nektar a worldwide, nonexclusive, royalty-free license under our patents and know-how solely to the extent useful or necessary for Nektar to fulfill its obligations under the agreement.

Either party may terminate the 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.

### ***Xemplar Pharmaceuticals***

In April 2006 we entered into a manufacturing and supply agreement with Xemplar Pharmaceuticals, LLC, or Xemplar, for the manufacture and supply by Xemplar to us of our clinical and commercial requirements of pressurized metered dose aerosol canisters containing placebo or active ingredient that are housed within a fully-assembled Tempo inhaler and packaged for clinical and commercial use.

Xemplar agreed to convert its manufacturing facility into a Good Manufacturing Practices, or GMP, contract manufacturing facility suitable for the commercial production of the product prior to or when Xemplar obtains the approvals necessary to manufacture these products in compliance with the manufacturing agreement.

We have agreed that, from the date the first NDA is submitted for a product and for a period of five years thereafter we will purchase the fully-assembled Tempo inhalers only from Xemplar, and Xemplar will manufacture and supply from its manufacturing facility all such devices as we require to support development



## **Table of Contents**

and commercialization. If Xemplar fails to supply on time under certain circumstances, we have the right to immediately terminate the manufacturing agreement by written notice and to manufacture the product ourselves or purchase it from a third party.

Either party may terminate the agreement upon a material, uncured breach or default by the other party. We may terminate the agreement upon 60 days' written notice upon our reasonable determination that Xemplar does not have the capability to manufacture the product in accordance with the warranty or in sufficient quantities.

## **Intellectual Property**

We protect our technology through the use of patents, trade secrets and proprietary know-how. We own or in-license over 20 issued U.S. patents, and over 30 U.S. patent applications, as well as their foreign counterparts, which relate to our product candidates or our proprietary technologies. The patents, patent applications and patent applications that may issue that we own and in-license, which we rely on for our UDB product, expire between 2014 and 2028. The patents, patent applications and patent applications that may issue that we own and in-license, which we rely on for our MAP0004 product, expire between 2017 and 2028. Our patent and patent applications include claims covering:

various formulations of compounds;

the processing of these compounds;

sterilization and stabilization of these compounds; and

the treatment of certain diseases via delivery of certain compounds to the lung.

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 protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We have rights to several third-party proprietary processing and manufacturing technologies related to our product candidates. See Collaborations and License Agreements. We rely on such third parties to protect the intellectual property we license, and we do not and have not had any control over the filing or prosecution of patent applications. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Our enforcement 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.

## **Manufacturing**

All of our manufacturing processes, which comply with current good manufacturing practices, or cGMP, are outsourced to third parties with oversight by our internal managers. We have limited cGMP manufacturing capacity in-house. We rely on third-party manufacturers to produce sufficient quantities of drug product for use in clinical trials. We intend to continue this practice for any future clinical trials and large-scale commercialization of UDB, MAP0004 and for any other potential products for which we retain significant development and commercialization rights.

The active pharmaceutical ingredient, or API, of UDB has been manufactured by a contract manufacturer, or CMO, located in Europe. Our CMO has extensive experience manufacturing steroids under cGMP and has the capacity to manufacture at commercial scale. We are exclusive licensees of the manufacturing process for production of processed budesonide bulk drug product intermediate, or BDPI. Under our worldwide collaboration with Elan, Elan will be responsible for the manufacture and supply of BDPI to be used in the development and commercialization of UDB. See Collaborations and License Agreements Elan Pharma

## **Table of Contents**

International Limited License Agreement. Final UDB drug product is currently packaged as a suspension in a unit dose vial at a third-party CMO.

The API of MAP0004 has been manufactured by a CMO located in Europe. Our CMO has extensive experience manufacturing MAP0004 under cGMP and has the capacity to manufacture at commercial scale. We are exclusive licensees of the manufacturing process for production of processed MAP0004 BDPI. Under our worldwide license from Nektar, we have enabled another CMO to manufacture clinical and commercial supply of BDPI to be used in the development and commercialization of MAP0004.

The Tempo inhaler is manufactured by third-party CMOs. The plastic component manufacturing and sub-assembly, valve manufacture, canister manufacture and canister fill with final assembly are each performed by a different third-party CMO. Each has extensive experience with medical-grade clinical and commercial scale device manufacture under cGMP.

## **Competition**

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 markets 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 experienced and convenience of administration and drug delivery. 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 future products developed by us. 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.

## ***Children with Asthma***

If approved for the treatment of asthma in children, we anticipate that UDB would compete with other marketed asthma therapeutics including:

*Inhaled corticosteroids:* Conventional nebulized budesonide is an FDA approved ICS for treating asthma in children from 12 months up to eight years of age and is available from our partner, AstraZeneca, as Pulmicort Respules. Pulmicort Respules generated approximately \$900 million in sales in the United States and approximately \$1.2 billion worldwide in 2007 according to data published by IMS Health.

*Leukotriene modifiers:* Singulair is currently marketed by Merck & Co., Inc., or Merck. Singulair achieved worldwide sales in 2007 of approximately \$4.3 billion. We estimate that approximately \$3.5 billion of these sales were in the United States, and we believe that prescriptions for children up to eight years of age generated approximately \$900 million of that total.

We may also face competition from potential generic entry of conventional nebulized budesonide. Teva Pharmaceuticals Industries Ltd., or Teva, and Breath Limited have filed a generic or abbreviated new drug application, or ANDA, for conventional nebulized budesonide based on Pulmicort Respules. In November 2008, the FDA approved Teva's ANDA. Also in November 2008, AstraZeneca entered into a settlement agreement in its patent infringement litigation against Teva, filed by AstraZeneca following Teva's ANDA submission. The settlement agreement will allow Teva to commence sales of budesonide inhalation suspension, a generic version of Pulmicort Respules, under a license from AstraZeneca beginning in December 2009. Although a generic version of conventional nebulized budesonide product could not be substituted for UDB, a generic version of

---

## **Table of Contents**

conventional nebulized budesonide may be more quickly adopted by health insurers and consumers than UDB, as 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. However, we believe if approved, UDB may have features that could differentiate it from conventional nebulized budesonide or a generic version of conventional nebulized budesonide.

### ***Migraine***

If approved for the acute treatment of migraine, we anticipate that MAP0004 would compete against other marketed migraine therapeutics. The majority of marketed prescription products for treatment of migraine are in the triptan class. According to data published by IMS Health, the worldwide triptan market totaled approximately \$3.3 billion in revenues for 2007. 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. There are 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 April 2008, GlaxoSmithKline's Treximet, a combination oral formulation of sumatriptan and naproxen sodium, was approved by the FDA for the acute treatment of migraine. In addition to marketed migraine therapies, there are several product candidates under development that could potentially be used to treat migraine and compete with MAP0004, including products under development by large pharmaceutical companies such as Merck and other smaller companies. Merck's MK-097, a calcitonin gene-related peptide antagonist, is in Phase 3 development.

In addition, we may face competition from generic sumatriptan, the active ingredient in Imitrex. Although generic sumatriptan could not be substituted for MAP0004, a generic version of sumatriptan may be more quickly adopted by health insurers and consumers than MAP0004, as 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. However, we believe if approved, MAP0004 may have features that could differentiate it from generic sumatriptan.

### **Government Regulation**

#### ***Federal Food, Drug and Cosmetic Act***

Prescription drug products are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of such products under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of the product from the market. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. All applications for FDA approval must contain, among other things, information relating to safety and efficacy, pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control.

#### ***New Drug Applications***

A new drug approval by the FDA is generally required before a drug may be marketed in the United States. This process generally involves:

completion of pre-clinical laboratory and animal testing in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an IND application for human clinical testing which must become effective before human clinical trials may begin in the United States;

## Table of Contents

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each intended use;

satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's current Good Manufacturing Practice, or cGMP, regulations; and

submission to and approval by the FDA of an NDA application.

The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of pre-clinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, covering each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the clinical trial until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. As a separate amendment to an IND, a sponsor may submit a request for a Special Protocol Assessment, or SPA, from the FDA. Under the SPA procedure, a sponsor may seek the FDA's agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the clinical trial begins, except in limited circumstances, such as when a substantial scientific issue essential to determining the safety and effectiveness of a product candidate is identified after a Phase 3 clinical trial is commenced. If the outcome of the clinical trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations, including regulations for informed consent.

For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following three sequential phases, which may overlap:

*Phase 1:* Clinical trials are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.

*Phase 2:* Clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials. In some cases, a sponsor may decide to run what is referred to as a Phase 2b evaluation, which is a second, confirmatory Phase 2 clinical trial that could, if positive and accepted by the FDA, serve as a pivotal trial in the approval of a product candidate.

*Phase 3:* These are commonly referred to as pivotal clinical trials. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites.

*Phase 4:* These are clinical trials conducted after a drug has been approved. In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct

## **Table of Contents**

additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post approval trials are typically referred to as Phase 4 clinical trials.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. Under the Prescription Drug User Fee Act, or PDUFA, the FDA agrees to specific goals for NDA review time through a two-tiered classification system, Standard Review and Priority Review. Standard Review is applied to a drug that offers at most only minor improvement over existing marketed therapies. Standard Review NDAs have a goal of being completed within a ten-month timeframe. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes the FDA to review an NDA is reduced such that the goal for completing a Priority Review initial review cycle is six months. It is likely that our product candidates will be granted a Standard Review. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and FDA may interpret data differently than we do. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials and surveillance programs, to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these postmarketing programs. Drugs may be marketed only for approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

### ***Section 505(b)(2) New Drug Applications***

As an alternate path to FDA approval for modifications to formulations of products previously approved by the FDA, an applicant may file an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and permits the filing of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness based on certain pre-clinical or clinical trials conducted for an approved product. The FDA may also require companies to perform additional clinical trials or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe

## **Table of Contents**

the already approved product's listed patent or that such patent is invalid is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification, the Section 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) NDA application also will not be accepted or approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product, has expired.

If the 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the referenced NDA and patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. Under the FFDCA, the filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, or until a court decides that the patent is invalid, unenforceable or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month stay if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45 day period, the applicant's NDA will not be subject to the 30 month stay.

### ***DEA Regulation***

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Some of these hazardous materials are considered to be controlled substances and subject to regulation by the U.S. Drug Enforcement Agency, or the DEA. Controlled substances are those drugs that appear on one of five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. The CSA governs, among other things, the distribution, recordkeeping, handling, security and disposal of controlled substances. We must be registered by the DEA in order to engage in these activities, and are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of the DEA registration, injunctions or civil or criminal penalties.

### ***International Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of any future products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of any future products.

---

## **Table of Contents**

### ***Third-Party Payor Coverage and Reimbursement***

Although none of our product candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private health care insurance companies and managed care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The United States Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

changing Medicare reimbursement methodologies;

fluctuating decisions on which drugs to include in formularies;

revising drug rebate calculations under the Medicaid program; and

reforming drug importation laws.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

### ***Manufacturing Requirements***

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA's cGMP regulations. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

### ***Other Regulatory Requirements***

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among other things, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and state and federal civil and criminal investigations and prosecutions.

## **Table of Contents**

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals, any one or more of which could have a material adverse effect on us.

### **Corporate History, Headquarters and Website Information**

We incorporated in the state of Delaware, were originally formed as a limited liability company on July 3, 2003 and converted to a corporation on December 11, 2003. We completed our initial public offering in October 2007. Our principal executive offices are located at 2400 Bayshore Parkway, Suite 200, Mountain View, California, 94043. Our telephone number is (650) 386-3100, and our web site address is [www.mapharma.com](http://www.mapharma.com). Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports are available free of charge on our web site as soon as reasonably practicable after we file these reports with the SEC. Our Code of Ethics can also be found on our website.

### **Employees**

As of December 31, 2008, we employed 95 full-time employees. Of the full-time employees, 72 were engaged in product development and clinical activities, and 23 were engaged in sales, general and administrative activities. We plan to continue to expand our product development programs. To support this growth, we will need to expand managerial, operations, development, regulatory, sales, marketing, finance and other functions. None of our employees are represented by a labor union, and we consider our employee relations to be good.

### **Financial Information**

See Item 6, *Selected Financial Data* and Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*.



---

**Table of Contents**

**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 \$25.8 million, \$40.1 million and \$72.9 million, for the years ended December 31, 2006, 2007 and 2008, respectively. As of December 31, 2008, we had a deficit accumulated during development stage of approximately \$175.9 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 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 may 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 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, debt financings and collaboration payments. 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. Additionally, pursuant to our license agreement with AstraZeneca AB, or AstraZeneca, entered into in December 2008 and effective in February 2009, AstraZeneca agreed to fund our remaining development activities for Unit Dose Budesonide, or UDB, and to reimburse us for costs we incur with respect to future UDB development activities conducted for the U.S. registration, subject to the terms and conditions of the license agreement. If the license agreement is terminated under certain conditions, AstraZeneca will not be obligated to pay for such costs. Revenues from potential additional strategic partnerships are uncertain because we may not enter into any additional 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

**Table of Contents**

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 and 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, UDB for asthma in children, 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 the study drug, other clinical materials and potentially approved products;

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 for 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, or FDCA, to seek FDA marketing approval of our product candidates;

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

our ability, and our partners' ability, to establish an effective sales and marketing infrastructure;

competition from existing products or new products that may emerge;

the impact of competition, including generics, in the pediatric asthma market on our ability, and our partners' ability, to commercialize UDB;

## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

the impact of competition, including generics, in the migraine market on our ability to commercialize 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;

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, including our collaboration with AstraZeneca;

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

---

**Table of Contents**

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.

***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, in which case the timing of any potential product approval may be delayed. We believe that our existing cash, including a \$40 million nonrefundable up-front payment we received in connection with our license agreement with AstraZeneca, cash equivalents, short-term investments and reimbursements from AstraZeneca for certain future costs, will be sufficient to fund our projected operating requirements for at least 12 months. In addition, we may need to raise substantial additional capital in the future in order to complete the development and commercialization of MAP0004 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 research and development programs and other expenses.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. 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 to 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

## **Table of Contents**

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, including our collaboration with AstraZeneca;

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.

***We have entered into a license agreement with AstraZeneca pursuant to which we may receive certain milestones and reimbursement for development expenses prior to commercialization of UDB, and we will not receive all of these amounts if AstraZeneca chooses to terminate the license agreement under certain circumstances.***

Our license agreement with AstraZeneca for UDB provided for a \$35 million milestone payment upon the successful achievement of specified primary endpoint and safety results for our initial Phase 3 clinical trial, as well as reimbursement of costs incurred by us in connection with future UDB development activities performed by us, as set forth in a development plan we have agreed on with AstraZeneca. In addition, upon the occurrence of certain events and conditions, we are eligible to receive up to \$240 million in other potential development and regulatory milestones. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in either of the two doses evaluated when compared to placebo. Our failure to meet the co-primary endpoints in our initial Phase 3 clinical trial gives AstraZeneca the right to terminate the agreement or continue with the collaboration without paying the \$35 million milestone. AstraZeneca has 60 days from deemed receipt of the complete data package from our initial Phase 3 clinical trial to decide whether to terminate the agreement. In the event that AstraZeneca terminates our agreement under these circumstances, we may not have adequate resources to continue with our Phase 3 program for UDB, or with our Phase 3 program for MAP0004, or both, without raising further funding.

### **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 are conducting Phase 3 clinical development programs for UDB and MAP0004. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in either dose evaluated when compared to placebo. Our clinical development programs for UDB and MAP0004 may not lead to regulatory approval from the FDA and similar foreign regulatory



## **Table of Contents**

agencies if we fail to demonstrate that the product candidates are safe and effective in our planned clinical trials, and we may therefore fail to commercialize any product candidates. Any failure to obtain regulatory approval of UDB and MAP0004 would have a material and adverse impact on our business.

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

***We will depend on our collaboration with AstraZeneca to complete the development and commercialization of our UDB product candidate and we may enter into additional collaborations with third parties to develop and commercialize some of our other product candidates, including MAP0004. These collaborations may place the development of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.***

In December 2008, we entered into an exclusive collaboration with AstraZeneca for the development and commercialization of UDB worldwide. We may enter into additional collaborations with third parties to develop and commercialize some of our other product candidates, including MAP0004. Our dependence on AstraZeneca for the development and commercialization of UDB subjects us to, and dependence on future partners for development and commercialization of our other product candidates will subject us to, a number of risks, including:

we may not be able to control the amount and timing of resources that our partners may devote to the development or commercialization of product candidates or to their marketing and distribution;

partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

disputes may arise between us and our partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

partners may experience financial difficulties;

partners may not properly maintain or defend our intellectual property rights, or may use our proprietary information, in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation;

business combinations or significant changes in a partner's business strategy may also adversely affect a partner's willingness or ability to complete its obligations under any arrangement;

a partner could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and

the collaborations with our partners may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

For example, we are jointly developing UDB with AstraZeneca in the United States. AstraZeneca will lead the registration of UDB in the United States and has rights to commercialize UDB in the United States and to develop and commercialize UDB worldwide. We cannot control the process for securing regulatory approvals for UDB or the amount and timing of resources that AstraZeneca may devote to the development or commercialization of UDB, or to its marketing and distribution. In addition, AstraZeneca can continue to



**Table of Contents**

commercialize Pulmicort Respules, and could, after a period of three years after the first commercial sale of UDB in the United States, direct its development and marketing resources to the development or commercialization of competitive products, which could delay or impair the commercialization of UDB and harm our business.

*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;

## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

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

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 currently are conducting Phase 3 clinical programs for UDB and MAP0004, and will need to conduct additional Phase 3

## **Table of Contents**

and Phase 2 clinical trials in order to obtain regulatory approval for these product candidates. We may not be able to obtain approval for indications that are as broad as intended or we may obtain approval for indications different than those indications for which we seek approval. Furthermore we may not be able to obtain approval for any of our product candidates.

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 advanced 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 have completed enrollment in both trials. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints, asthma control as assessed by changes from baseline in nighttime and daytime composite symptom scores, in the two doses evaluated when compared to placebo. In order to obtain regulatory approval for UDB and MAP0004, we will need to conduct additional Phase 3 and Phase 2 clinical trials. 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. In addition, 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 first Phase 3 clinical trial for UDB, patients were randomized and given 0.25 mg UDB, 0.135 mg UDB or placebo to evaluate changes in Nighttime and Daytime Composite Symptom Score. Our analysis of top-line data in our initial Phase 3 clinical trial indicated that UDB failed to demonstrate statistically significant improvements in asthma control in either the 0.135 mg dose or the 0.25 mg dose when compared with placebo. We may not demonstrate statistically significant efficacy for either dose in any future trial, in which case we would not receive regulatory approval for either dose. Also, we may only 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 or both doses.

***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

---

## **Table of Contents**

stage of the testing. Our clinical trials may produce negative or inconclusive results. For instance, in our initial Phase 3 clinical trial for UDB, top-line results indicated that the trial failed to meet the primary endpoints. In such cases, we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing, or we may decide not to pursue further development of a product candidate. 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. In our initial Phase 3 clinical trial for UDB, patients were randomized and given 0.25 mg UDB, 0.135 mg UDB or placebo to evaluate changes in Nighttime and Daytime Composite Symptom Scores. Top-line results indicated that the trial did not meet its co-primary endpoints in either dose evaluated when compared to placebo. In addition, the Phase 2 clinical trial of UDB compared two doses of UDB, at 0.135 mg and 0.25 mg administered twice a day. The study showed that 0.135 mg of UDB produced a statistically significant reduction in Nighttime and Daytime Composite Symptom Score when compared with placebo, but the 0.25 mg dose was not significantly better than placebo in Nighttime and Daytime Composite Symptom Score. If we are unable to show a statistically significant reduction in Nighttime and Daytime Composite Symptom Score at both doses, we will not be able to obtain regulatory approval for either dose of our UDB product candidate. If we are able to show a statistically significant reduction in Nighttime and Daytime Composite Symptom Scores at the 0.135 mg dose, but not 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, or may not obtain approval of either dose.

***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.***

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. We will rely on AstraZeneca to submit an NDA in the United States and to obtain approval for UDB in the United States and in other countries worldwide in which AstraZeneca chooses to seek regulatory approval.

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 or our partners 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 or our partners 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

## **Table of Contents**

review by those authorities. We cannot be certain that we or our partners 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 an 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 an 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 FDCA. 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

## Table of Contents

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 or our partners receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.*

The commercial success of our product candidates for which we or our partners, such as AstraZeneca, 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 efficacy and a less favorable safety profile 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, including generics, at similar or lower costs;

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

potential product liability claims.

Our and our partners' ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our and our partners' 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 and our partners' 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. AstraZeneca will support and fund the establishment of our focused sales force to co-promote UDB in the United States for a certain period of time after product launch. In order to commercialize MAP0004, we intend to

## **Table of Contents**

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. Many of these costs will 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.

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 and may adversely affect our ability to commercialize UDB.*

If approved for the treatment of asthma in children, we anticipate that UDB would compete with other marketed asthma therapeutics, including inhaled corticosteroids and leukotriene modifiers, and may compete with products currently under development by both large and small companies. Until November 2008, conventional nebulized budesonide was the only inhaled corticosteroid approved by the FDA for treating



asthma

38

---

**Table of Contents**

in children under four years old. Conventional nebulized budesonide is available from our partner AstraZeneca as Pulmicort Respules. Pulmicort Respules was introduced in the United States in 2000, and annual sales have grown to approximately \$900 million in the United States and approximately \$1.2 billion worldwide in 2007 according to data published by IMS Health. Leukotriene modifiers are an alternative to inhaled corticosteroids for asthmatic children. We believe that prescriptions of Merck & Co., Inc.'s Singulair, the leading leukotriene modifier, for children up to eight years of age generated approximately \$900 million in sales in 2007. In addition to 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 asthma in children.

We may also face competition from generic entry of conventional nebulized budesonide. For example, in November 2008 the FDA approved an abbreviated new drug application, or ANDA, filed by Teva Pharmaceuticals Industries Ltd, or Teva, for conventional nebulized budesonide based on Pulmicort Respules. Under an agreement with AstraZeneca, Teva has obtained a license to AstraZeneca patents relating to Pulmicort Respules and may begin selling its generic version of conventional nebulized budesonide in December 2009. Although we believe a generic version of conventional nebulized budesonide could not be substituted for UDB, 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 our ability to commercialize 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 that 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 product candidates under development by large pharmaceutical companies, such as Merck & Co., Inc., and other smaller companies, that could potentially be used to treat migraine and compete with MAP0004.

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

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

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental payors, 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

## **Table of Contents**

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 or our partners 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 and our partners 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 other countries. 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.

## **Table of Contents**

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

*Even if our product candidates receive regulatory approval, we and our partners 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, or fail to be made in compliance 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 or our partners will need to obtain FDA approval of the proposed product names for our product candidates and any failure or delay associated with such approval may adversely impact our business.*

Any name we or our partners intend to use for our product candidates will require approval from the FDA regardless of whether we or our partners have secured a formal trademark registration from the U.S. Patent and

## **Table of Contents**

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 product candidates. If we or our partners adopt an alternative name, we or our partners 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 or our partners 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.

### ***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



## **Table of Contents**

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.*

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 Tempo inhaler, 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 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 that meets all regulatory requirements.

---

**Table of Contents**

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.

***The success of commercialization of UDB, if any, depends in part on the performance of AstraZeneca, over which we have little or no control.***

Our ability to commercialize UDB, which we are developing with AstraZeneca, and to generate royalties from UDB sales depends on AstraZeneca's abilities to assist us in establishing the safety and efficacy of UDB, obtaining and maintaining regulatory approvals and achieving market acceptance of UDB once commercialized. AstraZeneca may elect to delay or terminate development of UDB, independently commercialize Pulmicort Respules, independently develop additional drugs that could compete with UDB after the period beginning three years after the first commercial sale of UDB in the United States or earlier if we fail to achieve specified endpoint and safety results or an alternative product has a materially better target product profile, or fail to commit sufficient resources to the marketing and distribution of UDB. AstraZeneca may not proceed with the development and commercialization of UDB with the same degree of urgency as we would because of other priorities AstraZeneca may have. If AstraZeneca fails to perform diligently, our potential for revenue from UDB could be dramatically reduced.

***If we are unable to establish marketing, sales and distribution collaborations with third parties, we may not be able to commercialize MAP0004 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 MAP0004 in order to effectively reach target markets in order to maximize its commercial opportunities. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize MAP0004 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 MAP0004.

***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

## **Table of Contents**

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 partners. 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 partners to help develop MAP0005 and MAP0001, but are unable to reach agreements with suitable partners, 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.

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

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

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

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

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

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

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

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

## **Table of Contents**

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 or our partners 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 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

## **Table of Contents**

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 December 31, 2008, we had 95 full-time employees. We will need to continue to expand our managerial, operational, administrative 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 with numerous vendors at numerous clinical sites; and

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

## **Table of Contents**

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

*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 73% 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.

**Table of Contents**

*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;

actions and decisions by our collaborators or partners, including AstraZeneca;

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

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

competition from existing products, new products or generics 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.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. Fluctuations in the market prices of many equity securities often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock.

*If 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



## **Table of Contents**

public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have also registered or plan to register 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.

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 potentially 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.

**Table of Contents**

*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 cash and 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 biotechnology and biopharmaceutical 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 2. PROPERTIES**

The following chart indicates the facilities that we lease, the location and size of each such facility and their designated use.

<b>Location</b>	<b>Approximate Square Feet</b>	<b>Operation</b>	<b>Expiration</b>
Mountain View, CA	43,000	Office and Laboratory	Lease expires June 2012 (with an option to renew for an additional three to five years)
Mountain View, CA	21,000	Office and Laboratory	Lease expires March 2010 (with an option to renew for an additional three to five years)

We believe that the facilities that we currently lease are suitable and adequate for our needs for the immediate future and that, should it be needed, additional space can be leased to accommodate any future growth.

**ITEM 3. LEGAL PROCEEDINGS**

We are not a party to any legal proceeding.

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

None

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock has been listed on The Nasdaq Global Market under the symbol MAPP since October 5, 2007. Prior to that time, there was no public market for our stock. The following table sets forth the high and low intra-day sales prices per share for our common stock on The Nasdaq Global Market for the indicated periods.

<b>Year Ended December 31, 2008:</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 17.69	\$ 10.39
Second Quarter	\$ 14.80	\$ 9.75
Third Quarter	\$ 11.75	\$ 6.68
Fourth Quarter	\$ 10.44	\$ 1.75
<b>Year Ended December 31, 2007:</b>		
Fourth Quarter (from October 5, 2007)	\$ 20.00	\$ 12.25

**Holders of Record**

As of February 28, 2009, there were approximately 25 stockholders of record of our common stock.

**Dividend Policy**

We have never declared or paid any cash dividend on our common stock and have no present plans to do so. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future.

**Table of Contents****Performance Graph**

This performance graph shall not be deemed soliciting material or to be filed with the Securities and Exchange Commission, or the SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of MAP Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph shows a comparison from October 5, 2007 (the date our common stock commenced trading on The Nasdaq Global Market) through December 31, 2008 of cumulative total return for our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the Nasdaq Composite Index and the Nasdaq Biotechnology Index assume reinvestment of dividends.

	<b>October 5, 2007</b>	<b>October 31, 2007</b>	<b>November 30, 2007</b>	<b>December 31, 2007</b>	<b>January 31, 2008</b>	<b>February 29, 2008</b>	<b>March 31, 2008</b>	<b>April 30, 2008</b>	<b>May 31, 2008</b>
MAP Pharmaceuticals, Inc	100.00	103.97	101.12	131.16	97.38	97.38	104.64	100.07	103.75
NASDAQ Composite	100.00	105.58	98.00	97.43	87.58	83.75	83.73	88.79	92.80
NASDAQ Biotechnology	100.00	104.28	101.17	94.93	93.04	91.77	91.90	92.54	94.55

  

	<b>June 30, 2008</b>	<b>July 31, 2008</b>	<b>August 31, 2008</b>	<b>September 30, 2008</b>	<b>October 31, 2008</b>	<b>November 30, 2008</b>	<b>December 31, 2008</b>
MAP Pharmaceuticals, Inc	77.38	73.71	74.16	75.81	31.16	34.46	52.28
NASDAQ Composite	84.59	84.53	85.69	75.06	61.54	55.10	56.76
NASDAQ Biotechnology	92.97	105.57	102.59	96.42	87.94	81.77	87.65

**Table of Contents**

**Recent Sales of Unregistered Securities**

None

**Use of Proceeds from the Sale of Registered Securities**

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

We paid \$4.8 million in underwriting discount and commissions to the underwriters, and we incurred an additional \$2.0 million of other expenses related to the offering during the fiscal year ended December 31, 2007. The net offering proceeds to us, after deducting underwriting discounts paid by us and offering costs, were \$62.1 million. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning 10% or more of our common stock, or to our affiliates. We have applied the net proceeds from the IPO to our working capital for general corporate purposes. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to capital preservation and liquidity. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus dated October 4, 2007 filed with the SEC.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

You should read the following selected consolidated financial data in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K.

We were incorporated in July 2003 and no expenses were incurred until 2004. The consolidated statements of operations data for the years ended December 31, 2008, 2007, 2006 and for the period from July 3, 2003 (date of inception) through December 31, 2008, and the consolidated balance sheet data at December 31, 2008 and 2007, are derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2005, 2004, and the consolidated balance sheet data at December 31, 2006, 2005 and 2004, are derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results to be expected in any future period. Our consolidated financial statements reflect a 1-for-1.77 reverse stock split of our common stock and preferred stock effected on October 4, 2007.

	Year Ended December 31,					Period from July 3, 2003 (Date of Inception) to December 31, 2008
	2008	2007	2006	2005	2004	
(in thousands, except per share data)						
<b>Statement of Operations Data:</b>						
Operating expenses						
Research and development	\$ 59,277	\$ 31,362	\$ 22,268	\$ 12,285	\$ 6,506	\$ 131,698
Sales, general and administrative	13,417	9,567	4,128	4,377	2,573	34,062
Total operating expenses	72,694	40,929	26,396	16,662	9,079	165,760
Loss from operations	(72,694)	(40,929)	(26,396)	(16,662)	(9,079)	(165,760)
Interest income	2,103	2,775	905	348	118	6,249
Interest expense	(2,056)	(1,343)	(235)			(3,633)
Other income (expense), net	(281)	(563)	(83)	65	130	(733)
Net loss	\$ (72,928)	\$ (40,060)	\$ (25,809)	\$ (16,249)	\$ (8,831)	\$ (163,877)
Net loss attributed to common stockholders	\$ (72,928)	\$ (45,635)	\$ (30,538)	\$ (18,850)	\$ (9,850)	\$ (177,802)
Net loss per share attributed to common stockholders basic and diluted(1)	\$ (3.58)	\$ (8.28)	\$ (43.11)	\$ (28.75)	\$ (16.06)	
Weighted average shares outstanding used in calculating net loss per share attributed to common stockholders basic and diluted(1)	20,350	5,510	708	656	614	

	As of Year Ended December 31,				
	2008	2007	2006	2005	2004
(in thousands)					
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 44,710	\$ 94,990	\$ 17,746	\$ 7,158	\$ 22,259
Working capital	22,091	83,337	13,258	4,115	21,057
Total assets	50,860	100,695	21,625	9,769	23,914
Long-term debt, net of current portion	14,229	6,357	10,061		
Redeemable convertible preferred stock warrant liability			411		
Redeemable convertible preferred stock			64,898	35,069	32,468
Deficit accumulated during the development stage	(175,894)	(102,966)	(58,686)	(28,569)	(9,801)
Total stockholders' equity (deficit)	13,147	81,606	(58,676)	(28,566)	(9,798)

- (1) Please see Note 2. Summary of Significant Accounting Policies in Part II, Item 8 of this Form 10-K for an explanation of the method used to calculate the net loss per share attributed to common stockholders and the number of shares used in the computation of the per share amounts.

In 2008, 2007 and 2006, loss from operations, net loss and basic and diluted net loss per common share attributed to common stockholders include the impact of Statement of Financial Accounting Standards, or SFAS, No. 123(R) stock-based compensation charges, which were not applicable in prior years. Please see Note 2. Summary of Significant Accounting Policies in Part II, Item 8 of this Form 10-K.

---

**Table of Contents**

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis together with Item 6 Selected Financial Data and the financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.*

**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 that address large market opportunities, including our two most advanced product candidates, Unit Dose Budesonide, or UDB, for the potential treatment of asthma in children and MAP0004 for the potential treatment of migraine. UDB is our proprietary nebulized version of budesonide intended to treat 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 nebulized treatment for asthma in children. 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.

In December 2008, we entered into a worldwide collaboration with AstraZeneca AB, or AstraZeneca, to develop and commercialize UDB. We are jointly developing UDB with AstraZeneca in the United States and have the rights to co-promote UDB in the U.S.

We announced positive results from Phase 2 clinical studies of UDB and MAP0004 in early 2007. We initiated a Phase 3 clinical program for UDB in January 2008, and in February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in the two doses evaluated when compared to placebo. We and our partner AstraZeneca are conducting further analyses of these data to determine appropriate next steps for the UDB program. For our MAP0004 migraine program we initiated a Phase 3 clinical program in July 2008 pursuant to a special protocol assessment, or SPA, from the U.S. Food and Drug Administration, or FDA. In order to obtain regulatory approval for UDB and MAP0004, we will need to conduct additional Phase 3 and Phase 2 clinical trials.

We hold worldwide commercialization rights for MAP0004 and our goal is to market MAP0004 in the United States through our own focused sales force targeting neurologists and headache specialists. We may establish partnerships with pharmaceutical companies to market and sell to primary care physicians and outside of the United States.

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<sup>®</sup> inhaler. While we do not plan to make further significant direct investment in these two product candidates, we plan to evaluate other potential product candidates which may utilize these technologies, as well as partnership opportunities for further development and commercialization of these two product candidates.

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 \$175.9 million as of December 31, 2008. We have financed our operations through equity financing, debt financing, the issuance of convertible notes and collaboration payments. Prior to our initial public offering, or IPO, in October 2007, we had received net



---

## **Table of Contents**

proceeds of \$106.7 million from the issuance of convertible notes 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 a loan facility agreement and borrowed \$10.0 million to finance working capital, or the 2006 Working Capital Loan, and a \$1.0 million loan facility to finance equipment purchases. 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.

### **AstraZeneca License Agreement**

On December 19, 2008, we entered into a license agreement with AstraZeneca. Pursuant to the terms of the agreement, we license to AstraZeneca global rights to develop and commercialize UDB, the next generation UDB therapy and certain combination nebulization therapies for the potential treatment of asthma in children. The agreement became effective on February 2, 2009 after expiration of the Hart-Scott-Rodino Act waiting period. We and AstraZeneca are jointly developing UDB in the United States with the Company executing the development plan. AstraZeneca will pay for up to a 60-person sales force for us to co-promote UDB in the United States after product launch. AstraZeneca will provide funding for this sales force for up to five years after the product launch. AstraZeneca has rights to commercialize UDB in the United States and to develop and commercialize UDB outside of the United States. AstraZeneca reimburses us for the costs of UDB development activities, beginning on the effective date, related to obtaining approval of UDB by the FDA, and will have the rights to develop follow-on products using different nebulizers and certain products combining budesonide with other drugs. In February 2009, AstraZeneca paid us a nonrefundable upfront cash payment of \$40 million. Under the terms of the agreement, we are eligible to receive up to \$240 million in development and regulatory milestones. The agreement also provides for additional progressively demanding sales performance-related milestone payments of up to \$585 million in the event the product is a considerable commercial success. We are eligible to receive significant and escalating double-digit royalty payments on worldwide sales.

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

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

While our significant accounting policies are more fully described in Note 2 Summary of Significant Accounting Policies in Part II, Item 8 of this Form 10-K, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

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

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

---

**Table of Contents**

contract and may result in uneven expenses and payment flows. Pre-clinical study and clinical trial expenses include the following:

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

fees paid to contract research organizations and investigative sites in connection with clinical trials; and

fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for use in pre-clinical studies and clinical trials.

Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain number of patients, site initiation and completion of clinical trial milestones. In accruing services fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and status meetings with CROs and review of contractual terms. Our estimates are dependent on the timeliness and accuracy of data provided by our CROs and other vendors. If we have incomplete or inaccurate information, we may underestimate or overestimate activity levels associated with various studies or clinical trials at a given point in time. In this event, we could record adjustments to research and development expenses in future periods when the actual activity levels become known.

***Stock-Based Compensation***

Effective January 1, 2006, we adopted the fair value provision of SFAS No. 123(R) which supersedes previous accounting under APB No. 25. SFAS No. 123(R) requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. SFAS No. 123(R) requires companies to estimate the fair value of the share-based payment awards on the date of grant using an option-pricing model. We adopted SFAS No. 123(R) using the prospective transition method, which requires that entities that used the minimum value method for either pro forma or financial statement recognition purposes apply SFAS No. 123(R) to option grants or modifications after the effective date of this standard. For options granted prior to the SFAS No. 123(R) effective date, for which the requisite service period has not been performed as of January 1, 2006, we will continue to recognize compensation expense on the remaining unvested awards under the intrinsic-value method of APB No. 25. All options grants valued after January 1, 2006 will be expensed on a straight-line basis over the vesting period. We selected the Black-Scholes valuation model as the most appropriate valuation method for stock option grants. The fair value of these stock options grants is estimated as of the date of grant using the Black-Scholes valuation model. The risk-free rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of our stock options. The expected stock price volatility for our common stock was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of our industry peers as we did not have any significant trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life-cycle and financial leverage. The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding and is based on the expected terms for industry peers as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock options. We will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for our common stock becomes available. The expected dividend yield is based on our history and expectation of dividend payouts. In addition, SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in a subsequent period if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience.

***Net Operating Loss Carryforwards***

At December 31, 2008, we had federal and state net operating loss carryforwards of approximately \$157.2 million and \$155.2 million, respectively. The net operating loss carryforwards expire between 2017 and 2029, if not utilized. We have established a full valuation allowance against our deferred tax assets due to our history of

**Table of Contents**

losses and the uncertainty of future taxable income. The valuation allowance increased by \$31.7 million and \$16.4 million during the years ended December 31, 2008 and 2007, respectively.

As of December 31, 2008, we also had federal and state research and development tax credit carryforwards of approximately \$4.4 million and \$2.5 million, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2025, and the state credits can be carried forward indefinitely. The Tax Reform Act of 1986 limits the use of net operating loss carryforwards in certain situations where changes occur in the stock ownership of a company. In the event we have a change in ownership, utilization of the carryforwards could be limited.

We adopted Financial Accounting Standards Board or FASB Interpretation 48, Accounting for Uncertainty in Income Taxes, or FIN 48, on January 1, 2007. As of December 31, 2008, we had no unrecognized tax benefits and do not expect any material change during the next year. As of December 31, 2008, we have not recorded any interest or penalties under FIN 48.

**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 December 31, 2008, we had incurred approximately \$131.7 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 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; however, beginning on the effective date of February 2, 2009, AstraZeneca will reimburse us for costs related to the UDB development program.

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 estimates.

	Year Ended December 31,			Period from
	2008	2007	2006	July 3, 2003 (Date of Inception) through December 31, 2008
Our most advanced product candidates:				
UDB	50%	39%	37%	45%
MAP0004	44%	51%	53%	47%
Other projects	6%	10%	10%	8%
Total	100%	100%	100%	100%

**Table of Contents**

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 other things, 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 may need to raise substantial additional capital in the future in order to complete the development and potential commercialization of UDB and MAP0004 and other product candidates.

**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 December 31, 2008, we had incurred approximately \$34.1 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 Years Ended December 31, 2008 and 2007**

	Year Ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2008	2007		
	(in thousands, except percentages)			
Research and development expenses	\$ 59,277	\$ 31,362	\$ 27,915	89%
Sales, general and administrative expenses	13,417	9,567	3,850	40%
Interest income	(2,103)	(2,775)	(672)	(24)%
Interest expense	2,056	1,343	713	53%
Other expense, net	281	563	(282)	(50)%

**Research and Development Expenses.** The increase in research and development expenses for the year ended December 31, 2008 compared to the year ended December 31, 2007 was primarily driven by an increase of \$21.5 million related to clinical expenses to support Phase 3 clinical programs initiated in 2008 for our two lead program candidates, UDB and MAP0004, \$4.2 million in personnel related expenses to support these clinical programs, \$1.1 million in manufacturing and \$0.7 million in stock-based compensation.

**Sales, General and Administrative Expenses.** The increase in sales, general and administrative expenses for the year ended December 31, 2008 compared to the year ended December 31, 2007 was primarily related to increases of \$1.2 million in stock-based compensation, \$1.2 million in personnel related expenses, \$0.5 million in outside services and \$0.4 million in professional fees.

**Interest Income.** The decrease in interest income was due primarily to decreased cash, cash equivalent and short-term investment balances in the year ended December 31, 2008 as compared to 2007 and a 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.** The increase in interest expense was due primarily to 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.

**Table of Contents**

*Other Expense, Net.* Other expense, net, for 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. Other income (expense), net, for 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.

**Comparison of Years Ended December 31, 2007 and 2006**

	Year Ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2007	2006		
	(in thousands, except percentages)			
Research and development expenses	\$ 31,362	\$ 22,268	\$ 9,094	41%
Sales, general and administrative expenses	9,567	4,128	5,439	132%
Interest income	(2,775)	(905)	1,870	207%
Interest expense	1,343	235	1,108	471%
Other expense, net	563	83	480	578%

*Research and Development Expenses.* The increase in research and development expenses for the year ended December 31, 2007 was primarily related to an increase of \$5.7 million in clinical trial expenses, \$3.0 million in personnel expenses to support our growth in preparation for our Phase 3 clinical programs related to our two lead product candidates and \$0.9 million in share-based compensation, partially offset by a decrease of \$1.0 million in milestone expenses predominantly related to our two lead product candidates.

*Sales, General and Administrative Expenses.* The increase in sales, general and administrative expenses for the year ended December 31, 2007 was primarily related to increases of \$1.5 million in personnel expenses, \$1.1 million in professional services related to becoming a public company, \$0.9 million in professional services for marketing activities, and \$0.7 million in share-based compensation.

*Interest Income.* The increase in interest income was due primarily to increased cash, cash equivalent and short-term investment balances in the year ended December 31, 2007 as compared to 2006, due primarily to the \$50.2 million Series D convertible preferred stock financing which closed in the first quarter of 2007 and, to a lesser extent, the proceeds from our IPO. We expect our interest income to fluctuate in the future with changes in average investment balances and market interest rates.

*Interest Expense.* The increase in interest expense for the year ended December 31, 2007 was due to the full year impact of the interest on the outstanding debt related to a loan agreement entered into in September and December 2006. We expect our interest expense to fluctuate in the future with average debt balances.

*Other Expense, Net.* Other expense, net primarily consisted of the change in carrying value of warrants to purchase redeemable convertible preferred stock. The increase was due to the increase in the value of the underlying redeemable convertible preferred stock leading up to the IPO. We expect no other expense from the change in carrying value of preferred warrants in 2008 as the warrants to purchase preferred stock converted into warrants to purchase common stock at the time of our IPO, with the carrying value included in equity.

**Liquidity and Capital Resources**

We have incurred losses and negative cash flow since our inception in July 2003 and, as of December 31, 2008, we had an accumulated deficit of \$175.9 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.

**Table of Contents**

We have financed our operations through equity financing, debt financing, the issuance of convertible notes and collaboration payments. 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 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 a loan facility agreement and borrowed \$10.0 million to finance working capital or the 2006 Working Capital Loan, and a \$1.0 million loan facility to finance equipment purchases. 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. As of December 31, 2008, we had approximately \$44.7 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, 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 received \$40.0 million as a nonrefundable upfront license fee from AstraZeneca in February 2009.

**Cash Flow**

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

	Year Ended December 31,		
	2008	2007	2006
	(in thousands)		
Cash, cash equivalents and short-term investments	\$ 44,710	\$ 94,990	\$ 17,746
Cash provided by (used in):			
Operating activities	(59,473)	(33,200)	(24,285)
Investing activities	31,546	(40,444)	(7,785)
Financing activities	10,738	111,669	36,003

*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, share-based compensation and changes in operating assets and liabilities. The increase for the year ended December 31, 2008 as compared to the year ended December 31, 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 provided by (used in) investing activities.* Net cash provided by investing activities was primarily related to investment activity, with more maturities than purchases of investments in 2008 as compared to 2007. Net cash used in investing activities for the year ended December 31, 2006 was primarily related to the purchase of investments and, to a lesser extent, the purchase of property and equipment, partially offset by the proceeds from the sale of short-term investments.

*Net cash provided by financing activities.* Net cash provided by financing activities in 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. Net cash provided by financing activities for the year ended December 31, 2007 was primarily attributable to the issuance of common stock in our IPO in October and the issuance of Series D convertible preferred stock in March, partially offset by repayment of debt. Net cash provided by financing activities for the year ended December 31, 2006 was primarily attributable to the issuance of Series C convertible preferred stock and the proceeds from our loan facility agreements.

**Table of Contents****Contractual Obligations**

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2008.

	Total	Payments Due by Period			Thereafter
		Less than 1 Year	2-3 Years	4-5 Years	
(in thousands)					
<b>Contractual Obligations:</b>					
Debt(1)	\$ 24,397	\$ 8,102	\$ 16,295	\$	\$
Operating lease obligation(2)	4,399	1,049	2,650	700	
Total	\$ 28,796	\$ 9,151	\$ 18,945	\$ 700	\$

(1) 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. The amounts in the table above include interest and principal repayments on the loan. As of December 31, 2008, we were in compliance with the loan covenants. Please see Note 5. Long-term Debt in Part II, Item 8 of this Form 10-K for additional information.

(2) The amounts in the table above include the minimum rental payments for our laboratory and office facilities in Mountain View, California. Please see Note 6. Commitments and Contingencies in Part II, Item 8 of this Form 10-K for additional information.

The table above reflects only payment obligations 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. Amounts and an estimate of significant payments related to licensing and other arrangements not included in the contractual obligations table above are as follows:

Under the June 2004 agreement, as amended, with Nektar Therapeutics UK Limited, or 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 December 31, 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. We paid \$0, \$1.0 million, \$0.5 million and \$2.6 million related to milestones for the year ended December 31, 2008, 2007, 2006 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2008, respectively. 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, or Elan Agreement, Elan granted to us a worldwide, exclusive, sub-licensable license under Elan's intellectual property rights to use, market, distribute, sell, have sold, offer for sale, import and export certain ingredients for our UDB product candidate. We also agreed to pay royalties at specified rates based on net sales. As of December 31, 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 \$0.8 million, \$0.8 million, \$2.0 million and \$4.0 million related to milestones for the year ended December 31, 2008, 2007, 2006 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2008, respectively. 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. We also entered into a services agreement with Elan Drug Delivery International in February 2005. In December 2008, in connection with the execution of the license agreement with AstraZeneca,

**Table of Contents**

we amended the Elan agreements, pursuant to which AstraZeneca will have certain rights to exercise and enforce certain of our rights with Elan prior to the expiration or termination of the AstraZeneca agreement. The amendment did not impact our consolidated financial statements.

***Operating Capital and Capital Expenditure Requirements***

Our future capital requirements will depend on many forward looking factors and are not limited to the following:

the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;

the status of our collaboration with AstraZeneca;

our ability to achieve milestones under our collaboration agreements including our agreement with AstraZeneca;

the outcome, the timing and the cost of regulatory approvals;

delays that may be caused by changing regulatory requirements;

the number of product candidates that we pursue;

the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;

the timing and terms of future in-licensing and out-licensing transactions;

the cost and timing of establishing sales, marketing and distribution capabilities;

the cost of procuring clinical and commercial supplies of our product candidates;

the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions; and

the possible costs of litigation.

We believe that our existing cash, including a \$40 million nonrefundable up-front payment we received in February 2009 in connection with our license agreement with AstraZeneca, cash equivalents, short-term investments and reimbursements from AstraZeneca for certain future costs, will be sufficient to fund our projected operating requirements for at least 12 months. In addition, we may need to raise substantial additional capital in the future in order to complete the development and commercialization of MAP0004 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 research and development programs and other expenses.



## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. 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

---

## **Table of Contents**

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.

### **Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement*, or SFAS No. 157. SFAS No. 157 provides a framework that clarifies the fair value measurement objective within GAAP and its application under the various accounting standards where fair value measurement is allowed or required. Under SFAS No. 157, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability, and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data. SFAS No. 157 requires fair value measurements to be separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. However, in February 2008, FSP No. 157-2 was issued which delayed the effective date of SFAS No. 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 (at least annually). FSP No. 157-2 partially defers the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008, including interim periods within that fiscal year, for items within its scope. As a result, FSP No. 157-2 is effective for us in the first quarter of fiscal 2009. Effective on January 1, 2008, we adopted SFAS No. 157, except as it applies to those nonfinancial assets and nonfinancial liabilities within the scope of FSP No. 157-2. Our partial adoption of SFAS No. 157 did not materially impact our consolidated financial statements. We do not believe that the adoption of SFAS No. 157 for our nonfinancial assets and nonfinancial liabilities will have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159, effective for us on 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 on January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the year ended December 31, 2008. Our adoption of SFAS 159 did not impact the consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, or SFAS No. 141R. SFAS No. 141R amends SFAS 141 and provides revised guidance for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree. It also provides disclosure requirements to enable users of the financial statements to evaluate the nature and financial effects of the business combination. It is effective for fiscal years beginning on or after December 15, 2008 and will be applied prospectively. As a result, SFAS 141R is effective for us in the first quarter of fiscal 2009. We do not believe that the adoption of SFAS 141R will have a material impact on our financial statements.

In December 2007, the EITF reached a consensus on EITF No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-01. EITF 07-01 discusses the appropriate income statement presentation and classification for the activities and payments between the participants in arrangements related to the development and commercialization of intellectual property. The sufficiency of disclosure related to these arrangements is also specified. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. As a result, EITF 07-01 is effective for us in the first quarter of fiscal 2009. We do not believe that the adoption of EITF 07-01 will have a material impact on our financial statements.

---

## **Table of Contents**

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*, or SFAS No. 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. As a result, SFAS 160 is effective for us in the first quarter of fiscal 2009. We do not believe that the adoption of SFAS No. 160 will have a material impact on our financial statements.

### **Off-Balance Sheet Arrangements**

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

### **ITEM 7A. 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.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. 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.

**Table of Contents**

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA  
MAP PHARMACEUTICALS, INC.**

**(a development stage enterprise)**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	68
<u>Consolidated Balance Sheets</u>	69
<u>Consolidated Statements of Operations</u>	70
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	71
<u>Consolidated Statements of Cash Flows</u>	72
<u>Notes to Consolidated Financial Statements</u>	73

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of MAP Pharmaceuticals, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of MAP Pharmaceuticals, Inc. and its subsidiaries (a development stage enterprise) at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, and cumulatively, for the period from July 3, 2003 (date of inception) to December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits (which was an integrated audit in 2008). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for uncertain tax positions in 2007.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 11, 2009

**Table of Contents****MAP PHARMACEUTICALS, INC.**

(a development stage enterprise)

**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share data)

	December 31,	
	2008	2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 31,927	\$ 49,116
Short-term investments	12,783	45,874
Prepaid expenses and other current assets	805	1,079
Total current assets	45,515	96,069
Property and equipment, net	5,007	4,183
Other assets	28	122
Restricted investment	310	321
Total assets	\$ 50,860	\$ 100,695
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,631	\$ 1,290
Accrued liabilities	15,445	7,622
Current portion of long-term debt	6,348	3,820
Total current liabilities	23,424	12,732
Long-term debt, net of current	14,229	6,357
Other liabilities	60	
Total liabilities	37,713	19,089
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock: \$0.01 par value; issuable in series; 5,000,000 shares authorized; none issued or outstanding		
Common stock: \$0.01 par value, 100,000,000 shares authorized; 20,546,450 and 20,228,362 shares issued and outstanding at December 31, 2008 and 2007, respectively	200	197
Additional paid-in capital	188,797	184,194
Deficit accumulated during the development stage	(175,894)	(102,966)
Accumulated other comprehensive income	44	181
Total stockholders' equity	13,147	81,606
Total liabilities and stockholders' equity	\$ 50,860	\$ 100,695

**Table of Contents****MAP PHARMACEUTICALS, INC.****(a development stage enterprise)****CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except share and per share amounts)**

	Years Ended December 31,			Cumulative Period from July 3, 2003 (Date of Inception) to December 31, 2008
	2008	2007	2006	
Operating expenses:				
Research and development	\$ 59,277	\$ 31,362	\$ 22,268	\$ 131,698
Sales, general and administrative	13,417	9,567	4,128	34,062
Total operating expenses	72,694	40,929	26,396	165,760
Loss from operations	(72,694)	(40,929)	(26,396)	(165,760)
Interest income	2,103	2,775	905	6,249
Interest expense	(2,056)	(1,343)	(235)	(3,633)
Other expense, net	(281)	(563)	(83)	(733)
Net loss	(72,928)	(40,060)	(25,809)	\$ (163,877)
Cumulative stock dividend attributed to preferred stockholders		(5,575)	(4,729)	(13,925)
Net loss attributed to common stockholders	\$ (72,928)	\$ (45,635)	\$ (30,538)	\$ (177,802)
Net loss per share attributed to common stockholders basic and diluted	\$ (3.58)	\$ (8.28)	\$ (43.11)	
Weighted average shares outstanding used in calculating net loss per share attributed to common stockholders basic and diluted	20,350,367	5,509,780	708,307	

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

**Table of Contents****MAP PHARMACEUTICALS, INC.**

(a development stage enterprise)

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

(In thousands, except share and per share data)

	Common Stock		Additional	Accumulated	Deficit	Total
	Shares	Amount	Paid-In	Other	Accumulated	Stockholders
			Capital	Comprehensive	During the	Equity
				Income	Development	(Deficit)
					Stage	
Issuance of common stock to founders in December 2003 at \$0.001 per share	610,164	\$ 1	\$	\$	\$	\$ 1
<b>Balances at December 31, 2003</b>	610,164	1				1
Issuance of restricted common stock at \$0.25 per share in August 2004 for services	208,270	2	49			51
Accretion of cumulative dividend on redeemable convertible preferred stock			(49)		(970)	(1,019)
Net loss					(8,831)	(8,831)
<b>Balances at December 31, 2004</b>	818,434	3			(9,801)	(9,798)
Stock-based compensation			82			82
Accretion of cumulative dividend on redeemable convertible preferred stock			(82)		(2,519)	(2,601)
Net loss					(16,249)	(16,249)
<b>Balances at December 31, 2005</b>	818,434	3			(28,569)	(28,566)
Issuance of common stock in conjunction with exercise of stock options	2,400		2			2
Employee share-based compensation expense recognized under SFAS 123(R)			279			279
Stock-based compensation expense from vesting of service award			140			140
Accretion of cumulative dividend on redeemable convertible preferred stock			(421)		(4,308)	(4,729)
Components of other comprehensive loss:						
Change in unrealized gain on marketable securities				6		6
Net loss					(25,809)	(25,809)
Total comprehensive loss						(25,803)
<b>Balances at December 31, 2006</b>	820,834	3		6	(58,686)	(58,677)
Conversion of redeemable convertible preferred stock to common stock at initial public offering	12,634,845	126	106,601			106,727
Issuance of redeemable convertible preferred stock dividend in common stock at initial public offering	928,314	9	13,916			13,925
Conversion of warrants from warrants for preferred stock to warrants for common stock			948			948
Elimination of fractional shares resulting from reverse stock split			6		(6)	
Issuance of common stock from initial public offering, net of issuance costs	5,750,000	58	62,063			62,121
Issuance of common stock in conjunction with exercise of stock options	94,369	1	61			62
Employee share-based compensation expense recognized under SFAS 123(R)			1,711			1,711
Stock-based compensation for non-employee services			249			249
			(1,361)		(4,214)	(5,575)



## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

Accretion of cumulative dividend on redeemable convertible preferred stock

Components of other comprehensive loss:						
Change in unrealized gain on marketable securities	175				175	
Net loss				(40,060)		(40,060)

Total comprehensive loss (39,885)

<b>Balances at December 31, 2007</b>	20,228,362	197	184,194	181	(102,966)	81,606
--------------------------------------	------------	-----	---------	-----	-----------	--------

Issuance of common stock in conjunction with exercise of stock options and purchase under employee stock purchase plan	318,088	3	719			722
--	---------	---	-----	--	--	-----

Employee share-based compensation expense recognized under SFAS 123(R)			3,359			3,359
--	--	--	-------	--	--	-------

Stock-based compensation for non-employee services			534			534
--	--	--	-----	--	--	-----

Adjustment to issuance cost related to IPO			(9)			(9)
--	--	--	-----	--	--	-----

Components of other comprehensive loss:						
Change in unrealized loss on marketable securities				(137)		(137)

Net loss					(72,928)	(72,928)
----------	--	--	--	--	----------	----------

Total comprehensive loss						(73,065)
--------------------------	--	--	--	--	--	----------

<b>Balances at December 31, 2008</b>	20,546,450	\$ 200	\$ 188,797	\$ 44	\$ (175,894)	\$ 13,147
--------------------------------------	------------	--------	------------	-------	--------------	-----------

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

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

	Years Ended December 31,			Cumulative Period from July 3, 2003 (Date of Inception) to December 31, 2008
	2008	2007	2006	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (72,928)	\$ (40,060)	\$ (25,809)	\$ (163,877)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,275	881	595	3,180
Accretion of investment discounts, net	(696)	(898)		(1,594)
Amortization of debt issuance costs	102	94	14	210
Accretion of debt payment premium	300			300
Change in carrying value of warrant liability		537	84	621
Issuance of common stock in exchange for services				51
Share-based compensation	3,893	1,960	419	6,354
Loss on disposal and other non-cash items	16	154	3	384
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	274	(636)	(446)	(1,030)
Other assets	67	8	29	65
Accounts payable	341	(501)	682	1,602
Accrued liabilities	7,823	5,261	144	15,414
Other liabilities	60			60
Net cash used in operating activities	(59,473)	(33,200)	(24,285)	(138,260)
<b>Cash flows from investing activities:</b>				
Purchase of intangible assets and in-process research and development				(412)
Purchase of property and equipment	(2,115)	(2,177)	(1,454)	(8,125)
Purchase of short-term investments	(55,642)	(86,671)	(27,185)	(169,497)
Sales and maturities of short-term investments	89,292	48,525	20,854	158,671
Sales (Purchase) of restricted investment	11	(121)		(310)
Net cash provided by (used in) investing activities	31,546	(40,444)	(7,785)	(19,673)
<b>Cash flows from financing activities:</b>				
Proceeds from issuance of convertible notes payable				4,300
Proceeds from issuance of debt	20,000		11,006	31,006
Adjustment to issuance cost related to IPO	(9)			(9)
Proceeds from sales of shares through equity plans	722	63	2	787
Repayment of debt	(9,975)	(750)	(105)	(10,829)
Proceeds from issuance of common stock in IPO, net of issuance costs(1)		62,177		62,177
Proceeds from issuance of convertible preferred stock, net of issuance costs		50,179	25,100	102,428
Net cash provided by financing activities	10,738	111,669	36,003	189,860
Net increase (decrease) in cash and cash equivalents	(17,189)	38,025	3,933	31,927
Cash and cash equivalents at beginning of period	49,116	11,091	7,158	

## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

Cash and cash equivalents at end of period	\$ 31,927	\$ 49,116	\$ 11,091	\$ 31,927
<b>Supplemental disclosures of cash flow information</b>				
Cash paid for interest	\$ 1,658	\$ 1,222	\$ 142	\$ 3,022
<b>Supplemental non-cash information</b>				
Conversion of notes payable to convertible preferred stock	\$	\$	\$	\$ 4,300
Issuance of convertible preferred stock warrants	\$	\$	\$ 327	\$ 327
Accretion of cumulative dividends on redeemable convertible preferred stock	\$	\$ 5,575	\$ 4,729	\$ 13,925
Conversion of redeemable convertible preferred stock to common stock upon IPO	\$	\$ 106,727	\$	\$ 106,727
Reclassification of preferred warrants to common warrants	\$	\$ 948	\$	\$ 948
Issuance of common stock to preferred stockholders as cumulative dividend	\$	\$ 13,925	\$	\$ 13,925

- (1) The difference between \$62.1 million and \$62.2 million in Note 1 is \$59,000 in offering costs accrued and not yet paid at December 31, 2007. The accompanying notes are an integral part of these consolidated financial statements.

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**(a development stage enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1. THE COMPANY**

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 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, or 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, 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. Prior to achieving profitable operations, we intend to continue to fund operations through public or private financings, strategic partnerships or other 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 research and development programs and other expenses.

***Reverse Stock Split***

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

***Consolidation***

The consolidated financial statements include our accounts and those of our wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Use of Estimates***

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

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

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

fees paid to contract research organizations and investigative sites in connection with clinical trials; and

fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for use in pre-clinical studies and clinical trials.

Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain number of patients, site initiation and completion of clinical trial milestones. In accruing services fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and status meetings with CROs and review of contractual terms. Our estimates are dependent on the timeliness and accuracy of data provided by our CROs and other vendors. If we have incomplete or inaccurate information, we may underestimate or overestimate activity levels associated with various studies or clinical trials at a given point in time. In this event, we could record adjustments to research and development expenses in future periods when the actual activity levels become known.

***Cash and Cash Equivalents***

We consider all highly liquid investments purchased with an original maturity of less than or equal to ninety days to be cash equivalents. Cash and cash equivalents primarily consist of money market funds.

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

We invest cash that is not currently being used for operational purposes in accordance with our investment policy. The policy allows for the purchase of debt securities such as those issued by the U.S. government and its agencies and corporations, subject to certain concentration limits. We also strive to limit risk by specifying a minimum credit quality of A1/P1 for commercial paper and AAA for other investments. The maximum maturity for these securities does not exceed 12 months. We believe our established guidelines for investment of our excess cash maintains safety and liquidity through our policies on diversification and investment maturity.

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

***Short-term Investments***

Investments that we designate as available-for-sale are reported at fair value with related unrealized gains and losses recorded in accumulated other comprehensive income (loss). The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. We recognize all realized gains and losses on our available-for-sale securities as interest income. See Note 3, Fair Value Measurements for additional information.



**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Property and Equipment, Net***

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are recorded at cost and amortized over the term of the lease or their useful life, whichever is shorter. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is recorded in other income (expense). Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized.

***Impairment of Long-Lived Assets***

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets to date.

***Restricted Investment***

Restricted investment represents collateral held at a financial institution for a letter of credit related to our facility lease.

***Research and Development Costs***

Research and development costs include, but are not limited to, payroll and other personnel expense, milestone payments paid to our collaborative partners who work on the processing and supply of clinical trial material, expenses incurred for our pre-clinical studies and clinical trials under agreements with contract research organizations and investigative sites, the cost of manufacturing clinical trial materials, administrative expenses and allocation of corporate costs, and share-based compensation expense. Costs related to research, design and development of products are expensed to research and development as incurred.

***Income Taxes***

We account for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax bases of our assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses and research and development credit carryforwards. A valuation allowance is provided against deferred tax assets unless it is more likely than not that they will be realized.

In June 2006, the FASB issued FIN 48 *Accounting for Uncertainties in Income Taxes*, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The provisions of FIN 48 were effective for us on January 1, 2007. See Note 11 for additional information.

***Share-Based Compensation***

Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004), *Share-Based Payment*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

share-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. Our financial statements reflect the impact of SFAS No. 123(R). We chose the straight-line attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period.

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

***Comprehensive Income***

We report comprehensive income in accordance with SFAS No. 130, *Reporting Comprehensive Income*. Included in other comprehensive income are adjustments to record unrealized gains and losses on available-for-sale securities. These adjustments are aggregated in accumulated other comprehensive income in the stockholders' equity section of the balance sheet.

***Redeemable Convertible Preferred Stock Warrants***

Prior to our IPO, we issued freestanding warrants related to redeemable shares which were accounted for in accordance with SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. The warrants were previously exercisable into convertible preferred stock and were classified as liabilities on the consolidated balance sheet, which were then re-measured at each balance sheet date and the change in fair value recognized as a component of other income or expense. We continued to adjust the liability for changes in fair value until the completion of our IPO, at which time all warrants converted into warrants to purchase common stock and the liability was reclassified to equity.

***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.

Upon completion of our IPO, all outstanding convertible preferred stock were converted, on a one-to-one conversion ratio, into shares of common stock. The basic and diluted net loss per share for the year ended December 31, 2007 reflects the conversion of all outstanding shares of convertible preferred stock, the payment of the accrued cumulative dividends in common stock, and the effect of the issuance of shares from the IPO.



**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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):

	Year Ended December 31,		
	2008	2007	2006
<b>Historical net loss per share:</b>			
Numerator			
Net loss, as reported	\$ (72,928)	\$ (40,060)	\$ (25,809)
Less: Cumulative stock dividend attributed to preferred stockholders		(5,575)	(4,729)
Net loss attributed to common stockholders	\$ (72,928)	\$ (45,635)	\$ (30,538)
Denominator			
Weighted-average common shares outstanding	20,360,491	5,568,356	818,950
Less: Weighted average shares subject to repurchase	(10,124)	(58,576)	(110,643)
Denominator for basic and diluted net loss per share	20,350,367	5,509,780	708,307
Basic and diluted net loss per share	\$ (3.58)	\$ (8.28)	\$ (43.11)

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

	Years Ended December 31,		
	2008	2007	2006
Options to purchase common stock	3,178,837	2,620,928	1,627,382
Common stock subject to repurchase		34,712	86,779
Warrants	73,989	73,989	73,989
Convertible preferred stock (on an as if converted basis)			8,685,934

**Business Segments**

We operate in one segment. Management uses one measure of profitability and does not segment its business for internal reporting.

**Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement*, or SFAS No. 157. SFAS No. 157 provides a framework that clarifies the fair value measurement objective within GAAP and its application under the various accounting standards where fair value measurement is allowed or required. Under SFAS No. 157, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability, and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data. SFAS No. 157 requires fair value measurements to be separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. However, in February 2008, FSP No. 157-2 was issued which delayed the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial

liabilities, except those that are recognized or

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

disclosed at fair value in the financial statements on a recurring basis (at least annually). FSP No. 157-2 partially defers the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008, including interim periods within that fiscal year, for items within its scope. As a result, FSP No. 157-2 is effective for us in the first quarter of fiscal 2009. Effective on January 1, 2008, we adopted SFAS No. 157, except as it applies to those nonfinancial assets and nonfinancial liabilities within the scope of FSP No. 157-2. Our partial adoption of SFAS No. 157 did not materially impact our consolidated financial statements. We do not believe that the adoption of SFAS No. 157 for our nonfinancial assets and nonfinancial liabilities will have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159, effective for us on 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 on January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the year ended December 31, 2008. Our adoption of SFAS 159 did not impact the consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, or SFAS No. 141R. SFAS No. 141R amends SFAS 141 and provides revised guidance for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree. It also provides disclosure requirements to enable users of the financial statements to evaluate the nature and financial effects of the business combination. It is effective for fiscal years beginning on or after December 15, 2008 and will be applied prospectively. As a result, SFAS 141R is effective for us in the first quarter of fiscal 2009. We do not believe that the adoption of SFAS 141R will have a material impact on our financial statements.

In December 2007, the EITF reached a consensus on EITF No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-01. EITF 07-01 discusses the appropriate income statement presentation and classification for the activities and payments between the participants in arrangements related to the development and commercialization of intellectual property. The sufficiency of disclosure related to these arrangements is also specified. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. As a result, EITF 07-01 is effective for us in the first quarter of fiscal 2009. We do not believe that the adoption of EITF 07-01 will have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*, or SFAS No. 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. As a result, SFAS 160 is effective for us in the first quarter of fiscal 2009. We do not believe that the adoption of SFAS No. 160 will have a material impact on our financial statements.

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**NOTE 3. FAIR VALUE MEASUREMENTS**

On January 1, 2008, we adopted SFAS, No. 157, *Fair Value Measurements*, or SFAS 157, as it relates to financial assets and financial liabilities. In February 2008, the FASB issued FASB Staff Position, or FSP, No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which delayed 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 at least an annual basis, until January 1, 2009 for calendar year-end entities. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements.

SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. This standard is now the single source in GAAP for the definition of fair value, except for the fair value of leased property as defined in SFAS No. 13, *Accounting for Leases*. SFAS 157 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under SFAS 157 are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following is a summary of our cash, cash equivalents and available-for-sale securities as of December 31, 2008 and 2007 (in thousands):

	As of December 31, 2008		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	\$ 3,021	\$	\$ 3,021
Certificates of deposit	310		310
Money market funds	27,895		27,895
Corporate debt securities	2,684	6	2,690
U.S. government and its agencies securities	11,066	38	11,104
	\$ 44,976	\$ 44	\$ 45,020
Reported as:			
Cash and cash equivalents			\$ 31,927
Short-term investments			12,783
Restricted investment			310
			\$ 45,020

	As of December 31, 2007		
	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Value
Cash	\$ 1,523	\$	\$ 1,523
Certificates of deposit	321		321
Money market funds	41,708		41,708
Corporate debt securities	42,221	159	42,380
U.S. government and its agencies securities	9,357	22	9,379
	\$ 95,130	\$ 181	\$ 95,311
Reported as:			
Cash and cash equivalents			\$ 49,116
Short-term investments			45,874
Restricted investment			321
			\$ 95,311

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 debt securities and certificates of deposits.



**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2008, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above was as follows (in thousands):

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Certificates of Deposit	\$	\$ 310	\$	\$ 310
Money Market Funds	27,895			27,895
Corporate Debt Securities		2,690		2,690
U.S. Government and Agency securities		11,104		11,104
<b>Total</b>	<b>\$ 27,895</b>	<b>\$ 14,104</b>	<b>\$</b>	<b>\$ 41,999</b>

As of December 31, 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.

Our investments in money market funds are measured at fair value on a recurring basis. Our money market funds comply with Rule 2a-7 of the Investment Company Act of 1940 and are required to be priced and have a fair value of \$1 net asset value per share. These money market funds are actively traded and reported daily through a variety of sources. Due to the structure and valuation required by the Investment Company Act of 1940 regarding Rule 2a-7 funds, the fair value of the money market fund investments are classified as Level 1.

The carrying amount reported in the consolidated balance sheet as of December 31, 2008 for long-term debt is \$20.6 million. Using a discounted cash flow technique that incorporates a market interest rate, we have determined the fair value of our debt to be \$19.6 million at December 31, 2008.

As of December 31, 2008, all of our investments have a term of less than one year.

To date we have not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value. We recognize an impairment charge when the decline in the estimated fair value of a marketable security below the amortized cost is determined to be other-than-temporary. We consider various factors in determining whether to recognize an impairment charge, including the duration of time and the severity to which the fair value has been less than our amortized cost, any adverse changes in the investees' financial condition and our intent and ability to hold the marketable security for a period of time sufficient to allow for any anticipated recovery in market value.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 4. BALANCE SHEET COMPONENTS***Property and Equipment, Net*

Property and equipment, net consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Laboratory equipment	\$ 5,416	\$ 2,759
Office furniture and fixtures	600	466
Computer equipment and software	959	736
Leasehold improvements	539	303
Construction-in-progress	523	1,748
	8,037	6,012
Less: Accumulated depreciation and amortization	(3,030)	(1,829)
	\$ 5,007	\$ 4,183

Depreciation and amortization expense were approximately \$1.3 million, \$0.9 million \$0.6 million and \$3.2 million for the years ended December 31, 2008, 2007, 2006 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2008, respectively.

*Accrued Liabilities*

Accrued liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Clinical trial related	\$ 11,329	\$ 5,440
Payroll and related expenses	2,791	1,619
Professional services and other	1,325	563
	\$ 15,445	\$ 7,622

**NOTE 5. LONG-TERM DEBT**

In September 2006, we entered into a \$3.0 million loan facility agreement for the purpose of financing equipment purchases, or 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, or 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, or 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,



Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

maturing in October 2011, and includes customary loan covenants. As of December 31, 2008, we were in compliance with the loan covenants. Expenses incurred in connection with the new loan agreement were not material.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 December 31, 2008 consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Principal amount	\$ 20,277	\$ 10,177
Plus: premium, based on imputed interest rate of 12%	300	
	20,577	10,177
Less: current portion of long-term debt	6,348	3,820
Long-term portion	\$ 14,229	\$ 6,357

As of December 31, 2008, debt payments, which include interest and principal, are as follows (in thousands):

<b>Year ending December 31,</b>	<b>Amount</b>
2009	\$ 8,102
2010	8,343
2011	7,952
2012	
Total debt payments	\$ 24,397

In connection with these loan facility agreements, we had 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 7 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, net. In accordance with these revaluations, we recorded expense of approximately \$0.5 million, \$84,000 and \$0.6 million for the years ended December 31, 2007 and 2006 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2007, respectively. We continued to adjust the liability for changes in fair value until the completion of our IPO in October 2007, at which time all unexercised warrants converted into warrants to purchase common stock, the liability was reclassified to equity and no longer adjusted for changes in fair value.

**NOTE 6. 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, or March 2008 Amendment, 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. The facility lease requires us to pay operating costs, including property taxes, insurance and maintenance in addition to monthly rent. 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 the space under the amended and restated lease agreement were effective

July 1, 2008.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Rent expense was approximately \$1.0 million, \$0.9 million, \$0.7 million, and \$3.4 million for the years ended December 31, 2008, 2007, 2006 and for the cumulative period from July 3, 2003, (date of inception) to December 31, 2008, respectively.

As of December 31, 2008, future minimum lease payments are as follows (in thousands):

<b>Year ending December 31,</b>	<b>Amount</b>
2009	\$ 1,049
2010	1,293
2011	1,357
2012	700
<b>Total minimum lease payments</b>	<b>\$ 4,399</b>

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 December 31, 2008 and 2007, respectively, which is shown as a restricted investment on our 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.

***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 future 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 its 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 enables us to recover a portion of any amounts paid for future potential claims.

**NOTE 7. LICENSE AND SUPPLY AGREEMENTS**

Under the June 2004 agreement, as amended, with Nektar Therapeutics UK Limited, or 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 December 31, 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. We paid \$0, \$1.0 million, \$0.5 million and \$2.6 million related to milestones for the year ended December 31, 2008, 2007, 2006 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2008, respectively. 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.



**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Under the April 2004 agreement, as amended, with Elan Pharma International Limited, or Elan Agreement, Elan granted to us a worldwide, exclusive, sub-licensable license under Elan's intellectual property rights to use, market, distribute, sell, have sold, offer for sale, import and export certain ingredients for our UDB product candidate. We also agreed to pay royalties at specified rates based on net sales. As of December 31, 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 \$0.8 million, \$0.8 million, \$2.0 million and \$4.0 million related to milestones for the year ended December 31, 2008, 2007, 2006 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2008, respectively. 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. We also entered into a services agreement with Elan Drug Delivery International in February 2005. In December 2008, in connection with the execution of the license agreement with AstraZeneca, we amended the Elan agreements, pursuant to which AstraZeneca will have certain rights to exercise and enforce certain of our rights with Elan prior to the expiration or termination of the AstraZeneca Agreement. The amendment did not impact our consolidated financial statements.

**NOTE 8. STOCKHOLDERS EQUITY*****Common Stock and Preferred Stock***

Our Certificate of Incorporation, as amended and restated in October 2007 in connection with the closing of our IPO, authorizes us to issue 100,000,000 shares of \$0.01 par value common stock and 5,000,000 shares of \$0.01 par value preferred stock. As of December 31, 2008 and 2007, there were no shares of preferred stock issued or outstanding.

In August 2004, we entered into a restricted stock agreement with an employee whereby we awarded 208,270 shares of restricted common stock in exchange for services. The restricted stock is subject to certain restrictions on transferability and forfeiture upon the termination of the employee as specified in the restricted stock agreement. The restrictions lapse in equal monthly installments over a four-year period. As of December 31, 2008 and 2007 there were none and 34,712 shares, respectively, subject to repurchase by us.

***Warrants***

As of December 31, 2008, we had outstanding exercisable warrants to purchase 73,989 shares of common stock at \$7.43 per share. The warrants were issued in connection with the working capital loan and equipment loan facility agreements. The warrants expire in September 2013.

***Equity Plans******2005 Equity Incentive Plan***

In 2005, we adopted the 2005 Equity Incentive Plan, or 2005 Plan, as amended in February 2006, which provides for the grant of stock options to employees and consultants of the Company. Stock options granted under the 2005 Plan may be either incentive stock options, or ISOs, or nonqualified stock options, or NSOs. ISOs may be granted only to employees. NSOs may be granted to employees, consultants and directors. Stock options under the 2005 Plan may be granted with a term of up to ten years and at prices no less than fair market value as determined by the Board of Directors. To date, stock options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the vesting commencement date and 1/48th per month thereafter. Subsequent to the IPO in October 2007, no further stock options were granted under the 2005 Plan. Upon the completion of the IPO, 394,580 shares of common stock remained available for issuance under the 2005 Plan and were made available for future grant under the 2007 Equity Award Plan.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***2007 Equity Award Plan*

In September 2007, we adopted the 2007 Equity Award Plan, or 2007 Plan, which became effective upon the completion of the IPO. The remaining common stock available for issuance under the 2005 Plan was made available for future grant under the 2007 Plan. Outstanding options under the 2005 Plan that expire or are canceled without having been exercised in full or are repurchased or forfeited will be available for future issuance under the 2007 Plan. We issue new shares of common stock upon exercise of stock options.

Stock options granted under the 2007 Plan may be either ISOs or NSOs. ISOs may be granted only to employees. NSOs may be granted to employees, consultants and directors. Stock options under the 2007 Plan may be granted with a term of up to ten years and at prices no less than the fair market value of our common stock on the date of grant. To date, stock options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the vesting commencement date and 1/48th per month thereafter. As of December 31, 2008 we had 1,697,112 shares of common stock available for grant under the 2007 Plan.

Option activity under both the 2005 Plan and the 2007 Plan is as follows:

	Shares Available for Grant	Number of Shares	Outstanding Options Weighted Average Exercise Price	Aggregate Intrinsic Value (In thousands)
Shares reserved at inception	1,043,150			
Options granted	(899,495)	899,495	\$ 0.64	
Options cancelled	6,778	(6,778)	\$ 0.64	
<b>Balances, at December 31, 2005</b>	150,433	892,717	\$ 0.64	
Additional shares reserved	1,173,746			
Options granted	(887,228)	887,228	\$ 0.74	
Options exercised		(2,400)	\$ 0.64	\$ 5(1)
Options cancelled	150,163	(150,163)	\$ 0.66	
<b>Balances, at December 31, 2006</b>	587,114	1,627,382	\$ 0.70	
Additional shares reserved	2,947,457			
Options granted	(1,179,302)	1,179,302	\$ 6.76	
Options exercised		(94,369)	\$ 0.67	\$ 1,058(1)
Options cancelled	91,387	(91,387)	\$ 3.84	
<b>Balances, at December 31, 2007</b>	2,446,656	2,620,928	\$ 3.32	
Options granted	(1,070,650)	1,070,650	\$ 11.71	
Options exercised		(191,635)	\$ 1.45	\$ 1,952(1)
Options cancelled	321,106	(321,106)	\$ 7.52	
<b>Balances, at December 31, 2008</b>	1,697,112	3,178,837	\$ 5.83	\$ 9,327(2)

## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

- (1) Amounts represent the difference between the exercise price and our estimate of the deemed fair value of MAP Pharmaceutical stock at the time of exercise.
- (2) Amount represents the difference between the exercise price and \$6.98, the closing price of MAP Pharmaceuticals stock on December 31, 2008, as reported on The NASDAQ Global Market, for all in-the-money options outstanding.



**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about options outstanding at December 31, 2008:

Exercise Price	Options Outstanding at December 31, 2008		Options Exercisable and Vested at December 31, 2008	
	Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
\$0.64 - \$0.74	1,289,314	7.0	969,059	\$ 0.69
\$3.36 - \$6.39	744,530	8.3	292,435	\$ 5.30
\$7.41 - \$9.44	282,500	9.7		
\$12.19 - \$13.75	862,493	9.0	104,816	\$ 12.56
	3,178,837	8.1	1,366,310	\$ 2.59

Options outstanding that have vested and are expected to vest as of December 31, 2008 are as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value(1) (In thousands)	Weighted Average Remaining Contractual Life (In years)
Vested	1,366,310	\$ 2.59	\$ 6,589	7.3
Vested and expected to vest(2)	3,120,815	\$ 5.73	\$ 9,322	8.1

(1) Amounts represent the difference between the exercise price and \$6.98, the closing price of MAP Pharmaceuticals stock on December 31, 2008, as reported on The NASDAQ Global Market, for all in-the-money options outstanding.

(2) Options outstanding that have vested and expected to vest are net of estimated future option forfeitures in accordance with the provisions of SFAS No. 123(R).

The weighted-average grant-date fair value of options granted was \$6.75 in 2008, \$6.89 in 2007 and \$2.17 in 2006

The total fair value of options granted to employees that vested during the years ended December 31, 2008, 2007 and 2006 was approximately \$5.4 million, \$1.0 million and \$240,000, respectively. As of December 31, 2008, there were unrecognized compensation costs of approximately \$7.0 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 2.5 years.

*Employee Stock Purchase Plan*

Upon the effectiveness of the IPO in October 2007, we adopted the Employee Stock Purchase Plan, or Purchase Plan. We reserved a total of 500,000 shares of common stock for issuance under the Purchase Plan. The Purchase Plan permits eligible employees to purchase common stock

## Edgar Filing: MAP Pharmaceuticals, Inc. - Form 10-K/A

at a discount through payroll deductions during defined offering periods. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. As of December 31, 2008, 373,547 shares of common stock were available for future grant and 126,453 shares of common stock have been issued under the employee stock purchase plan.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Other Information Related to Equity Plans*

We received \$722,000, \$63,000 and \$2,000 in cash from sales of shares through our equity plans for the years ended December 31, 2008, 2007 and 2006, respectively and \$787,000 for the cumulative period from July 3, 2003 (date of inception) through December 31, 2008.

In December 2008, the Board of Directors authorized increasing the number of shares under the 2007 Equity Award Plan by one million shares and the number of shares under Employee Stock Purchase Plan by 205,000 shares to be effective January 1, 2009.

*Share-Based Compensation*

Our consolidated statements of operations for the years ended December 31, 2008, 2007 and 2006 reflect the impact of SFAS No. 123(R). We estimate the fair value of stock based awards using the Black-Scholes option valuation model, and amortize the fair value on a straight-line basis over the requisite service period of the awards. Share-based compensation expense recorded under SFAS No. 123(R) related to stock options and employee stock purchase plan are as follows (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Research and development	\$ 1,152	\$ 744	\$ 112
Sales, general and administrative	2,207	967	167
	<b>\$ 3,359</b>	<b>\$ 1,711</b>	<b>\$ 279</b>

We used the following assumptions to estimate the fair value of options granted under our stock option plans for the years ended December 31, 2008, 2007 and 2006:

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Risk-free interest rate	1.75%-3.60%	3.77%-4.77%	4.55-4.99%
Expected volatility	63%-65%	56%-63%	52%-62%
Expected term (in years)	5.5	5.5	5.5
Expected dividend yield			

Upon the effectiveness of the IPO in October 2007, we adopted the employee stock purchase plan. We used the following assumptions to estimate the fair value of shares purchased under our employee stock purchase plan for the years ended December 31, 2008 and 2007:

	<b>Years Ended</b>	
	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Risk-free interest rate	0.27%-2.91%	2.91%
Expected volatility	76%-83%	81%
Expected term (in years)	0.5-0.6	0.6
Expected dividend yield		

*Risk-Free Interest Rate:* The risk-free rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of our stock options.

*Expected Volatility:* The expected stock price volatility for our common stock was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of our industry peers

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

as we did not have any significant trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life-cycle and financial leverage.

*Expected Term:* The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding and is based on the expected terms for industry peers as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock options. We will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for our common stock becomes available.

*Expected Dividend Yield:* The expected dividend yield of 0% is based on our history and expectation of dividend payouts. We have not paid and do not anticipate paying any dividends in the near future, other than a certain cumulative dividend on preferred stock pursuant to the terms of our certificate of incorporation, which was paid in connection with our IPO.

*Forfeitures:* As stock-based compensation expense recognized in the consolidated statement of operations for the year ended December 31, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on our historical experience.

***Stock-Based Compensation for Non-Employees***

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. Management believes that the fair value of the stock options is more reliably measurable than the fair value of the service received. The fair value of stock options granted to non-employees is calculated at each grant date and remeasured at each reporting date. The stock-based compensation expense will fluctuate as the price of our common stock fluctuates. We recorded stock-based compensation expense for non-employees of \$0.5 million and \$0.3 million for the year ended December 31, 2008 and 2007, respectively and \$0.8 million for the cumulative period from July 3, 2003 (date of inception) through December 31, 2008.

**NOTE 9. LONG-TERM INCENTIVE PLAN**

In March 2004, our Board of Directors adopted the 2004 Long-Term Incentive Plan, or Incentive Plan, which provides cash-based and equity-based incentives to eligible persons, including employees, non-employee directors, and consultants, advisors or independent contractors designated by the compensation committee of the board of directors. Cash and equity-based awards are generally based upon the attainment of performance goals over a particular period. The Board of Directors may specify a vesting period for cash and equity awards that may be longer than the performance period. The expense related to the cash and equity awards will be recognized over the performance period or the vesting period, whichever is longer, on a straight line basis. The Incentive Plan shall terminate on February 1, 2014, unless sooner terminated by the Board of Directors. As of December 31, 2008, no incentives under this plan remained available for grant.

**NOTE 10. EMPLOYEE BENEFIT PLAN**

In January 2005, we implemented a 401(k) Plan covering certain employees. Eligible employees may make pre-tax salary deferral contributions up to a specified maximum. Since the inception of the plan we have not made any contributions to this plan.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 11. INCOME TAXES**

We have not recorded any income tax expense for the periods ended December 31, 2008, 2007 and 2006 due to our history of operating losses.

The tax effects of temporary differences and carry forwards that give rise to significant portions of the deferred tax assets are as follows:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Deferred tax assets</b>		
Net operating loss carryforwards	\$ 62,504	\$ 34,586
Tax credit carryforwards	6,082	3,194
Capitalized intangibles	61	142
Accruals and reserves	1,061	125
Total deferred tax assets	69,708	38,047
Less: Valuation allowance	(69,708)	(38,047)
Net deferred tax assets	\$	\$

At December 31, 2008, we had net operating loss carry forwards of approximately \$157.2 million and \$155.2 million available to reduce future taxable income, if any, for both Federal and California state income tax purposes, respectively. The net operating loss carry forwards expire between 2017 and 2029, and valuation allowances have been reserved, where necessary.

We also had federal and state research and development credit carry forwards of approximately \$4.4 million and \$2.5 million, respectively, at December 31, 2008. The federal credits will expire starting in 2025 if not utilized.

Pursuant to SFAS No. 123(R) footnote 82, the benefit of stock options will only be recorded to equity when they reduce cash taxes payable. As of December 31, 2008, the portion of the federal and state net operating loss related to stock options is approximately \$548,860.

Utilization of the net operating loss carry forward may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of the net operating loss before utilization.

We adopted FIN 48 on January 1, 2007. As of December 31, 2008, we had no unrecognized tax benefits and do not expect any material change during the next year. As of December 31, 2008, we have not recorded any interest or penalties under FIN 48.

We file U.S. and state income tax returns with varying statutes of limitations. The tax years 2003 forward remain open to examination due to the carryover of unused net operating losses or tax credits.

**NOTE 12. SUBSEQUENT EVENTS**

In December 2008, we entered into a license agreement with AstraZeneca, which became effective in February 2009. Pursuant to the terms of the agreement, we licensed to AstraZeneca global rights to develop and commercialize our proprietary nebulized formulation of UDB, our next generation UDB therapy and certain combination nebulization therapies for the potential treatment of asthma in children.



**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We are jointly developing UDB in the United States with AstraZeneca, and we are responsible for executing the development plan. AstraZeneca reimburses us for the costs of future UDB development activities beginning on the effective date, and has the right to develop follow-on products using different nebulizers and certain products combining nebulized budesonide with other drugs. AstraZeneca has rights to commercialize UDB in the United States and to develop and commercialize UDB outside of the United States.

AstraZeneca will pay for up to a 60-person sales force for the company to co-promote UDB with AstraZeneca in the United States after product launch. AstraZeneca will provide funding for this sales force for up to five years after product launch. In February 2009, under the terms of this agreement, AstraZeneca paid us a nonrefundable upfront cash payment of \$40 million. The agreement also provided for a \$35 million milestone payment payable upon the successful achievement of co-primary endpoints and safety results in our initial Phase 3 clinical trial. In addition, we are eligible to receive up to \$240 million in other development and regulatory milestones. The agreement also provides for additional progressively demanding sales performance-related milestone payments of up to \$585 million in the event the product is a considerable commercial success.

We are also eligible to receive significant and escalating double-digit royalty payments on worldwide sales, as well as reimbursement for all royalties payable to Elan Pharma International Limited or Elan under our license agreement with Elan. These payments will begin following the date of the first commercial sale of UDB or any other licensed product. We are also eligible to receive reimbursement for a portion of certain milestone payments payable to Elan. Under the terms of the agreement, both companies agree, under certain circumstances, for a period until three years after the first commercial sale of a licensed product in the United States, not to commercialize or assist any third party in commercializing certain competing products. We also have the right to terminate the agreement in relation to licensed products developed for administration solely using jet nebulizers if AstraZeneca commercializes certain competing products for use in jet nebulizers.

Either party may terminate the agreement upon a material, uncured default of the other party. AstraZeneca may terminate the agreement, with or without cause, at any time upon 90 days' written notice. If AstraZeneca terminates the agreement under certain circumstances, AstraZeneca will be obligated to reimburse our remaining development costs under the development plan. Our failure to meet co-primary endpoints in our initial Phase 3 clinical trial, gives AstraZeneca the right to terminate the agreement, or continue with the collaboration without paying the \$35 million milestone. AstraZeneca has 60 days from deemed receipt of the complete data package from our initial Phase 3 clinical trial to decide whether to terminate the agreement. If AstraZeneca proceeds with the collaboration, AstraZeneca will be responsible for reimbursing the remaining development costs we incur under the development plan.

On February 23, 2009, we announced top-line results of our initial Phase 3 clinical trial of UDB for the potential treatment of children with asthma. We announced that the clinical trial did not meet our co-primary endpoints, asthma control as assessed by changes from baseline in nighttime and daytime composite symptom scores, in either of the doses evaluated when compared with placebo.



**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 13. UNAUDITED SELECTED QUARTERLY FINANCIAL DATA (in thousands, except per share amounts)**

The following tables summarize the unaudited quarterly financial data for the last two fiscal years.

	<b>Fiscal 2008 Quarter Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
Loss from operations	\$ (14,955)	\$ (16,149)	\$ (20,195)	\$ (21,395)
Net loss attributable to common stockholders	\$ (14,300)	\$ (16,457)	\$ (20,363)	\$ (21,808)
Basic and diluted net loss per common share	\$ (0.71)	\$ (0.81)	\$ (1.00)	\$ (1.07)
Weighted-average number of common shares used in computing basic and diluted net loss per common share	20,210	20,314	20,399	20,476

	<b>Fiscal 2007 Quarter Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
Loss from operations	\$ (6,266)	\$ (9,024)	\$ (9,876)	\$ (15,763)
Net loss attributable to common stockholders	\$ (8,043)	\$ (10,978)	\$ (11,744)	\$ (14,870)
Basic and diluted net loss per common share	\$ (10.77)	\$ (14.29)	\$ (14.07)	\$ (0.76)
Weighted-average number of common shares used in computing basic and diluted net loss per common share	747	768	834	19,535

**Table of Contents**

**ITEM 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

As required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15, our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of December 31, 2008, the period covered by this report.

**Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision of our Chief Executive Officer and Chief Financial Officer and with the participation of our management, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008 based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears in Item 8 of this Annual Report on Form 10-K.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 and 15d-15 that occurred during our last fiscal quarter that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None

**Table of Contents**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2009 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2008.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2009 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2008.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2009 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2008.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2009 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2008.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2009 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2008.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) We have filed the following documents as part of this Form 10-K:

(1) *Consolidated Financial Statements*

<u>Report of Independent Registered Public Accounting Firm</u>	68
Financial Statements	
<u>Consolidated Balance Sheets</u>	69
<u>Consolidated Statements of Operations</u>	70
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	71
<u>Consolidated Statements of Cash Flows</u>	72
<u>Notes to Consolidated Financial Statements</u>	73

(2) *Financial Statement Schedules*

All financial statement schedules have been omitted because they are not required, not applicable, or the required information is otherwise included.

(3) *Exhibits.*

A list of exhibits filed with this report or incorporated herein by reference is found in the Exhibit Index immediately following the signature page of this report.

(b) Exhibits:

See Item 15(a)(3) above.

(c) Financial Schedules:

See Item 15(a)(2) above.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K/A to be signed on its behalf by the undersigned, thereunto duly authorized, on March 9, 2010.

**MAP PHARMACEUTICALS, INC.**

By: /s/ TIMOTHY S. NELSON  
**Timothy S. Nelson**

**President and Chief Executive Officer**

**POWER OF ATTORNEY**

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K/A has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ TIMOTHY S. NELSON  <b>Timothy S. Nelson</b>	President and Chief Executive Officer, Director (Principal Executive Officer)	March 9, 2010
/s/ CHRISTOPHER Y. CHAI  <b>Christopher Y. Chai</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2010
*  <b>Steven A. Elms</b>	Chairman of the Board of Directors	March 9, 2010
*  <b>Thomas A. Armer, Ph. D.</b>	Director	March 9, 2010
*  <b>John G. Freund, M.D.</b>	Director	March 9, 2010
*  <b>Carl S. Goldfischer, M.D.</b>	Director	March 9, 2010
*  <b>Gerri A. Henwood</b>	Director	March 9, 2010
*  <b>Bernard J. Kelley</b>	Director	March 9, 2010



**Table of Contents**

	<b>Signature</b>	<b>Title</b>	<b>Date</b>
	*	Director	March 9, 2010
	<b>Matthew V. Mcpherron</b>		
	*	Director	March 9, 2010
	<b>Scott R. Ward</b>		
	*	Director	March 9, 2010
	<b>H. Ward Wolff</b>		
*By:	/s/ <b>TIMOTHY S. NELSON</b> <b>Timothy S. Nelson</b>		
	<b>Attorney-in-fact</b>		

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
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).
4.2	Third Amended and Restated Registration Rights Agreement dated March 21, 2007 (filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
4.3	Warrant to purchase shares of Series C Preferred Stock issued to Silicon Valley Bank dated September 14, 2006 (filed as Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
4.4	Warrant to purchase shares of Series C Preferred Stock issued to Horizon Technology Funding Company II LLC dated September 14, 2006 (filed as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
4.5	Warrant to purchase stock issued to Oxford Finance Corporation effective as of September 19, 2006 (filed as Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
4.6	Warrant to purchase stock issued to Silicon Valley Bank effective as of September 19, 2006 (filed as Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.1#	MAP Pharmaceuticals, Inc. 2004 Long-Term Equity Incentive Plan (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.2#	MAP Pharmaceuticals, Inc. Amended and Restated 2005 Equity Incentive Plan and forms of agreements relating thereto (filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.3#	MAP Pharmaceuticals, Inc. 2007 Equity Award Plan and forms of agreements relating thereto (filed as Exhibit 10.3 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).
10.4#	MAP Pharmaceuticals, Inc. Employee Stock Purchase Plan (filed as Exhibit 10.30 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).
10.5#	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers (filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-143823), filed on July 30, 2007, and incorporated herein by reference).



**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.6#	Employment Agreement dated March 20, 2005, between Timothy S. Nelson and the Registrant (filed as Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.7#	Amendment to Employment Agreement dated July 22, 2005, between Timothy S. Nelson and the Registrant (filed as Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.8#	Employment Agreement dated April 14, 2008, between Thomas A. Armer and the Registrant (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33719), filed on May 14, 2008, and incorporated herein by reference).
10.9#	Restricted Stock Agreement dated August 12, 2004, between Thomas A. Armer and the Registrant (filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.10#	Offer Letter dated September 14, 2006, between Christopher Y. Chai and the Registrant (filed as Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.11#	Amended and Restated Offer Letter dated September 11, 2007, between Anastasios Gianakakos and the Registrant (filed as Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.12#	Form of Change in Control Agreement between the named executive officers of the Registrant and the Registrant (filed as Exhibit 10.12 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).
10.13	Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated June 10, 2004 (filed as Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.14	First Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated August 2, 2004 (filed as Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.15	Second Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated July 26, 2006 (filed as Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.16	Venture Loan and Security Agreement among Horizon Technology Funding Company, Silicon Valley Bank and the Registrant dated September 14, 2006 (filed as Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.17	First Amendment to Venture Loan and Security Agreement among Horizon Technology Funding Company, Silicon Valley Bank, Oxford Finance Corporation and the Registrant dated December 27, 2006 (filed as Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.18	Loan and Security Agreement among Silicon Valley Bank, Oxford Finance Corporation and the Registrant dated September 19, 2006 (filed as Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.19	License Agreement between Elan Pharma International Ltd. and the Registrant dated February 3, 2005 (filed as Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.20	Services Agreement between Elan Drug Delivery, Inc. and the Registrant dated February 3, 2005 (filed as Exhibit 10.24 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.21	Research and Development, License and Supply Agreement between the Registrant and Eiffel Technologies Limited dated September 22, 2005 (filed as Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.22	First Amendment to License Agreement between Elan Pharma International Ltd. and the Registrant dated September 15, 2006 (filed as Exhibit 10.26 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.23	Restated and Amended License Agreement between Nektar Therapeutics and the Registrant dated August 7, 2006 (filed as Exhibit 10.27 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.24	Manufacturing and Supply Agreement between Xemplar Pharmaceuticals, LLC and the Registrant dated April 26, 2006 (filed as Exhibit 10.28 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.25	Second Amendment to License Agreement between Elan Pharma International Ltd. and the Registrant dated June 18, 2007 (filed as Exhibit 10.29 to the Registrant's Registration Statement on Form S-1/A (File No. 333-143823), filed on August 20, 2007, and incorporated herein by reference).
10.26*	Amendment to Restated and Amended License Agreement between Nektar Therapeutics UK Limited and the Registrant dated October 8, 2007 (filed as Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
10.27	Third Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated November 30, 2007 (filed as Exhibit 10.27 to the Registrant's Annual Report on Form 10-K filed on March 20, 2008, and incorporated herein by reference).
10.28	Loan and Security Agreement by and among the Registrant, Oxford Finance Corporation and Silicon Valley Bank dated May 2, 2007 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 7, 2008, and incorporated herein by reference).
10.29	Fourth Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated March 26, 2008 (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 14, 2008, and incorporated herein by reference).
10.30	Transfer and Assignment Agreement dated June 19, 2008 between Telesso Technologies Limited and the Registrant (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 13, 2008, and incorporated herein by reference).
10.31	Amended and Restated Fourth Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated July 15, 2008 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 13, 2008, and incorporated herein by reference).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.32	License Agreement by and between AstraZeneca AB and the Registrant dated December 19, 2008 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 20, 2008, and incorporated herein by reference).
10.33 ^	Third Amendment to License Agreement between Elan Pharma International Ltd. and the Registrant dated December 18, 2008.
10.34 ^	First Amendment to Services Agreement between Elan Drug Delivery, Inc. and the Registrant dated December 18, 2008.
10.35 ^	Second Amendment to Services Agreement between Elan Drug Delivery, Inc. and the Registrant dated February 17, 2009.
10.36 ^	Third Amendment to Services Agreement between Elan Drug Delivery, Inc. and the Registrant dated March 2, 2009
10.37#^	Offer Letter dated July 5, 2007, between Charlene A. Friedman and the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Principal Executive Officer Required Under Rules 13a-14(a) or 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) or 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.

- # Indicates management contract or compensatory plan.  
Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.
- \* Confidential treatment requested for certain portions.
- ^ Previously filed on Form 10-K with the SEC on March 12, 2009 and incorporated herein by reference.