

MAP Pharmaceuticals, Inc.  
Form 10-K  
March 20, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(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, 2007

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-33719

**MAP PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

**2400 Bayshore Parkway, Suite 200**

**Mountain View, California**  
(Address of principal executive offices)

**94043**  
(Zip code)

**(650) 386-3100**

(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
<b>Common Stock per 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 Exchange 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 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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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

The initial public offering of MAP Pharmaceutical, Inc.'s Common Stock, par value \$0.01 per share, commenced on October 4, 2007. There was no public market for the Company's Common Stock prior to that date.

As of March 14, 2008, the registrant had outstanding 20,253,766 shares of Common Stock.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant's 2008 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2007.

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	26
Item 2. <u>Properties</u>	47
Item 3. <u>Legal Proceedings</u>	47
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	47
<b>PART II</b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	48
Item 6. <u>Selected Financial Data</u>	51
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	52
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	62
Item 8. <u>Financial Statements and Supplementary Data</u>	63
Item 9A(T). <u>Controls and Procedures</u>	84
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	84
Item 11. <u>Executive Compensation</u>	84
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	84
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	84
Item 14. <u>Principal Accountant Fees and Services</u>	84
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	85

---

**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 pediatric asthma and MAP0004 for migraine. We have announced positive results from Phase 2 clinical studies of UDB and MAP0004 in 2007. We initiated a Phase 3 clinical program for UDB in January 2008 and anticipate initiating a Phase 3 clinical program for MAP0004 in early 2008. We hold worldwide commercialization rights for each of our product candidates and intend to market UDB and MAP0004 in the United States through our own focused sales force targeting pediatricians for UDB and neurologists and headache specialists for MAP0004. For MAP0004, we may establish partnerships with pharmaceutical companies to market and sell to primary care physicians.

Our proprietary technologies enable us to develop proprietary drug candidates for delivery 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 most advanced product candidates:

***Unit Dose Budesonide*** is our proprietary nebulized version of budesonide intended to treat pediatric asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide, which is the current leading treatment for pediatric asthma. Conventional nebulized budesonide is the only inhaled corticosteroid that is approved by the U.S. Food and Drug Administration, or the FDA, for treating asthma in children under the age of four in the United States. In 2006, sales of conventional nebulized budesonide generated revenues of approximately \$700 million in the United States and approximately \$900 million 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 allows for faster delivery and efficacy at a lower dose, which together may offer improved safety, compliance and convenience. We announced positive results from a Phase 2 clinical program for UDB in February 2007, and we initiated our Phase 3 clinical program in January 2008. Our program for UDB will include Phase 3 pivotal efficacy clinical trials as well as additional trials evaluating the uptake of UDB by the body, known as pharmacokinetic trials.

***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 2006, triptans generated revenues of approximately \$2.1 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 inhaler. DHE is available as an intravenous 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. MAP0004 has been shown to retain the rapid onset and long-lasting effectiveness of intravenous DHE while avoiding the nausea that intravenous administration

---

**Table of Contents**

can cause. 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 January 2008, we completed the special protocol assessment, or SPA, process with the U.S. Food and Drug Administration, or FDA, for the first Phase 3 clinical trial of MAP0004, and reached agreement with the FDA on the design of the protocol. The study, if successful, could support the potential approval of MAP0004 as a treatment for migraine. We anticipate initiating a Phase 3 clinical program in early 2008. Our program for MAP0004 will include Phase 3 pivotal efficacy clinical trials as well as an additional pharmacokinetic trial and a trial evaluating the effect of MAP0004 on the body, known as a pharmacodynamic trial.

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 partnership opportunities for further development and commercialization of these two product candidates as well as other product candidates which may utilize these technologies.

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. We are demonstrating this capability with 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. This product candidate demonstrates our ability to apply our proprietary technology to combine two drugs within a single particle, in this case a corticosteroid with a LABA, in a pre-specified ratio and deliver it to the respiratory tract using our proprietary Tempo inhaler. The two drugs utilized in MAP0005 are well characterized and previously approved by the FDA both as single drugs and in combination use. We initiated a Phase 2a clinical trial with MAP0005 for the treatment of asthma and COPD in October 2007 outside the United States. We have not filed, and nor did we file, an investigational new drug application, or IND, with the FDA for MAP0005 because our Phase 2a trial is not being conducted in the United States.

We have also demonstrated our ability to apply our proprietary technologies to formulate and stabilize biologically-active proteins and peptides. Without the need for excipients or other additives, we design and incorporate our protein formulations 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 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. We believe our proprietary formulation coupled with our Tempo inhaler 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 developed small particles of insulin which allow the drug to be inhaled deeply in the lungs, with only a small percentage of insulin deposited in the back of the mouth and throat. In a Phase 1a clinical study conducted in Australia, MAP0001 was shown to be biologically active and achieved maximum therapeutic blood levels as quickly as Novorapid subcutaneous injection, a widely used injectable insulin. We have not filed, and we were not required to file, an IND with the FDA for MAP0001 because our Phase 1a trial was 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 FDCA, which, if available to us, would allow any new drug

**Table of Contents**

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>Indication</b>	<b>Status of Clinical Programs</b>	<b>Commercial Rights</b>
Unit Dose Budesonide (UDB)	Pediatric asthma in children from 12 months to eight years of age	Phase 3	Worldwide
MAP0004	Acute migraine with or without aura	Initiating Phase 3 clinical program in early 2008	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 Pediatric Asthma***

UDB is our proprietary nebulized version of budesonide for treating pediatric asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at doses lower than those approved for conventional nebulized budesonide, which is the current leading treatment for pediatric asthma. Conventional nebulized budesonide is the only inhaled corticosteroid, or ICS, approved by the FDA for treating asthma in children under the age of four in the United States. Conventional nebulized budesonide was first introduced in Europe in 1990, and in the United States in 2000. Our version of 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 is ineffective and may result in local and systemic side effects. We announced positive results from our Phase 2 clinical trial in February 2007, and then conducted an end of Phase 2 meeting with the FDA. We initiated our Phase 3 clinical program in January 2008. Our program for UDB includes Phase 3 pivotal efficacy clinical trials as well as additional pharmacokinetic trials.

***Pediatric Asthma Market***

According to the Centers for Disease Control and Prevention, or CDC, pediatric 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.





---

## **Table of Contents**

According to the CDC, of the estimated 22 million patients diagnosed with asthma in the United States, approximately 6.8 million are children under 18 years of age and approximately 1.2 million are children under five 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 asthmatics may be underestimated since 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. Currently, conventional nebulized budesonide is the only FDA-approved ICS for treating asthma in children under four years old, and is the only approved nebulized corticosteroid product for the treatment of pediatric asthma in children ages 12 months to eight years, marketed as Pulmicort Respules by AstraZeneca plc, or AstraZeneca. According to data published by IMS Health, prescriptions of Pulmicort Respules, which was introduced in the United States in 2000, exceeded three million in the United States in 2006. Since its introduction, annual sales of Pulmicort Respules have grown to approximately \$700 million in the United States and approximately \$900 million worldwide in 2006.

In the United States, children under the age of five will 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 under five years old, physicians sometimes prescribe leukotriene antagonists since they can be given orally and avoid concerns about possible adverse effect associated with high doses of ICS, such as suppression of bone development. Leukotriene antagonists, 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 antagonist, Singulair, to children under the age of six generated approximately \$500 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 its safety relative to other corticosteroids, budesonide has been widely adopted for use in pediatric asthma. GINA and NAEPP guidelines indicate ICS therapy should be used as the first line of treatment.

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, more convenient and to have potentially faster drug administration times.

---

## **Table of Contents**

*Delivery of therapeutic dose late in the administration cycle:* We believe that much of the conventional nebulized budesonide dose is delivered much later 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 as well as 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 pediatric asthma therapies.

Based on our clinical studies, 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 studies 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 studies 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 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 cortisol suppression has been observed in our clinical studies with UDB to date.

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

UDB has been shown in our clinical studies to be effective in improving asthma symptoms and to be well tolerated when compared to placebo. Nebulization time has been shown to be three to five minutes. We

---

**Table of Contents**

announced positive results from a Phase 2 clinical trial in February 2007, and we initiated a Phase 3 clinical program for UDB in pediatric asthmatics in January 2008.

*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 pediatric asthma. The trial included 205 asthmatic children aged one to 18 years old across multiple sites in the United States. The objective of the study was to evaluate the efficacy, tolerability and pharmacokinetics of UDB. The study 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 study 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 study 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 study. 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 study period.

*Phase 3 Clinical Program.* We are currently conducting a Phase 3 pivotal efficacy clinical trial to provide evidence of efficacy and safety of UDB for the treatment of pediatric asthma. The first Phase 3 trial, which we initiated in January 2008, is a multi-center, randomized, double-blind, placebo controlled efficacy and safety trial in approximately 360 asthmatic children 12 months to eight years of age. Patients are randomized to either a 0.25 mg dose of UDB, a 0.135 mg dose of UDB or placebo given twice a day over a 12 week treatment period. The primary efficacy endpoint is the change from baseline for both Nighttime and Daytime Composite Symptom scores. We will follow these patients in a long-term safety extension study. Our second Phase 3 trial will be a confirmatory efficacy trial with a similar design to the first Phase 3 trial. We also plan to conduct the following additional two pharmacokinetic trials: a 14 day active controlled crossover trial in approximately 30 adult asthmatics; and a 12 week active controlled trial in approximately 100 patients.

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 studies 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.

---

## **Table of Contents**

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

MAP0004 is our proprietary orally inhaled version of dihydroergotamine, or DHE, intended to treat migraine. Our Phase 2 studies showed that MAP0004 provided pain relief in as fast as ten minutes after dosing and that 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 intravenous 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. MAP0004 has been shown to retain the rapid onset and long-lasting effectiveness of intravenous DHE while avoiding the nausea that intravenous administration can cause. We announced positive results from our Phase 2 clinical trials in March 2007, and then conducted an end of Phase 2 meeting with the FDA. 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 study if successful could support the potential approval of MAP0004 as a treatment for migraine. We anticipate initiating a Phase 3 clinical program in early 2008.

### ***Migraine Market***

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 the United States suffer from migraines. According to data published by IMS Health, the total sales revenue for prescription drugs used to treat migraine is approximately \$3.5 billion worldwide. Within this market, triptans are the major class of migraine-specific drugs used for the treatment of acute migraines, with 2006 sales totaling approximately \$2.1 billion in the United States and approximately \$3.0 billion worldwide. Approximately 90% of triptan prescriptions are for oral formulations, with the remaining 10% split between injectable and nasal formulations. Of the approximately \$2.1 billion triptan market in the United States, oral, injectable and nasal formulations accounted for approximately \$1.7 billion, \$200 million and \$100 million in sales in 2006, 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 \$1.5 billion worldwide in 2006.

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.

## **Table of Contents**

### ***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. The treatment paradigm typically involves patients self-medicating with over-the-counter drugs when pain is mild and attacks are infrequent. Patients with more frequent or severe migraines 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 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***

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 intravenous DHE and faster onset of pain relief than oral and nasal triptans. A clinical study showed that MAP0004 provided pain relief as early as within ten minutes of dosing.

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

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

*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.

---

**Table of Contents**

*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 studies 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 studies, in which migraine-associated nausea also decreased with treatment. In addition, there were no indications of arterial constriction in our clinical studies. There were no reports of bitter taste or local inflammation associated with the dose of MAP0004 selected for further development.

**MAP0004 Clinical Development Program**

MAP0004 has been shown in our clinical studies to be effective in providing pain relief to migraine sufferers within ten minutes of dosing and to be 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 study if successful could support the potential approval of MAP0004 as a treatment for migraine. We anticipate initiating a Phase 3 clinical program for MAP0004 in migraine patients in early 2008.

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

The objective of the first study 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 study was a randomized, double blind, placebo-controlled study of three doses of MAP0004 in 86 patients. The study consisted of two treatment periods. The first treatment period evaluated two doses of MAP0004, 1.0 mg and 0.5 mg vs. placebo and the second treatment period re-randomized responders in the first treatment period to evaluate a lower dose, 0.25 mg vs. 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 study's primary endpoint ( $p = 0.019$ ), and sustained pain relief in 43% of the patients at 24 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 study also showed clinically significant trends in the resolution of phonophobia, photophobia and nausea (reaching  $p < 0.05$ ) at certain time points. Unlike conventional intravenous 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 study 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 vs. placebo. No significant benefit was seen with this lowest dose when compared to placebo.

The objective of the second Phase 2 study was to evaluate the safety and tolerability of MAP0004 in subjects with asthma, a common cause of compromised lung function, 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 trial was a randomized, double blind, placebo-controlled study 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 study 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 study. 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 the drug itself.

*Phase 3 Clinical Program.* 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

---

**Table of Contents**

protocol. The study, if successful, could support the potential approval of MAP0004 as a treatment for migraine. This multi-center Phase 3 trial will include a randomized, double blind, placebo-controlled component to evaluate the efficacy and safety of MAP0004 in treating a single acute attack of migraine in approximately 850 patients followed by a 12-month open-label safety assessment. The primary efficacy endpoints will be pain relief at two hours, and freedom from nausea, photophobia and phonophobia at two hours. The second Phase 3 trial will be a confirmatory efficacy trial with a similar design to the efficacy component of the first Phase 3 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.

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 studies 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 for the Treatment of Asthma and COPD***

MAP0005 utilizes 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. We are demonstrating this capability with 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. We initiated a Phase 2a clinical trial evaluating MAP0005 for the potential treatment of asthma and COPD in October 2007. According to Datamonitor, the potential market for asthma and COPD was estimated at approximately \$19 billion in 2006, with expected growth to approximately \$30 billion by 2015. Current ICS/LABA products such as GlaxoSmithKline's Advair and AstraZeneca's Symbicort reached worldwide sales of approximately \$7.0 billion and \$1.6 billion in 2007, respectively.

We have developed a novel formulation of a combination ICS and LABA suitable for use in both pressurized MDIs and DPIs to treat adolescent and adult asthma and COPD. This product candidate demonstrates our ability to apply our proprietary technology to combine two drugs within a single particle, in this case a corticosteroid with a LABA, in a pre-specified ratio and deliver it to the respiratory tract using our proprietary Tempo inhaler. We believe this approach, as compared to current ICS/LABA combinations, will 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. This approach potentially has broad applicability for a number of additional combination drug products in diverse indications via inhalation and other routes of delivery. In addition, our approach provides for improved dose-to-dose consistency, also potentially reducing the amount of systemic drug exposure and improving patient safety. The two drugs utilized in MAP0005 are well characterized and previously approved, individually and in combination use by the FDA. As such, marketing approval of MAP0005 under Section 505(b)(2) of the FDCA, if available, would allow any new drug application, or NDA, filed 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. In our development program, we intend to rely on at least some information from studies that we have not conducted or sponsored ourselves, such as data typically collected in prior clinical trials for approved products.

We initiated a Phase 2a clinical trial evaluating MAP0005 for the potential treatment of asthma and COPD in October 2007. The Phase 2a clinical trial is a randomized, open-label, active-controlled, crossover, safety and



## **Table of Contents**

dose response study investigating the pharmacokinetics and pharmacodynamics of MAP0005 in approximately 18 adult asthmatic patients. The trial compares two different doses of MAP0005 with one dose of a commercially marketed combination product, all administered by inhalation. The primary endpoints of the trial are the change in FEV<sub>1</sub> from baseline, the time to maximum change in FEV<sub>1</sub> and the plasma levels for the ICS. We have not filed, and nor did we file, an IND with the FDA for MAP0005 because our Phase 2a trial is not being conducted in the United States.

We believe MAP0005 serves as a proof of concept for the robust, specific delivery of two therapeutic agents which 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.

### ***MAP0001 for the Treatment of Diabetes***

MAP0001 demonstrates our ability to apply our proprietary technologies to formulate and stabilize biologically-active proteins and peptides. Without the need for excipients or other additives, we design and incorporate our protein formulations 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 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. We have completed a Phase 1a clinical trial for MAP0001. This product candidate demonstrates our ability to apply our proprietary technology to deliver biologically-active proteins and peptides to the lung. The global diabetes market was estimated at approximately \$18.5 billion in 2005, with approximately \$7.4 billion of these sales from insulin, according to Business Insights.

Our proprietary technology takes advantage of advances in supercritical fluid technology to yield a stable insulin particle which is 10 to 20% of the size of the FDA approved inhalable insulin. Our small insulin particle size allows the drug to be inhaled deeply in the lungs, with only a small percentage of insulin deposited in the back of the mouth and throat. Phase 1a data for this product candidate suggests that we may be able to provide the rapid onset of injected insulin in our Tempo inhaler, at a treatment cost comparable to currently marketed injected insulin products. 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, and we were not required to file, an IND with the FDA for MAP0001 because our Phase 1a trial was not conducted in the United States.

We believe our proprietary formulation coupled with the Tempo inhaler may overcome many of the issues currently associated with inhalable insulin, including adverse side effects, dose-to-dose inconsistency, the inability of the patient to adjust the dose easily, inconvenient and cumbersome administration and high cost relative to subcutaneous injection. MAP0001 does not use excipients, which are non-active ingredients used in a formulation to keep it stable or inhalable but which may cause adverse side effects such as local toxicity or inflammatory response in the lung. The lack of excipients in our product candidate may improve tolerability of the drug and the long-term safety of the drug by avoiding such adverse side effects. Further, because MAP0001 does not require refrigeration and our hand-held Tempo inhaler can contain multiple insulin doses, MAP0001 may be more convenient to administer than certain other inhalable insulin treatments.

### ***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 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

## **Table of Contents**

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 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 20 issued U.S. patents and over 25 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 products 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.

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

## **Table of Contents**

highly precise particle size distributions. The particles have very 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, but overcomes 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 still suffer from inconsistent dosing and the 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 time in the breathing cycle to allow the released drug to reach the area of the respiratory tract being targeted. For example, data from a clinical study 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 carried into the lungs with the inhaled air.

*Dose consistency:* Our studies indicate that the Tempo inhaler's dose-to-dose consistency is comparable to oral dosing. Tempo inhaler also includes a 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 inadvertent overdosing.

*Convenient, multiple dose use:* The Tempo inhaler does not use electronics or batteries, can conveniently contain multiple doses and is relatively easy and cost 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 they would like MDI manufacturers to achieve. However, they have 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 are currently developing three product candidates which utilize our Tempo inhaler. In addition to MAP0004, we initiated a Phase 2a clinical trial evaluating MAP0005 for the potential treatment of asthma and COPD in October 2007. We also have completed a Phase 1a clinical trial of MAP0001 for the treatment of diabetes.

### **Our Strategy**

Key elements of our strategy include:

*Obtain regulatory approval for our two most advanced product candidates, UDB and MAP0004:* We have announced positive results from our Phase 2 clinical development programs for our two most advanced product candidates, UDB and MAP0004. We initiated a Phase 3 clinical program for UDB in January 2008 and anticipate initiating a Phase 3 clinical program for MAP0004 in early 2008. We believe the risk of clinical trial failure is 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, in-house products with clearly defined patient benefits.

*Build a focused sales force to commercialize UDB and MAP0004:* We intend 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.

*Expand the market opportunity for our most advanced product candidates:* In order to expand the commercial opportunity of 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.

### **Collaborations, Commercial and License Agreements**

#### ***Elan Pharma International Limited License Agreement***

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.

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.

## **Table of Contents**

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, 2007, when and if certain milestones are met we may be obligated to pay Elan up to \$17.3 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.

### ***Xemplar Pharmaceuticals, LLC Manufacturing and Supply Agreement***

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 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 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.

### ***Nektar Therapeutics Amended Restated and Amended License Agreement***

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, or 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

## **Table of Contents**

development milestones. As of December 31, 2007, 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.

### ***Eiffel Research and Development, License and Supply Agreement***

In September 2005 we entered into a research and development, license and supply agreement, or the R&D agreement, with Eiffel Technologies Limited, or Eiffel, pursuant to which Eiffel agreed to research and develop certain methods for manufacturing formulations of beta-agonists, alone or with any steroid, steroids, or insulin, using Eiffel's supercritical fluid particle formulation technology to formulate such compounds for inclusion in inhalable pharmaceutical products. Eiffel also agreed to manufacture pre-clinical and clinical supplies of such formulations.

Under the R&D agreement, Eiffel granted to us an exclusive, worldwide, sublicensable license under certain of its intellectual property rights to develop, use, make, sell, offer for sale, export and import the formulations it develops under the agreement with an appropriate delivery device for use in either pulmonary delivery, or in pulmonary and nasal delivery, depending on the type of formulation being developed.

In addition to certain payments made to Eiffel for research and development activities performed by Eiffel, we must make payments to Eiffel upon our achievement of certain development milestones. As of December 31, 2007, when and if certain milestones are achieved we may be obligated to pay Eiffel up to \$10.8 million in total future development milestone payments for both of our MAP0005 and MAP0001 product candidates. In addition, we must pay to Eiffel royalties based on sales by us or our affiliates of products that include the formulations developed by Eiffel on a product by product and country by country basis until the later of the date upon which the manufacture, use, sale, offer for sale or import of such product is no longer covered by an issued and unexpired patent or pending patent application controlled by Eiffel in that country, or 10 years after commercial launch of the product in that country. Additionally, we must pay to Eiffel a percentage of amounts we receive from our sublicensees, less any milestone payments we have made to Eiffel.

Either party may terminate the agreement upon a material, uncured default of the other party or if the other party becomes insolvent. We may terminate the agreement, with or without cause, at any time upon three months' written notice.

### **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 25 U.S. patent applications, as well as their foreign counterparts, which relate to our product candidates or our proprietary technologies. The patents and patent applications we own and in-license upon which we rely for our UDB product expire between 2014 and 2027. The patents and patent applications we own and in-license upon which we rely for our MAP0004 product expire between 2017 and 2027. 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.



## **Table of Contents**

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, Commercial 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, Commercial and License Agreements Elan Pharma 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 have 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



---

**Table of Contents**

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.

***Pediatric Asthma***

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

*Inhaled corticosteroids:* Conventional nebulized budesonide is the only FDA approved ICS for treating asthma in children under four years old and is available from AstraZeneca as Pulmicort Respules. Pulmicort Respules generated approximately \$700 million in sales in the United States and approximately \$900 million worldwide in 2006 according to data published by IMS Health.

*Leukotriene antagonists:* 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 less than six years old generated approximately \$500 million of that total.

We may also face competition from potential generic entry of conventional nebulized budesonide. Teva Pharmaceuticals Industries Ltd. has filed a generic or abbreviated new drug application, or ANDA, for conventional nebulized budesonide based on Pulmicort Respules. Although a generic product could not be substituted for UDB, if approved, a generic version of conventional nebulized budesonide may be more quickly adopted by health insurers and 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 which could differentiate it from conventional nebulized budesonide or a potential generic version of conventional nebulized budesonide.

***Migraine***

If approved for the treatment of acute 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 \$3.0 billion in revenues for 2006. The largest selling triptan is Imitrex from GlaxoSmithKline, with 2006 sales of approximately \$1.2 billion in the United States and \$1.5 billion worldwide. 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 addition to the marketed migraine therapeutics, there are several product candidates under development that could potentially be used to treat migraines and compete with MAP0004 including several products under development by large pharmaceutical companies such as GlaxoSmithKline and Merck, and other smaller companies.

In addition, we may face competition from generic sumatriptan, the active ingredient in Imitrex. Although generic sumatriptan could not be substituted for MAP0004, if approved, 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 which could differentiate it from generic sumatriptan.

---

## **Table of Contents**

### **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 FFDCA 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 (NDAs)***

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;

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 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 study 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 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 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.



---

## **Table of Contents**

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:* Studies 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:* Studies 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 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 studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 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 studies 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 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 studies.

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 us. 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 studies, and surveillance programs to monitor the effect of approved products which 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 the 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.

---

**Table of Contents**

***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 studies 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 studies conducted for an approved product. The FDA may also require companies to perform additional studies 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 studies 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 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 FDCA, 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.

## **Table of Contents**

### ***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 our future products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product 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 our future products.

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

Although none of our product candidates has been commercialized for any indication, once 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 who 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

## **Table of Contents**

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 restriction 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 others, 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.

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.

### **Employees**

As of December 31, 2007, we employed 72 full-time employees. Of the full-time employees, 56 were engaged in product development and clinical activities, and 16 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.

---

**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 in each year since our inception, including net losses of approximately \$16.2 million, \$25.8 million and \$40.1 million, for the years ended December 31, 2005, 2006 and 2007, respectively. As of December 31, 2007, we had a deficit accumulated during development stage of approximately \$103.0 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 proceed with our Phase 3 clinical programs for our two most advanced product candidates and conduct our other clinical trials. In addition, if we are required by the U.S. Food and Drug Administration, or the FDA, to perform studies in addition to those we currently anticipate, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We also expect an increase in our expenses associated with our manufacturing work and with preparing for commercialization and we expect to continue to incur costs to support operations as a public company. As a result, we expect to incur substantial and increasing net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders equity (deficit) and working capital.

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

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

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

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



**Table of Contents**

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

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

our ability to manage our supply chain for 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 concerning MAP0004;

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

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

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

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

market acceptance of our product candidates;

our ability to establish an effective sales and marketing infrastructure;

competition from existing products or new products that may emerge;

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

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

guidelines and recommendations of therapies published by various organizations;

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

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

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

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

guidelines and recommendations of therapies published by various organizations;

potential product liability claims;

potential liabilities associated with hazardous materials;

our ability to maintain adequate insurance policies;

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

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

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

costs related to and outcomes of potential intellectual property litigation;

compliance with obligations under intellectual property licenses with third parties;

our ability to adequately support future growth;

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

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

---

## **Table of Contents**

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, and the timing of any potential product approval may be delayed. We currently have no commitments or arrangements for any additional financing to fund the research and development of our product candidates. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operating requirements for at least 12 months. However, we will need to raise substantial additional capital in the future in order to complete the development and commercialization of UDB and MAP0004 given the cost of developing and commercializing two product candidates in parallel, and to fund the development and commercialization of our other product candidates.

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

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

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

the costs and timing of regulatory approval;

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

the effect of competing technological and market developments;

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

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

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



---

**Table of Contents**

**Risks Relating to the Development, Regulatory Approval and Commercialization of Our Product Candidates**

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

We have invested a significant portion of our efforts and financial resources in the development of our two most advanced product candidates, UDB and MAP0004. Our ability to generate product revenue, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and regulatory approval of these product candidates. We may have inadequate financial or other resources to advance these product candidates through the clinical trial process, depending on the requirements of the FDA. We have initiated a Phase 3 clinical trial for UDB. In addition we reached agreement with the FDA on an SPA for the first Phase 3 clinical trial for MAP0004, and we intend to initiate this trial in early 2008. However, our clinical development programs for UDB and MAP0004 may not lead to regulatory approval from the FDA and similar foreign regulatory agencies if we fail to demonstrate that the product candidates are safe and effective in our planned clinical trials, and we may therefore fail to commercialize any product candidates. Any failure to obtain regulatory approval of UDB and MAP0004 would have a material and adverse impact on our business.

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

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

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;

---

**Table of Contents**

maintaining and supplying clinical trial material on a timely basis; and

complying with design protocols of any applicable SPAs

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

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

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

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

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

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, particularly for our UDB and MAP0004 product candidates, we may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. Based upon our discussions with the FDA, we initiated a Phase 3 clinical program for UDB and intend to initiate our Phase 3 clinical program for MAP0004 in early 2008. Our programs for UDB and MAP0004 will include Phase 3 pivotal efficacy clinical trials as well as additional trials of the uptake of UDB by the body, known as pharmacokinetic trials, and with respect to MAP0004, a pharmacokinetic trial and a trial of the effect of MAP0004 on the body, known as a pharmacodynamic trial. Furthermore, we may not be able to obtain approval for indications that are as broad as intended or entirely different than those indications for which we sought approval.

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

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

Success in pre-clinical 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 anticipate initiating a Phase 3 clinical program for MAP0004 in early 2008. We anticipate conducting additional Phase 2 clinical studies for UDB and MAP0004. Specifically, we intend to conduct two pharmacokinetic trials for UDB and a pharmacokinetic trial and a separate pharmacodynamic trial for MAP0004. The data collected from our clinical trials may not be adequate to support regulatory approval of UDB, MAP0004 or any of our other product candidates. Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase 3 or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval

---

**Table of Contents**

to market our product candidates. For instance, the Phase 2 clinical trial of UDB compared two doses of UDB, at 0.135 mg and 0.25 mg administered twice a day. The study showed that 0.135 mg of UDB produced a statistically significant reduction in Nighttime and Daytime Composite Symptom Score, a measure of asthma severity, when compared to placebo, but the 0.25 mg dose was not significantly better than placebo in Nighttime and Daytime Composite Symptom Score. In our Phase 3 clinical trial for UDB, patients will be randomized and given 0.25 mg UDB, 0.135 mg UDB or placebo to evaluate changes in Nighttime and Daytime Composite Symptom Score. We may not demonstrate statistically significant efficacy for the 0.25 mg dose or the 0.135 mg dose, which could make it difficult to receive regulatory approval for either dose.

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

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

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

Our failure to adequately demonstrate the efficacy and safety of UDB, MAP0004 or any other product candidates would prevent regulatory approval and, ultimately, the commercialization of that product candidate. For example, the Phase 2 clinical trial of UDB compared two doses of UDB, at 0.135 mg and 0.25 mg administered twice a day. The study showed that 0.135 mg of UDB produced a statistically significant reduction in Nighttime and Daytime Composite Symptom Score when compared with placebo, but the 0.25 mg dose was not significantly better than placebo in Nighttime and Daytime Composite Symptom Score. In our Phase 3 clinical trial for UDB, patients will be randomized and given 0.25 mg UDB, 0.135 mg UDB or placebo to evaluate changes in Nighttime and Daytime Composite Symptom Score. If we are unable to show a statistically significant reduction in Nighttime and Daytime Composite Symptom Score at the 0.25 mg dose, we may only obtain approval for our UDB product candidate at the single 0.135 mg dose, thereby potentially limiting our sales opportunities.

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

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.

---

## **Table of Contents**

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

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

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

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

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



## **Table of Contents**

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

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

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

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

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

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

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

lower demonstrated clinical safety and efficacy compared to other products;

prevalence and severity of adverse effects;

ineffective marketing and distribution efforts;

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

lack of cost-effectiveness;

timing of market introduction and perceived effectiveness of competitive products;

availability of alternative therapies at similar or lower costs;

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

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

potential product liability claims.

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

## **Table of Contents**

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

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

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

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

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.



---

**Table of Contents**

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

If approved for the treatment of pediatric asthma, we anticipate that UDB would compete with other marketed asthma therapeutics, including inhaled corticosteroids and leukotriene antagonists, and may compete with products currently under development by both large and small companies. Conventional nebulized budesonide is the only inhaled corticosteroid approved by the FDA for treating asthma in children under four years old and is available from AstraZeneca plc as Pulmicort Respules. Pulmicort Respules was introduced in the United States in 2000, and annual sales have grown to approximately \$700 million in the United States and approximately \$900 million worldwide in 2006 according to data published by IMS Health. Leukotriene antagonists are an alternative to inhaled corticosteroids for asthmatic children. Prescriptions of Singulair, the leading leukotriene antagonist, for children under the age of six generated approximately \$500 million in sales in 2007. In addition to the marketed asthma therapies, there are several inhaled corticosteroid product candidates under development by large pharmaceutical companies, such as GlaxoSmithKline plc, or GlaxoSmithKline, and other smaller companies, that could potentially be used to treat pediatric asthma.

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

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

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

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

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

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

---

## **Table of Contents**

commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

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

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

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

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

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

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

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

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

regulatory authorities may withdraw their approval of the product and require us to take our approved drug off the market;

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

we may have limitations on how we promote our drugs;

## **Table of Contents**

sales of products may decrease significantly;

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

our reputation may suffer.

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

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

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

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

issue warning letters;

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

impose other civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing clinical trials;

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

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

seize or detain products or require a product recall.



## **Table of Contents**

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

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

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

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

***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

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

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

## **Table of Contents**

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

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

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

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

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

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

***We have no experience manufacturing large clinical-scale or commercial-scale pharmaceutical products and we do not own or operate a manufacturing facility. As a result, we are dependent on numerous third parties for the manufacture of our product candidates and our supply chain, and if we experience problems with any of these suppliers the manufacturing of our products could be delayed.***

We do not own or operate manufacturing facilities for clinical or commercial manufacture of our product candidates, which includes drug substance and drug packaging, including the components of the device used to administer certain of our drug candidates. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently outsource all manufacturing and packaging of our pre-clinical and clinical product candidates to third parties. In addition, we do not currently have all necessary agreements with third-party manufacturers for the long-term commercial supply of many of our product candidates. We may be unable to enter agreements for commercial supply with all third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements or, for those agreements that we have already entered into, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time. We may not be able to establish additional sources of supply for our products prior to commercialization. Such suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating

## **Table of Contents**

to our product candidates, and are subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier who meets all regulatory requirements.

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

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

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

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

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

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

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

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

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

## **Table of Contents**

### **Risks Relating to Our Intellectual Property**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

## **Table of Contents**

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the

---

## **Table of Contents**

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, 2007, we had 72 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. To support this growth, we expect to hire additional employees within the next 12 months. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

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

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

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

*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.



---

## **Table of Contents**

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

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

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

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

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

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

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock together control approximately 70% of our outstanding common stock. If these persons were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, will control the election of directors and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including obtaining a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

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

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

results of our clinical trials;

results of clinical trials of our competitors' products;

**Table of Contents**

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

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

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

competition from existing product or new products that may emerge;

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

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

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

market conditions for biopharmaceutical stocks in general; and

general economic and market conditions.

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

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

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

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

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

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers may in the

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

future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

## **Table of Contents**

***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 revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

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

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

**Table of Contents**

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

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

**ITEM 2. PROPERTIES**

Our corporate headquarters are located in Mountain View, California, where we occupy approximately 32,000 square feet of office space. The term of the lease expires June 2008. We have two options to extend the lease for additional terms of three to five years each, subject to certain conditions. We believe that the facilities that we currently lease are 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**

No matters were submitted to a vote of our security holders during the fourth quarter of 2007.

---

**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>Fiscal Year 2007 Quarters Ended:</b>	<b>High</b>	<b>Low</b>
December 31, 2007 (from October 5, 2007)	\$ 20.00	\$ 12.25

**Holders of Record**

As of March 14, 2008, there were approximately 37 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 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, 2007 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>
MAP Pharmaceuticals Inc.	\$ 100.00	\$ 103.97	\$ 101.12	\$ 131.16
NASDAQ Composite Index	100.00	105.61	98.11	97.56
NASDAQ Biotechnology Index	100.00	104.45	101.29	95.53

---

## **Table of Contents**

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

The following sets forth information regarding all unregistered securities sold by us during the year ended December 31, 2007 (with share amounts adjusted to give effect to a 1-for-1.77 reverse stock split effected in connection with our initial public offering):

(1) In March 2007, we issued and sold 3,948,911 shares of Series D convertible preferred stock to certain existing and new investors at a per share price of approximately \$12.74, for aggregate consideration of approximately \$50.3 million. The shares of our Series D preferred stock converted into shares of our common stock at the rate of one share of common stock for each share of Series D preferred stock in connection with the closing of our initial public offering.

(2) From January 1, 2007 to December 31, 2007, we granted options under our 2005 Equity Incentive Plan and our 2007 Equity Award Plan to purchase 1,179,302 shares of common stock at a weighted-average exercise price of \$6.76 per share. During this period, options to purchase 91,387 shares of common stock related to our 2005 Equity Incentive Plan and our 2007 Equity Award Plan were canceled without being exercised. Also during this period, options to purchase 94,369 shares of common stock were exercised under our 2005 Equity Incentive Plan.

The offers, sales and issuances of the securities described in paragraph (1) were exempt from registration under the Securities Act under Section 4(2) of the Securities Act and Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. All of the purchasers of securities for which we relied on Rule 506 of Regulation D and Section 4(2) represented that they were accredited investors as defined under the Securities Act or a person described under Rule 506(b)(2)(ii) under the Securities Act. We believe that the issuances are exempt from the registration requirements of the Securities Act on the basis that (a) the purchasers in each case represented to us that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about us or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

The sales and issuances of the securities described in paragraph (2) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 promulgated under the Securities Act pursuant to certain compensatory benefit plans and contracts approved by our board of directors.

### **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 Securities and Exchange Commission on October 4, 2007, which registered an aggregate of 5,750,000 shares of our common stock. On October 4, 2007, we sold 5,000,000 shares of common stock at an initial public offering price of \$12.00 per share, for aggregate gross proceeds of \$60.0 million, managed by Merrill Lynch & Co., Morgan Stanley & Co. and Deutsche Bank Securities. On October 8, 2007, in connection with the exercise of the underwriters' over-allotment option, 750,000 additional shares of common stock were sold on our behalf at the initial public offering price of \$12.00 per share, for aggregate gross proceeds of \$9.0 million. 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. As of December 31, 2007, we had applied the aggregate net proceeds of approximately \$62.1 million from our initial public offering in cash equivalents and short-term investment accounts pursuant to our investment guidelines.



**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, 2007, 2006, 2005, and for the period from July 3, 2003 (date of inception) through December 31, 2007, and the consolidated balance sheet data at December 31, 2007 and 2006, 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 year ended December 31, 2004, and the consolidated balance sheet data at December 31, 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, 2007
	2007	2006	2005	2004	
(in thousands, except per share data)					
<b>Statement of Operations Data:</b>					
Operating expenses					
Research and development	\$ 31,362	\$ 22,268	\$ 12,285	\$ 6,506	\$ 72,421
Sales, general and administrative	9,567	4,128	4,377	2,573	20,645
Total operating expenses	40,929	26,396	16,662	9,079	93,066
Loss from operations	(40,929)	(26,396)	(16,662)	(9,079)	(93,066)
Interest income	2,775	905	348	118	4,146
Interest expense	(1,343)	(235)			(1,577)
Other income (expense)	(563)	(83)	65	130	(452)
Net loss	\$ (40,060)	\$ (25,809)	\$ (16,249)	\$ (8,831)	\$ (90,949)
Net loss attributed to common stockholders	\$ (45,635)	\$ (30,538)	\$ (18,850)	\$ (9,850)	\$ (104,874)
Net loss per share attributed to common stockholders - basic and diluted(1)	\$ (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)	5,510	708	656	614	

	As of Year Ended December 31,			
	2007	2006	2005	2004
(in thousands)				
<b>Balance Sheet Data:</b>				
Cash, cash equivalents and short-term investments	\$ 94,990	\$ 17,746	\$ 7,158	\$ 22,259
Working capital	83,337	13,258	4,115	21,057
Total assets	100,695	21,625	9,769	23,914
Long-term debt, net of current portion	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	(102,966)	(58,686)	(28,569)	(9,801)
Total stockholders' equity (deficit)	81,606	(58,676)	(28,566)	(9,798)

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

- (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 2006 and 2007, loss from operations, net loss and basic and diluted net loss per common share attributed to common stockholders include the impact of SFAS No. 123(R) stock-based compensation charges, which were not present 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 which address large market opportunities, including our two most advanced product candidates, Unit Dose Budesonide, or UDB, for pediatric asthma and MAP0004 for migraine. UDB is our proprietary nebulized version of budesonide intended to treat pediatric asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide, which is the current leading treatment for pediatric asthma. MAP0004 is our proprietary orally inhaled version of dihydroergotamine intended to treat migraine. MAP0004 is designed to provide faster onset and longer lasting pain relief than triptans, the class of drugs most often prescribed for treating migraine.

We announced positive results from Phase 2 clinical studies of UDB and MAP0004 in early 2007 and initiated a Phase 3 clinical program for UDB in January 2008. Following completion of the special protocol assessment, or SPA, process with the FDA for our first Phase 3 clinical trial in January 2008, we anticipate initiating a Phase 3 clinical program for MAP0004 in early 2008. We hold worldwide commercialization rights for each of our product candidates and intend to market UDB and MAP0004 in the United States through our own focused sales force targeting pediatricians for UDB and neurologists and headache specialists for MAP0004. Our program for UDB includes Phase 3 pivotal efficacy clinical trials as well as trials of the uptake of UDB by the body, and with respect to MAP0004, our program will include Phase 3 pivotal efficacy clinical trials as well as a pharmacokinetic trial and a trial of the effect of MAP0004 on the body.

Our product portfolio also includes two earlier stage product candidates, both of which highlight the broad applicability of our technologies to a diverse range of potential future products. MAP0005 is our proprietary combination of an inhaled corticosteroid and a long-acting beta-agonist for the potential treatment of asthma and chronic obstructive pulmonary disease, or COPD, and MAP0001 is our proprietary form of insulin for the potential treatment of Type 1 and Type 2 diabetes via pulmonary delivery using our proprietary Tempo inhaler. In October 2007, we initiated a Phase 2a clinical trial with MAP0005 for the treatment of asthma and COPD. We have no current intention to further develop either of these earlier stage product candidates independently.

We are a development stage company and have not generated any product revenues. Since our inception, we have incurred losses and have an accumulated deficit of \$103.0 million as of December 31, 2007. We have financed our operations through equity financing, debt financing and the issuance of convertible notes. Prior to our initial public offering, or IPO, in October 2007, we had received net proceeds of \$106.7 million from the issuance of convertible notes payable and convertible preferred stock. With the completion of our initial public offering we received net proceeds of \$62.1 million after expenses and underwriters' discounts and commissions. In 2006, we entered into loan facility agreements and borrowed \$10.0 million to finance working capital and \$1.0 million to finance equipment purchases.

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,

## **Table of Contents**

seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential U.S. Food and Drug Administration, or FDA, approval of our product candidates. We will need to expand our commercial organization to launch any products. Significant capital is required to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

In connection with the IPO, we initiated a 1-for-1.77 reverse stock split effective on October 4, 2007. All shares and per share amounts have been retroactively adjusted to give effect to the reverse stock split.

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

#### ***Stock-Based Compensation***

Prior to January 1, 2006, we accounted for share-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25), and related interpretations and complied with the disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation. Under APB

**Table of Contents**

No. 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of our stock and the exercise price.

Effective January 1, 2006, we adopted the fair value provision of SFAS No. 123(R) which supersedes previous accounting under APB No. 25. SFAS No. 123(R) requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. SFAS No. 123(R) requires companies to estimate the fair value of the share-based payment awards on the date of grant using an option-pricing model. We adopted SFAS No. 123(R) using the prospective transition method, which requires that entities that used the minimum value method for either pro forma or financial statement recognition purposes, shall apply SFAS No. 123(R) to 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 with the following weighted-average assumptions for stock options granted during the years ended December 31, 2007 and 2006, respectively:

	Years Ended December 31,	
	2007	2006
Risk-free interest rate	3.77%-4.77%	4.55-4.99%
Volatility	56%-63%	52%-62%
Expected term (in years)	5.5	5.5
Expected dividend yield	0.00%	0.00%

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 for the year ended December 31, 2007 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 assumption of 0% 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.

Using the Black-Scholes option pricing model, we recorded non-cash stock-based compensation expenses related to employee stock options granted of approximately \$1.7 million in 2007 and approximately \$280,000 in 2006, in accordance with the requirements of SFAS No. 123(R).

**Net Operating Loss Carryforwards**

At December 31, 2007, we had federal and state net operating loss carryforwards of approximately \$87.0 million and \$86.0 million, respectively. The net operating loss carryforwards expire between 2014 and 2027, if

## **Table of Contents**

not utilized. We have established a full valuation allowance against our deferred tax assets due to our history of losses and the uncertainty of future taxable income. The valuation allowance increased by \$16.4 million and \$10.9 million during the years ended December 31, 2007 and 2006, respectively.

As of December 31, 2007, we also had federal and state research and development tax credit carryforwards of approximately \$2.4 million and \$1.3 million, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2024, 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 FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), on January 1, 2007. As a result of the implementation of FIN 48, we did not recognize any adjustment to the liability for uncertain tax positions and therefore did not record any adjustment to the beginning balance of retained earnings on the consolidated balance sheet. As of the date of adoption and at December 31, 2007, we had no unrecognized tax benefits and we do not expect any material change during the next year. Interest and penalties are zero, and our policy is to account for interest and penalties in tax expense in the income statement.

## **Financial Overview**

### ***Research and Development Expenses***

Research and development expenses consist of: (i) milestone payments paid to our collaborative partners who work on our processing and supply of clinical trial material; (ii) expenses incurred under agreements with contract research organizations and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (iii) the cost of manufacturing clinical trial materials; (iv) payments to contract service organizations, as well as consultants; (v) employee-related expenses, which include salaries and benefits; (vi) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies; and (vii) 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, 2007, we had incurred approximately \$72.4 million in research and development expenses since our inception in 2003. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our research and development expenses for the foreseeable future in order to complete development of our two most advanced product candidates, UDB and MAP0004, and our earlier-stage research and development projects.

**Table of Contents**

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

	Year Ended December 31,			Period from
	2007	2006	2005	July 3, 2003 (Date of Inception) through December 31, 2007
Our most advanced product candidates:				
UDB	39%	37%	43%	42%
MAP0004	51%	53%	47%	49%
Other projects	10%	10%	10%	9%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are currently focused on developing our two most advanced product candidates. However, we will need to raise substantial additional capital in the future in order to complete the development and commercialization of UDB and MAP0004 following the submission of new drug applications, or NDAs, and to fund the development and commercialization of our 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, and consulting fees. We expect these expenses to increase as we continue to grow our business.

**Table of Contents****Results of Operations***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 income (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 Income (Expense), Net.* Other income (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.

*Comparison of Years Ended December 31, 2006 and 2005*

	Year Ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2006	2005		
	(in thousands, except percentages)			
Research and development expenses	\$ 22,268	\$ 12,285	\$ 9,983	81%
Sales, general and administrative expenses	4,128	4,377	(249)	(6)%
Interest income	905	348	557	160%
Interest expense	(235)		(235)	
Other income (expense), net	(83)	65	(148)	(228)%



## **Table of Contents**

*Research and Development Expenses.* The increase in research and development expenses for the year ended December 31, 2006 compared to the year ended December 31, 2005 was primarily due to an increase of \$4.9 million in manufacturing costs associated with MAP0004 and UDB, an increase of \$3.9 million in Phase 2 clinical trial expenses incurred in 2006 compared to Phase 1 clinical trial expenses incurred in 2005 for UDB and MAP0004, an increase of \$2.2 million in personnel costs resulting from increased headcount, an increase of \$1.1 million in development costs related to the Tempo device and an increase of \$1.0 million related to facility and information technology expenses. These increases were offset by a decrease of \$2.0 million related to pre-clinical studies primarily for UDB and MAP0004 and a decrease of \$1.3 million related to milestone expenses.

*Sales, General and Administrative Expenses.* The decrease in sales, general and administrative expenses for the year ended December 31, 2006 compared to the year ended December 31, 2005 was primarily due to a decrease in facility and information technology expenses. In addition, legal and consulting expenses increased by \$350,000, and expenses relating to stock-based compensation increased by \$250,000, as offset by a decrease of \$220,000 relating to recruiting activities.

*Interest Income.* The increase in interest income was due primarily to higher cash balances primarily relating to the closing of our \$25.1 million Series C convertible preferred stock financing in January 2006.

*Interest Expense.* Interest expense increased due to the outstanding debt related to the loan facility agreements entered into in September and December 2006.

*Other Income (Expense), Net.* The decrease in other income (expense), net is primarily due to the non-cash expense associated with redeemable convertible preferred stock warrants issued in September 2006 in conjunction with loan facility agreements and the non-cash charge of approximately \$85,000 related to the revaluation of such warrants.

## **Liquidity and Capital Resources**

We have incurred losses since our inception in July 2003 and, as of December 31, 2007, we had an accumulated deficit of \$103.0 million. 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 will continue to increase and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

We have financed our operations through equity financing, debt financing and issuance of convertible notes. Prior to our IPO in October 2007, we had received net proceeds of \$106.7 million from the issuance of convertible notes payable and convertible preferred stock. Through our IPO we received net proceeds of \$62.1 million after expenses and underwriters' discounts and commissions. In 2006, we entered into loan facility agreements and borrowed \$10.0 million to finance working capital and \$1.0 million to finance equipment purchases.

As of December 31, 2007, we had \$95.0 million in cash, cash equivalents and short-term investments. Our cash and short-term investment balances are held in a variety of interest bearing instruments, including commercial paper, U.S. government agencies 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.

**Table of Contents**

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

	Year Ended December 31,		
	2007	2006	2005
	(in thousands)		
Cash, cash equivalents and short-term investments	\$ 94,990	\$ 17,746	\$ 7,158
Cash provided by (used in):			
Operating activities	(33,200)	(24,285)	(13,810)
Investing activities	(40,444)	(7,785)	(1,291)
Financing activities	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, stock-based compensation and changes in operating assets and liabilities. The increase for each year is primarily driven by an increase in operating expenses related to our clinical development programs and an increase in headcount across all departments.

*Net cash used in investing activities.* Net cash used in investing activities for the years ended December 31, 2007 and 2006 was primarily related to the purchase of investments and, to a lesser extent, the purchase of property and equipment offset somewhat by the proceeds from the sale of short-term investments. Net cash used in investing activities for the year ended December 31, 2005 was related to the purchase of property and equipment. The receipt of net IPO proceeds of \$62.1 million in October 2007 primarily drove the increase in cash used for investing activities in 2007 as these proceeds were used to purchase short-term investments in accordance with our investment policy.

*Net cash provided by financing activities.* 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.

**Contractual Obligations**

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2007.

	Total	Payments due by period			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
	(in thousands)				
<b>Contractual Obligations:</b>					
Debt(1)	\$ 11,772	\$ 4,827	\$ 6,945	\$	\$
Operating lease obligation(2)	465	465			
Total	\$ 12,237	\$ 5,292	\$ 6,945	\$	\$

- (1) During 2006, we entered into loan facility agreements and borrowed \$11.0 million for the purpose of financing working capital and purchasing equipment. The working capital loans of \$10.0 million allow for interest only payments through July 1, 2007 on \$3.0 million of the debt and through January 1, 2008 on \$7.0 million of the debt, and bear interest at an annual rate of 11.9%. The equipment loan of \$1.0 million is repayable in equal monthly payments and bears interest at an annual interest rate of 9.5%. The amounts in the table above include interest and principal repayments on these loans. Please see Note 5. Debt in Part II, Item 8 of this Form 10-K for additional information.

---

**Table of Contents**

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

The table above reflects only payment obligations for development products that are fixed and determinable. Milestone payments and royalty payments under our license and supply agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur. Please see Note 5. Debt in Part II, Item 8 of this Form 10-K for additional information. Amounts and an estimate of significant payments related to licensing and other arrangements not included in the contractual obligations table above are as follows:

*Nektar Therapeutics License Agreement* . In June 2004, as amended in August 2006 and October 2007, we entered into an agreement with Nektar Therapeutics UK Limited, or Nektar. Under the terms of the agreement, MAP was granted a worldwide, exclusive license, with a right to sublicense, under Nektar patents and know-how, to develop and commercialize any formulation of a form of dihydroergotamine for administration by inhalation using a device. As of December 31, 2007, the agreement requires us to make aggregate future nonrefundable milestone payments of up to \$5.0 million when and if certain regulatory and commercial milestones with respect to MAP0004 are met and to pay royalties at specified rates based on net sales.

*Elan Pharma International Limited License Agreement* . In April 2004, as amended in February 2005 and June 2007, we entered into an agreement with Elan Pharma International Limited, or Elan. Under the terms of the agreement, Elan granted to us a worldwide, exclusive, sub-licensable license under Elan's intellectual property rights to use, market, distribute, sell, import and export ingredients for UDB. As of December 31, 2007, the agreement requires us to make aggregate future nonrefundable and sales milestone payments of up to \$17.3 million when and if certain regulatory and commercial milestones with respect to UDB are met and to pay royalties at specified rates based on net sales.

*Eiffel Research and Development, License and Supply Agreement* . In September 2005, we entered into a research and development, license and supply agreement, with Eiffel Technologies Limited, or Eiffel. Under the terms of the agreement, Eiffel agreed to research and develop certain methods for manufacturing formulations for steroids, steroid beta-agonist combinations or insulin. Eiffel agreed to manufacture pre-clinical and clinical supplies of such formulations and granted to us an exclusive, worldwide, sub-licensable license under certain of its intellectual property rights to develop, use, make, sell, export and import the formulations it develops under the agreement. As of December 31, 2007, the agreement requires us to make aggregate future nonrefundable milestone payments of up to a total of \$10.8 million when and if certain milestones related to clinical development and regulatory progress of both MAP0005 and MAP0001 are met. In addition, we also agreed to pay royalties at specified rates based on net sales and a percentage of sublicense fees.

***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;

our ability to achieve milestones under our collaboration agreements;

outcome, timing and cost of regulatory approvals;

delays that may be caused by changing regulatory requirements;

the number of product candidates that we pursue;

---

**Table of Contents**

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

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

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

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

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

possible costs of litigation.

We believe that our existing cash, cash equivalents and short-term investments will enable us to maintain our currently planned operations through at least 12 months. However, we may be required to raise substantial additional capital to complete the development and commercialization of UDB and MAP0004 given the cost of developing and commercializing two product candidates in parallel. Our capital requirements are likely to increase. As a result, we will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through public or private financings, strategic partnerships or other arrangements. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. We will need substantial additional funding, and if we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs.

**Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value, and enhances fair value measurement disclosure. In February 2008, the FASB issued FASB Staff Position (FSP) 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13* (FSP 157-1) and FSP 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-1 amends SFAS No. 157 to remove certain leasing transactions from its scope. FSP 157-2 delays the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until the beginning of the first quarter of fiscal 2009. The measurement and disclosure requirements related to financial assets and financial liabilities are effective for us beginning in the first quarter of fiscal 2008. The adoption of SFAS No. 157 for financial assets and financial liabilities will not have a significant impact on our consolidated financial statements. However, the resulting fair values calculated under SFAS No. 157 after adoption may be different from the fair values that would have been calculated under previous guidance. We are currently evaluating the impact that SFAS No. 157 will have on our consolidated financial statements when it is applied to non-financial assets and non-financial liabilities beginning in the first quarter of 2009.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 permits companies to choose to measure certain financial instruments and other items at fair value. The standard requires that unrealized gains and losses are reported in earnings for items measured using the fair value option. SFAS No. 159 is effective for us beginning in the first quarter of fiscal year 2008. The adoption of SFAS No. 159 is not expected to have a significant impact on our consolidated financial statements.

## **Table of Contents**

In June 2007, the FASB ratified EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development (R&D) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into beginning in the first quarter of fiscal year 2008. Prior to adoption, we recognized these non-refundable advance payments as an expense upon payment. The adoption of EITF 07-3 is not expected to have a significant impact on our consolidated financial statements.

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

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

### **ITEM 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 capture 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.

**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>	64
<u>Consolidated Balance Sheets</u>	65
<u>Consolidated Statements of Operations</u>	66
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	67
<u>Consolidated Statements of Cash Flows</u>	68
<u>Notes to Consolidated Financial Statements</u>	69

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of MAP Pharmaceuticals, Inc. (A development stage enterprise):

In our opinion, the accompanying consolidated balance sheets and the related consolidated statement of operations, of stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of MAP Pharmaceuticals, Inc. and its subsidiaries (the Company) (a development stage enterprise) at December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, and cumulatively, for the period from July 3, 2003 (date of inception) to December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for stock-based compensation in 2006.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 20, 2008

**Table of Contents****MAP PHARMACEUTICALS, INC.****(a development stage enterprise)****CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share data)**

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 49,116	\$ 11,091
Short-term investments	45,874	6,655
Prepaid expenses and other current assets	1,079	443
Total current assets	96,069	18,189
Property and equipment, net	4,183	2,852
Other assets	122	384
Restricted investment	321	200
Total assets	\$ 100,695	\$ 21,625
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,290	\$ 1,762
Accrued liabilities	7,622	2,329
Current portion of long-term debt	3,820	840
Total current liabilities	12,732	4,931
Long-term debt, net of current	6,357	10,061
Redeemable convertible preferred stock warrant liability		411
Total liabilities	19,089	15,403
Commitments and contingencies (Note 4)		
Redeemable convertible preferred stock: no shares authorized and no shares issued and outstanding at December 31, 2007; \$0.01 par value, 8,876,961 shares authorized at December 31, 2006 and 8,685,934 shares issued and outstanding at December 31, 2006		64,898
Stockholders' equity (deficit):		
Common stock: \$0.01 par value, 100,000,000 and 12,526,854 shares authorized at December 31, 2007 and December 31, 2006, 20,228,362 and 820,834 shares issued and outstanding shares at December 31, 2007 and December 31, 2006	197	4
Additional paid-in capital	184,194	
Accumulated other comprehensive income	181	6
Deficit accumulated during the development stage	(102,966)	(58,686)
Total stockholders' equity (deficit)	81,606	(58,676)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 100,695	\$ 21,625



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

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 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, 2007
	2007	2006	2005	
Operating expenses:				
Research and development	\$ 31,362	\$ 22,268	\$ 12,285	\$ 72,421
Sales, general and administrative	9,567	4,128	4,377	20,645
Total operating expenses	40,929	26,396	16,662	93,066
Loss from operations	(40,929)	(26,396)	(16,662)	(93,066)
Interest income	2,775	905	348	4,146
Interest expense	(1,343)	(235)		(1,577)
Other income (expense), net	(563)	(83)	65	(452)
Net loss	(40,060)	(25,809)	(16,249)	\$ (90,949)
Cumulative stock dividend attributed to preferred stockholders	(5,575)	(4,729)	(2,601)	(13,925)
Net loss attributed to common stockholders	\$ (45,635)	\$ (30,538)	\$ (18,850)	\$ (104,874)
Net loss per share attributed to common stockholders basic and diluted	\$ (8.28)	\$ (43.11)	\$ (28.75)	
Weighted average shares outstanding used in calculating net loss per share attributed to common stockholders basic and diluted	5,509,780	708,307	655,723	

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 Paid-In Capital	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficit)
	Shares	Amount				
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

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

Accretion of cumulative dividend on redeemable convertible preferred stock	(1,361)	(4,214)	(5,575)
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
--------------------------------------	------------	----	-----	----	---------	----	-----	----	-----------	----	--------

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, 2007
	2007	2006	2005	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (40,060)	\$ (25,809)	\$ (16,249)	\$ (90,949)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	881	595	322	1,905
Accretion of investment discounts, net	(898)			(898)
Amortization of debt issuance costs	94	14		108
Change in carrying value of warrant liability	537	84		621
Issuance of common stock in exchange for services				51
Share-based compensation	1,960	419	82	2,461
Loss on disposal and other non-cash items	154	3	211	368
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(636)	(446)	(181)	(1,304)
Other assets	8	29	(16)	(2)
Accounts payable	(501)	682	340	1,261
Accrued liabilities	5,261	144	1,681	7,591
Net cash used in operating activities	(33,200)	(24,285)	(13,810)	(78,787)
<b>Cash flows from investing activities:</b>				
Purchase of intangible assets and in-process research and development				(412)
Purchase of property and equipment	(2,177)	(1,454)	(1,291)	(6,010)
Purchase of short-term investments	(86,671)	(27,185)		(113,855)
Sales and maturities of short-term investments	48,525	20,854		69,379
Purchase of restricted investment	(121)			(321)
Net cash used in investing activities	(40,444)	(7,785)	(1,291)	(51,219)
<b>Cash flows from financing activities:</b>				
Proceeds from issuance of convertible notes payable				4,300
Proceeds from issuance of debt		11,006		11,006
Proceeds from exercise of common stock options	63	2		65
Repayment of debt	(750)	(105)		(854)
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	111,669	36,003		179,122
Net increase (decrease) in cash and cash equivalents	38,025	3,933	(15,101)	49,116
Cash and cash equivalents at beginning of period	11,091	7,158	22,259	
Cash and cash equivalents at end of period	\$ 49,116	\$ 11,091	\$ 7,158	\$ 49,116

**Supplemental disclosures of cash flow information**

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

Cash paid for interest	\$ 1,222	\$ 142	\$	\$ 1,364
<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	\$ 2,602	\$ 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 pediatric asthma in children from 12 months to eight years of age; and a proprietary orally inhaled version of dihydroergotamine for the potential treatment of migraine. We are in the development stage and since inception have devoted substantially all of our efforts to research and development, raising capital and recruiting personnel.

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

We have incurred losses since our inception in July 2003. Prior to achieving profitable operations, we intend to continue to fund operations through public or private financings, strategic partnerships or other arrangements.

***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.

***Fair Value of Financial Instruments***

Carrying amounts of our financial instruments, including cash and cash equivalents, short-term investments, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate their fair values due to their short maturities. Based on the borrowing rates available to us for loans with similar terms, the





**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

carrying value of the borrowings approximates their fair value. The carrying amounts of our restricted investment and other assets approximate their fair values based upon their nature and size.

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

A substantial portion of our pre-clinical studies and all of our clinical trials have been performed by third-party contract research organizations and other vendors. Pre-clinical study and clinical trial expenses are based on the services received pursuant to organizations that conduct and manage pre-clinical studies and clinical trials on our behalf. Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly.

***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.

The carrying amounts of cash equivalents approximate fair value due to their short-term nature. The carrying amounts of borrowings under our debt facilities approximate fair value based on the current interest rates for similar borrowing arrangements.

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.

***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

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

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.

***Share-Based Compensation***

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS No. 123(R)), using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards granted, modified and settled to 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 (EITF) No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction

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

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.

***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.

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,		
	2007	2006	2005
<b>Historical net loss per share:</b>			
Numerator			
Net loss, as reported	\$ (40,060)	\$ (25,809)	\$ (16,249)
Less: Cumulative stock dividend attributed to preferred stockholders	(5,575)	(4,729)	(2,601)
Net loss attributed to common stockholders	\$ (45,635)	\$ (30,538)	\$ (18,850)
Denominator			
Weighted-average common shares outstanding	5,568,356	818,950	818,434
Less: Weighted average shares subject to repurchase	(58,576)	(110,643)	(162,711)
Denominator for basic and diluted net loss per share	5,509,780	708,307	655,723
Basic and diluted net loss per share	\$ (8.28)	\$ (43.11)	\$ (28.75)

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

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,		
	2007	2006	2005
Options to purchase common stock	2,620,928	1,627,382	892,717
Common stock subject to repurchase	34,712	86,779	138,847
Warrants	73,989	73,989	
Convertible preferred stock (on an as if converted basis)		8,685,934	5,289,384

**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 Measurements* (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value, and enhances fair value measurement disclosure. In February 2008, the FASB issued FASB Staff Position (FSP) 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13* (FSP 157-1) and FSP 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-1 amends SFAS No. 157 to remove certain leasing transactions from its scope. FSP 157-2 delays the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until the beginning of the first quarter of fiscal 2009. The measurement and disclosure requirements related to financial assets and financial liabilities are effective for us beginning in the first quarter of fiscal 2008. The adoption of SFAS No. 157 for financial assets and financial liabilities will not have a significant impact on our consolidated financial statements. However, the resulting fair values calculated under SFAS No. 157 after adoption may be different from the fair values that would have been calculated under previous guidance. We are currently evaluating the impact that SFAS No. 157 will have on our consolidated financial statements when it is applied to non-financial assets and non-financial liabilities beginning in the first quarter of 2009.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 permits companies to choose to measure certain financial instruments and other items at fair value. The standard requires that unrealized gains and losses are reported in earnings for items measured using the fair value option. SFAS No. 159 is effective for us beginning in the first quarter of fiscal year 2008. The adoption of SFAS No. 159 is not expected to have a significant impact on our consolidated financial statements.

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development (R&D) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into beginning in the first quarter of fiscal year 2008. Prior to adoption, we recognized these non-refundable advance payments as an expense upon payment. The adoption of EITF 07-3 is not expected to have a significant impact on our consolidated financial statements.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 3. BALANCE SHEET COMPONENTS***Short-term investments*

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

	Amortized Cost	Unrealized Gains	Estimated Fair Market Value
<b>At December 31, 2007:</b>			
Corporate debt securities	\$ 36,336	\$ 159	\$ 36,495
U.S. government and its agencies	9,357	22	9,379
	\$ 45,693	\$ 181	\$ 45,874
<b>At December 31, 2006:</b>			
Corporate debt securities	\$ 5,199	\$ 6	\$ 5,205
Auction rate securities	1,450		1,450
	\$ 6,649	\$ 6	\$ 6,655

*Property and Equipment, Net*

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

	December 31,	
	2007	2006
Laboratory equipment	\$ 2,759	\$ 1,989
Office furniture and fixtures	466	441
Computer equipment and software	736	406
Leasehold improvements	303	267
Construction-in-progress	1,748	727
	6,012	3,831
Less: Accumulated depreciation and amortization	(1,829)	(979)
	\$ 4,183	\$ 2,852

Depreciation and amortization expense for the years ended December 31, 2007, 2006, 2005 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2007 were approximately \$870,000, \$580,000, \$310,000 and \$1.9 million, respectively.

*Accrued Liabilities*

Accrued liabilities consist of the following (in thousands):

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

	December 31,	
	2007	2006
Clinical trial related	\$ 5,440	\$ 1,410
Payroll and related expenses	1,619	847
Professional services and other	563	72
	\$ 7,622	\$ 2,329

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

**NOTE 4. COMMITMENTS AND CONTINGENCIES**

***Operating Leases***

In June 2004, we entered into a lease agreement for laboratory and office facilities in Mountain View, California and in August 2006 amended our lease agreement to include additional square footage within the same building. The amended lease agreement expires in June 2008. We have two options to extend the term of the lease, each for three to five years, subject to certain conditions. Rent is subject to a 3.5% increase on May 15 of each year for the duration of the lease.

In June 2004, we obtained an irrevocable letter of credit from a bank in the amount of \$200,370 which was later increased to \$320,926 in the second quarter of 2007, as required by the operating lease. If we default under the terms of the lease, the lessor will be entitled to borrow upon the letter of credit in the amount necessary to cure the default. The letter of credit is renewed annually and will expire on the lease termination date of June 30, 2008. As collateral for the letter of credit, we are required to maintain a deposit account with the bank which is shown as a restricted investment on the consolidated balance sheet at December 31, 2007 and 2006.

We recognize rent expense on a straight-line basis over the noncancelable term of the operating lease. Rent expense was approximately \$0.9 million, \$0.7 million, \$0.6 million, and \$2.4 million for the years ended December 31, 2007, 2006, 2005 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2007, respectively. Under the current agreement expiring June 30, 2008, aggregate future minimum lease facility payments of \$465,000 are expected through June 30, 2008.

***License and Supply Agreements***

Under the June 2004 agreement, as amended in August 2006 and October 2007, with Nektar Therapeutics UK Limited (the Nektar Agreement), we were granted a worldwide, exclusive license, with a right to sublicense, under Nektar patents and know-how, to develop and commercialize any formulation of a form of dihydroergotamine for administration by inhalation using a device. As of December 31, 2007, 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 \$1.0 million and \$500,000 related to milestones for the years ended December 31, 2007 and December 31, 2006, respectively, and \$2.6 million during the cumulative period from July 3, 2003 (date of inception) to December 31, 2007. We also agreed to pay royalties at specified rates based on net sales as noted in the Nektar Agreement. No royalty expense has been recognized through December 31, 2007. 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 in February 2005 and July 2007, with Elan Pharma International Limited (the Elan Agreement), Elan granted to us a worldwide, exclusive, sub-licensable license under Elan's intellectual property rights to use, market, distribute, sell, import and export ingredients for our UDB product candidate. As of December 31, 2007, we are required to make future nonrefundable milestone payments of up to \$17.3 million related to products currently being developed under this agreement, when and if certain regulatory and commercial milestones are met with respect to our UDB product candidate. We paid \$750,000 and \$2.0 million related to milestones for the years ended December 31, 2007 and December 31, 2006, respectively, and \$3.3 million during the cumulative period from July 3, 2003 (date of inception) to December 31, 2007. We also agreed to pay royalties at specified rates based on net sales as noted in the Elan Agreement. No royalty expense has been recognized through December 31, 2007. 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.

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

Under the September 2005 agreement with Eiffel Technologies Limited (the Eiffel Agreement), Eiffel agreed to research and develop certain methods for manufacturing formulations for steroids, steroid beta-agonist combinations or insulin. Eiffel agreed to manufacture pre-clinical and clinical supplies of such formulations and granted to us an exclusive, worldwide, sub-licensable license under certain of its intellectual property rights to develop, use, make, sell, export and import the formulations it develops under the Eiffel Agreement. As of December 31, 2007, the Eiffel Agreement requires us to make future nonrefundable milestone payments to Eiffel of up to \$10.8 million related to products currently being developed under this agreement, upon achievement of certain development milestones related to clinical development and regulatory progress. We also agreed to pay royalties at specified rates based on net sales and a percentage of sublicense fees. We paid \$250,000 related to a milestone for the year ended December 31, 2007 and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2007. Through December 31, 2007 no royalties or sublicense revenue sharing have been recognized. Either party may terminate the Eiffel Agreement upon a material, uncured default of the other party or if the other party becomes insolvent. We may terminate the Eiffel Agreement, with or without cause, at any time upon three months' written notice.

***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 5. DEBT**

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

All Working Capital Loan amounts are collateralized by all of our assets, excluding intellectual property, while all Equipment Loan amounts are collateralized by our equipment purchased by such borrowed funds.

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-



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

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 and \$84,000 for the years ended December 31, 2007 and 2006, respectively. For the cumulative period from July 3, 2003 (date of inception) to December 31, 2007, approximately \$0.6 million was recorded as expense as a result of the revaluation.

We continued to adjust the liability for changes in fair value until the completion of our IPO, at which time all unexercised warrants converted into warrants to purchase common stock and the liability was reclassified to equity.

The future minimum payments on our loan facility agreements as of December 31, 2007 are as follows (in thousands):

The year ended December 31,	Working Capital Loan	Equipment Loan	Total
2008	\$ 4,443	\$ 384	\$ 4,827
2009	4,644	288	4,932
2010	2,013		2,013
	\$ 11,100	\$ 672	11,772
Less: amount representing interest			(1,595)
Less: current portion			(3,820)
Long-term portion			\$ 6,357

**NOTE 6. REDEEMABLE CONVERTIBLE PREFERRED STOCK**

As of December 31, 2007, there were no shares of redeemable convertible preferred stock issued or outstanding as all shares of preferred stock converted to shares of common stock on a one-to-one basis upon completion of the IPO.

As of December 31, 2006, preferred stock consists of the following:

Series	Shares		Proceeds Net of Issuance Costs	Accrued Dividends	Carrying Amount	Liquidation Amount
	Authorized	Outstanding				
A	610,169	610,168	\$ 1,498,800	\$ 365,462	\$ 1,864,262	\$ 1,865,462
B	4,679,222	4,679,216	29,949,740	6,065,099	36,014,839	36,065,151
C	3,587,570	3,396,550	25,099,988	1,919,000	27,018,988	27,168,997
	8,876,961	8,685,934	\$ 56,548,528	\$ 8,349,561	\$ 64,898,089	\$ 65,099,610

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

**NOTE 7. STOCKHOLDERS EQUITY (DEFICIT)**

***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, 2007, there were no shares of preferred stock issued or outstanding.

In August 2004, we entered into a restricted stock agreement (the 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 Agreement. The restrictions lapse in equal monthly installments over a four-year period. As of December 31, 2007 and 2006 there were 34,712 and 86,779 shares, respectively, subject to repurchase by us.

***Stock Option and Award Plans***

***2005 Equity Incentive Plan***

In 2005, we adopted the 2005 Equity Incentive Plan (the 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 (ISOs) or nonqualified stock options (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. The remaining common stock available for issuance under the 2005 Plan were made available for future grant under the 2007 Plan.

***2007 Equity Award Plan***

In September 2007, we adopted the 2007 Equity Award Plan (the 2007 Plan) which became effective upon the completion of the IPO. The remaining common stock available for issuance under the 2005 Plan were 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, 2007 we had reserved 2,446,656 shares of common stock for issuance under the 2007 Plan.

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

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 Plan inception	1,043,150			
Options granted	(899,495)	899,495	\$ 0.64	
Options cancelled	6,778	(6,778)	\$ 0.64	
<b>December 31, 2005</b>	150,433	892,717	\$ 0.64	
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>December 31, 2006</b>	587,114	1,627,382	\$ 0.70	
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>December 31, 2007</b>	2,446,656	2,620,928	\$ 3.32	\$ 37,200(2)

(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 \$17.51, the closing price of MAP Pharmaceuticals stock on December 31, 2007, as reported on The NASDAQ Global Market, for all in-the-money options outstanding.

The following table summarizes information about options outstanding at December 31, 2007:

Exercise Price	Options Outstanding and Exercisable at December 31, 2007		Options Exercisable and Vested at December 31, 2007	
	Number of Options	Weighted Average Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
\$0.64	683,476	7.4	463,592	\$ 0.64
\$0.74	812,715	8.4	313,484	\$ 0.74

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

\$3.36	304,951	9.2	1,412	\$ 3.36
\$6.39	600,314	9.3		\$
\$12.37	166,092	9.6		\$
\$13.75	53,380	9.7		\$
	2,620,928	8.5	778,488	\$ 0.69

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

Options outstanding that have vested and are expected to vest as of December 31, 2007 are as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value(1) (In thousands)
Vested	778,488	\$ 0.69	\$ 13,096
Vested and expected to vest(2)	2,587,157	\$ 3.26	\$ 36,874

(1) Amounts represent the difference between the exercise price and \$17.51, the closing price of MAP Pharmaceuticals stock on December 31, 2007, as reported on The NASDAQ Global Market, for all in-the-money options outstanding.

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

The total fair value of options granted to employees that vested during the years ended December 31, 2007 and 2006 was approximately \$1.0 million and \$240,000, respectively. As of December 31, 2007, there was 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 3.1 years.

*Employee Stock Purchase Plan*

Upon the effectiveness of the IPO in October 2007, we adopted the Employee Stock Purchase Plan (the Purchase Plan). We reserved a total of 500,000 shares of common stock for issuance under the Purchase Plan. We issue new shares of common stock upon exercise of stock options. The Purchase Plan permits eligible employees to purchase common stock 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. For the year ended December 31, 2007, no shares of common stock were purchased under the Purchase Plan.

*Share-Based Compensation*

Our financial statements as of and for the years ended December 31, 2007 and 2006 reflect the impact of SFAS No. 123(R). We estimate the fair value of stock options 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 options granted to employees was allocated to the following departments:

	Years Ended December 31,	
	2007	2006
Research and development	\$ 744	\$ 112
Sales, general and administrative	967	167
	\$ 1,711	\$ 279



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

We based the weighted average estimated values of employee stock option grants, as well as the weighted average assumptions used in calculating these values, on estimates at the date of grant, as follows:

	<b>Years Ended December 31,</b>	
	<b>2007</b>	<b>2006</b>
Weighted-average estimated fair values	\$10.34	\$2.65
Risk-free interest rate	3.77%-4.77%	4.55-4.99%
Volatility	56%-63%	52%-62%
Expected term (in years)	5.5	5.5
Expected dividend yield	0.00%	0.00%

*Risk-Free Interest Rate:* We based the risk-free interest rate by using a weighted average assumption equivalent to the expected term based on the U.S. Treasury maturity rate as of the date of grant.

*Expected Volatility:* We used an average historical stock price volatility of comparable companies to be representative of future stock price volatility as we did not have sufficient 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 represents the period for which our stock-based awards are expected to be outstanding and is based on the options vesting term, contractual term and industry peers. We did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

*Expected Dividends:* 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, 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 of \$0.3 million for the year ended December 31, 2007 and for the cumulative period from July 3, 2006 (date of inception) through December 31, 2007.

**NOTE 8. LONG-TERM INCENTIVE PLAN**

In March 2004, our Board of Directors adopted the 2004 Long-Term Incentive Plan (Incentive Plan) which provides cash-based and equity-based incentives to eligible persons, including employees, nonemployee

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

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, 2007, no incentives under this plan remained available for grant.

**NOTE 9. 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.

**NOTE 10. INCOME TAXES**

Deferred tax assets consist of the following (in thousands):

	December 31,	
	2007	2006
<b>Deferred tax assets</b>		
Net operating loss carryforwards	\$ 34,586	\$ 19,897
Tax credit carryforwards	3,194	1,580
Capitalized intangibles	142	76
Accruals and reserves	125	56
Total deferred tax assets	38,047	21,609
Less: Valuation allowance	(38,047)	(21,609)
Net deferred tax assets	\$	\$

At December 31, 2007, we had federal and state net operating loss carryforwards of approximately \$87.0 million and \$86.0 million, respectively. The net operating loss carryforwards expire between 2014 and 2027, if not utilized. We have established a full valuation allowance against our deferred tax assets due to our history of losses and the uncertainty of future taxable income. The valuation allowance increased by \$16.4 million and \$10.9 million during the years ended December 31, 2007 and 2006, respectively.

As of December 31, 2007, we also had federal and state research and development tax credit carryforwards of approximately \$2.4 million and \$1.3 million, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2024, 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 FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), on January 1, 2007. As a result of the implementation of FIN 48, we did not recognize any adjustment to the liability for uncertain tax positions and therefore did not record any adjustment to the beginning balance of retained earnings on the consolidated balance sheet. As of the date of adoption and at December 31, 2007, we had no unrecognized tax benefits and we do not expect any material change during the next year. Interest and penalties are zero, and our policy is to account for interest and penalties in tax expense in the income statement.





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

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

**NOTE 11. QUARTERLY FINANCIAL DATA (unaudited)**

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

	<b>March 31,</b>	<b>Fiscal 2007 Quarter Ended</b>		<b>December 31,</b>
		<b>June 30,</b>	<b>September 30,</b>	
		<b>(in thousands, except per share data)</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

	<b>March 31,</b>	<b>Fiscal 2006 Quarter Ended</b>		<b>December 31,</b>
		<b>June 30,</b>	<b>September 30,</b>	
		<b>(in thousands, except per share data)</b>		
Loss from operations	\$ (5,356)	\$ (5,635)	\$ (6,973)	\$ (8,432)
Net loss attributable to common stockholders	(6,219)	(6,552)	(8,001)	(9,766)
Basic and diluted net loss per common share	\$ (9.03)	\$ (9.34)	\$ (11.20)	\$ (13.40)
Weighted-average number of common shares used in computing basic and diluted net loss per common share	688	702	715	729

**Table of Contents**

**ITEM 9A(T). CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures.**

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term disclosure controls and procedures as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation as of December 31, 2007, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective.

There have been no changes in our internal controls over financial reporting during the fourth quarter of the year ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Exemption from Management's Report on Internal Control Over Financial Reporting for 2007**

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly-public companies.

**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 2008 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2007.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2008 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2007.

**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 2008 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2007.

**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 2008 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2007.

**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 2008 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2007.

**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>	64
Financial Statements	
<u>Consolidated Balance Sheets</u>	65
<u>Consolidated Statements of Operations</u>	66
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	67
<u>Consolidated Statements of Cash Flows</u>	68
<u>Notes to Consolidated Financial Statements</u>	69
(2) <i>Financial Statement Schedules</i>	

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 to be signed on its behalf by the undersigned, thereunto duly authorized, on March 19, 2008.

**MAP PHARMACEUTICALS, INC.**

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

**President and Chief Executive Officer**

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Timothy S. Nelson and Christopher Y. Chai, jointly and severally, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K 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 19, 2008
/s/ CHRISTOPHER Y. CHAI <b>Christopher Y. Chai</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2008
/s/ STEVEN A. ELMS <b>Steven A. Elms</b>	Chairman of the Board of Directors	March 19, 2008
/s/ THOMAS A. ARMER, PH. D. <b>Thomas A. Armer, Ph. D.</b>	Director	March 20, 2008
/s/ JOHN G. FREUND, M.D. <b>John G. Freund, M.D.</b>	Director	March 19, 2008
/s/ CARL S. GOLDFISCHER, M.D. <b>Carl S. Goldfischer, M.D.</b>	Director	March 19, 2008
/s/ GERRI A. HENWOOD <b>Gerri A. Henwood</b>	Director	March 18, 2008

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

/s/ BERNARD J. KELLEY

Director

March 18, 2008

**Bernard J. Kelley**

/s/ MATTHEW V. MCPHERRON

Director

March 20, 2008

**Matthew V. Mcpherron**

**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).
10.6#	Employment Agreement dated as of 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).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.7#	Amendment to Employment Agreement dated as of 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 as of August 13, 2004, between Thomas A. Armer and the Registrant (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.9#	Restricted Stock Agreement dated as of 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 as of 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 as of 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).
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).



**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
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 as of 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 as of 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 as of 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.
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.