

MAP Pharmaceuticals, Inc.  
Form 10-K  
March 30, 2012  
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, 2011

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)  
**2400 Bayshore Parkway, Suite 200**  
**Mountain View, California**  
(Address of principal executive offices)

**20-0507047**  
(I.R.S. Employer  
Identification No.)  
**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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company)  
Accelerated filer   
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 aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$340.0 million, computed by reference to the price at which the common equity was last sold on the NASDAQ Global Market as of June 30, 2011, which was the last business day of the registrant's most recently completed second fiscal quarter, which was during its fiscal year ended December 31, 2011. Shares of Common Stock held by each officer and director and by each person who may be deemed to be an affiliate have been excluded. This

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

determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 26, 2012, the registrant had outstanding 30,654,435 shares of Common Stock.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission, or the SEC, pursuant to Regulation 14A in connection with the registrant's 2012 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, 2011.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
PART I	
Item 1. <u>Business</u>	5
Item 1A. <u>Risk Factors</u>	27
Item 1B. <u>Unresolved Staff Comments</u>	51
Item 2. <u>Properties</u>	52
Item 3. <u>Legal Proceedings</u>	52
Item 4. <u>Mine Safety Disclosures</u>	52
PART II	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	53
Item 6. <u>Selected Financial Data</u>	55
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	56
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	71
Item 8. <u>Financial Statements and Supplementary Data</u>	72
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	101
Item 9A. <u>Controls and Procedures</u>	101
Item 9B. <u>Other Information</u>	102
PART III	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	103
Item 11. <u>Executive Compensation</u>	103
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	103
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	103
Item 14. <u>Principal Accountant Fees and Services</u>	103
PART IV	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	104
<u>Signatures</u>	105
<u>Exhibit Index</u>	107

---

**Table of Contents**

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This report and other publicly available documents, including the documents incorporated herein and therein by reference, contain, and our officers and representatives may from time to time make, forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as anticipate, intend, plan, goal, seek, believe, project, estimate, expect, strategy, future, likely, may, should, will and similar references to future performance. Forward-looking statements include, among others, statements we make regarding our plans to:

obtain regulatory approval for our most advanced product candidate, LEVADEX® orally inhaled migraine drug, for the potential acute treatment of migraine in adults;

build a specialized sales force to commercialize directly LEVADEX to neurologists and pain specialists in the United States (U.S.) and Canada;

commercialize LEVADEX to additional physicians in the U.S. and Canada and to physicians in markets outside the U.S. and Canada;

advance and expand our neurology product pipeline by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional potential product candidates offering unique features and benefits, including submitting an Investigational New Drug Application, or IND, in 2012 and another IND in 2013;

outsource certain of the manufacturing, marketing, sales, distribution and other essential services for LEVADEX and other products that we commercialize; and

obtain and maintain 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.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements are set forth under the caption Risk factors and include, among others, the following:

our ability to accurately predict future performance because of our limited operating history;

our needs for additional funding and our ability to obtain such additional funding when needed;

our dependence on our lead product candidate, LEVADEX;

our ability to realize fully the potential benefits of our collaboration with Allergan, Inc. in order to obtain significant sales within the neurology and pain specialist segment of the migraine market;

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

our ability to commercialize our product candidates, including LEVADEX, to primary care physicians in the United States and to physicians in markets outside the United States;

the progress and timing of our research, development and clinical programs and the timing of regulatory activities, including approvals by the United States Food and Drug Administration (FDA) for LEVADEX for the potential acute treatment of migraine;

uncertainties regarding our ability 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;

our estimates of the dates by which we expect to report results of our clinical trials and the anticipated results of these trials;

**Table of Contents**

competition and competitive factors relating to our existing and future product candidates within the migraine market;

our reliance upon future collaborations with third parties for manufacturing, marketing, sales, distribution and other essential services for LEVADEX and other products that we commercialize; and

uncertainties associated with obtaining and enforcing patents, intellectual property licenses and other proprietary rights; and

risks relating to our managements, determination that there was a material weakness in our internal control over financial reporting. Any forward-looking statement made by us in this report is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

---

**Table of Contents**

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. We are developing proprietary product candidates that address large market opportunities in the field of neurology.

Our strategy is to commercialize and develop differentiated neurology product candidates that can address significant unmet medical needs and overcome limitations of existing products. Key elements of our strategy include:

Obtain regulatory approval for our most advanced product candidate, LEVADEX<sup>®</sup> orally inhaled migraine drug, for the potential acute treatment of migraine in adults;

Build a specialized sales force to commercialize LEVADEX to neurologists and pain specialists in the United States of America (U.S.);

Expand the market opportunity for LEVADEX; and

Advance and expand our neurology product pipeline by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional potential product candidates offering unique features and benefits. Our current focus is to advance our lead product candidate, LEVADEX, formerly known as MAP0004, a proprietary orally inhaled version of dihydroergotamine mesylate, or DHE, for the potential acute treatment of migraine. We are in the development stage and since our inception, we have devoted substantially all of our efforts to research and development, raising capital and recruiting personnel. We completed clinical development for LEVADEX in 2010 and in May 2011 we submitted our New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA. The FDA reviewed our NDA and on March 26, 2012, we received a Complete Response letter. FDA issues a Complete Response letter to an applicant to communicate the Agency's decision that an NDA will not be approved in its current form. In the Complete Response Letter, the FDA described the reasons it was unable to approve our NDA and identified issues that the Company needs to address in order to obtain FDA approval for LEVADEX. Specifically, FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter. In collaboration with Allergan, Inc., we plan to commercialize LEVADEX directly to neurologists and pain specialists in the U.S. and Canada, if approved. We are also evaluating options to commercialize LEVADEX to additional physicians in the U.S. and Canada and to physicians in markets outside the U.S. and Canada.

**Our Lead Product Candidate LEVADEX<sup>®</sup>**

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. Migraines 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.





---

**Table of Contents**

Migraine is a major public health problem that affects approximately 12% of the population in the U.S. and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people in the U.S. suffer from migraine. Migraine is more common in women, with about 18% of women affected and 6% of men. Migraine prevalence is highest during the peak productive ages of 25 to 55, which results in high costs to employers and managed care organizations.

Migraine is listed in the top 20 causes of disabling conditions and in the top four neurologic disabling conditions by the World Health Organization, or WHO. Related disability from migraine is substantial, with over 90% of sufferers experiencing functional impairment with their migraine that can disrupt every aspect of day to day life, including work, school, family and social relationships. More than half of the sufferers report severe impairment or the need for bed rest as a result of their migraines, according to published surveys. The economic burden of migraine remains substantial despite existing treatments with patients losing four to six work days each year due to migraine. The combination of direct and indirect costs of migraine in the U.S. is estimated at over \$20 billion annually.

In 2011, there were approximately 13 million migraine-specific prescriptions written for the acute treatment of migraine, generating approximately \$1.7 billion in revenues in the U.S. The majority of the prescriptions written were in the triptan class, and the leading branded agent, Maxalt, generated approximately \$450 million in revenues in the U.S. However, in 2008 when the leading migraine-specific agent, Imitrex, became generic, the total market for migraine-specific prescriptions generated approximately \$2.5 billion in revenues in the U.S.

LEVADEX is an easy to use, at-home therapy in development that patients self-administer using our proprietary hand-held TEMPO<sup>®</sup> inhaler. We have designed LEVADEX to provide faster onset and longer-lasting migraine relief than triptans, the class of drugs most often prescribed for treating migraine. DHE currently is available as an intravenous, or IV, therapy which has been used in clinical settings for over 50 years for the safe and effective treatment of migraine, particularly forms of migraine that are severe or do not respond to triptans or other therapies. We believe LEVADEX has the potential to be suitable as a first-line therapy for some migraine patients.

The LEVADEX clinical development program was a comprehensive program under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, that evaluated the efficacy, safety, pharmacokinetics and pharmacodynamics of LEVADEX in approximately 1,000 patients across nine trials. In our clinical trials conducted for LEVADEX, no drug-related serious adverse events have been reported.

In the efficacy portion of our pivotal Phase 3 FREEDOM-301 clinical trial, LEVADEX met all four primary endpoints, showing statistically significant improvement in pain relief ( $p < 0.0001$ ), freedom from phonophobia (sensitivity to sound) ( $p < 0.0001$ ), freedom from photophobia (sensitivity to light) ( $p < 0.0001$ ) and freedom from nausea ( $p = 0.02$ ) as reported two hours after dosing. Additional endpoints showed that LEVADEX provided rapid pain relief in 30 minutes and sustained pain relief for up to 48 hours after dosing. LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at 6%, with 2% of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at 5%, compared with 2% for placebo. We completed a 12 month open-label safety extension of our FREEDOM 301 trial, which evaluated lung function and cardiovascular parameters, during which approximately 9,500 headaches were treated and over 250 subjects completed 12 months of exposure. There were no mean decreases in lung function, as measured by spirometry, between the LEVADEX and placebo groups. There were no drug-related serious adverse events reported in the trial.

We also have completed additional clinical pharmacology trials that include a pharmacokinetic (PK) trial in smokers, a pharmacodynamics (PD) trial evaluating pulmonary artery pressure using echocardiogram, a thorough QT trial, a PK trial in asthmatics and a drug-drug interaction trial.

On January 28, 2011, we entered into a Collaboration Agreement and a Co-Promotion Agreement with Allergan, Inc., Allergan USA, Inc. and Allergan Sales, LLC (collectively, Allergan ) to co-promote LEVADEX to neurologists and pain specialists within the U.S. Under the terms of these agreements, following potential FDA

---

## **Table of Contents**

approval, together with Allergan, we will co-promote LEVADEX to neurologists and pain specialists in the U.S. Specifically, Allergan will leverage its existing U.S. sales force dedicated to headache specialists using BOTOX® for Chronic Migraine, which will be complemented by a MAP Pharmaceuticals field sales force targeting neurologists and pain specialists. If LEVADEX receives FDA approval, we will distribute LEVADEX and anticipate booking product revenues, and profits and losses from sales of LEVADEX generated from commercialization to neurologists and pain specialists in the U.S. will be shared equally between us and Allergan. The companies also have agreed, following potential approval of LEVADEX for the acute treatment of migraine in adults, to jointly fund and develop LEVADEX for the treatment of pediatric migraine and for another additional indication to be determined jointly by both companies. In 2011, Allergan executed an option to expand the collaboration to include Canada for neurologists and pain specialists. We retain all rights to commercialize LEVADEX to additional physicians including primary care physicians within the U.S. and Canada, as well as all rights to LEVADEX outside the U.S. and Canada. In 2011, we received \$80.0 million from Allergan, consisting of an up-front payment of \$60.0 million and a milestone payment of \$20.0 million based on the acceptance for filing by the FDA of our LEVADEX NDA submission. We may also receive up to an additional \$77.0 million in milestone payments, including a \$50.0 million milestone for the first commercial sale associated with the initial indication (the acute treatment of migraine), up to \$25.0 million in milestones for the achievement of certain FDA-approved product labeling in the U.S. and a \$2.0 million milestone for regulatory approval of the initial indication for LEVADEX in Canada.

### **Neurology Pipeline**

We are exploring options to advance and expand our neurology product pipeline by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional neurological product candidates offering unique features and benefits.

Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. Our strategy is to develop differentiated neurology products that address large market opportunities with significant unmet medical needs. We intend to commercialize potential future products through the sales force we intend to build upon the potential commercialization of LEVADEX. Our goal is to submit an Investigational New Drug Application, or IND, in 2012 and another IND in 2013. We are currently developing two early stage, pre-clinical product candidates, including one in Parkinson's disease and another in epilepsy.

### ***Information about our Development Programs***

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

LEVADEX is our proprietary orally inhaled version of DHE. The FDA reviewed our LEVADEX NDA for the potential acute treatment of migraine in adults. We received a Complete Response letter from the FDA on March 26, 2012. Migraine is a syndrome characterized by four symptoms: pain, nausea, phonophobia, or abnormal sensitivity to sound, and photophobia, or abnormal sensitivity to light. LEVADEX is an easy to use, non-invasive, at-home therapy in development that patients self-administer using our proprietary handheld TEMPO inhaler. DHE is available as an IV therapy which has been used in clinical settings for over 50 years for the safe and effective treatment of migraine, particularly forms of migraine that are severe or do not respond to triptans or other therapies. We believe DHE's adoption as a first-line therapy has been limited by its invasive mode of administration and high incidence of nausea.

The LEVADEX clinical development program is a comprehensive 505(b)(2) program that evaluated the efficacy, safety, pharmacokinetics and pharmacodynamics of LEVADEX in approximately 1,000 patients across nine trials. In our clinical trials conducted for LEVADEX, no drug-related serious adverse events have been reported. In May 2011, we submitted an NDA to the FDA for our LEVADEX orally inhaled migraine drug for the potential acute treatment of migraine. On March 26, 2012, we received a Complete Response letter in which

## **Table of Contents**

the FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle. We currently are working to address the issues identified in the Complete Response letter.

### ***Migraine***

#### ***Background***

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.

#### ***Prevalence***

Migraine is a major public health problem that affects up to approximately 12% of the population in the U.S. and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people in the U.S. suffer from migraine. Migraine is more common in women, with about 18% of women affected and 6% of men. Migraine prevalence is highest during the peak productive ages of 25 to 55, which results in high costs to employers and managed care organizations.

#### ***Migraine disability and economic impact***

Migraine is listed in the top 20 causes of disabling conditions and in the top four neurologic disabling conditions by the WHO. Related disability from migraine is substantial, with over 90% of sufferers experiencing functional impairment with their migraine that can disrupt every aspect of day to day life, including work, school, family and social relationships. More than half of sufferers report severe impairment or the need for bed rest as a result of their migraines, according to published surveys. The economic burden of migraine remains substantial despite existing treatments with patients losing four to six work days each year due to migraine. The combination of direct and indirect costs of migraine in the U.S. is estimated at over \$20 billion annually.

#### ***Current treatments***

There are two general categories of migraine therapies: acute and preventive. Acute therapies dominate the migraine market and are used during infrequent acute 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 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. The American Academy of Neurology Migraine Treatment Guidelines supports the use of DHE in the treatment of migraine.

Migraine preventative therapies are designed to reduce the frequency and severity of migraine attacks, to make migraine attacks more responsive to acute therapies and to improve the quality of life for patients. Topiramate is the market leader among preventive drugs. BOTOX injection was recently approved to prevent headaches in adult patients with chronic migraine, which is defined as experiencing a headache more than 15 days of the month. Other drug categories used in migraine prophylaxis include beta blockers, tricyclic antidepressants and calcium channel blockers.

#### ***Prescribers of migraine therapies***

Most migraine patients are first diagnosed, treated and managed by primary care physicians and internists. Referral to a neurologist or headache specialist usually occurs when the patient suffers more frequent, severe and disabling migraines or does not respond to first line treatment options. There are approximately 10,000

## **Table of Contents**

neurologists in the U.S. and they are responsible for approximately 20% of the triptan prescriptions written. About half of the neurologists account for over 90% of the triptan prescriptions written by this specialty, making a specialized sales force strategy executable.

### *Market size*

In 2011, there were approximately 13 million migraine-specific prescriptions written for the acute treatment of migraine, generating approximately \$1.7 billion in revenues in the U.S. The majority of the prescriptions written were in the triptan class, and the leading branded agent, Maxalt, generated approximately \$450 million in revenues in the U.S. However, in 2008 when the leading migraine-specific agent, Imitrex, became generic, the total market for migraine-specific prescriptions generated approximately \$2.5 billion in revenues in the U.S.

### *Limitations of Current Migraine Therapies*

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

Triptans have three major limitations:

*Slow and variable onset of action and short duration of effect:* While triptans have improved the treatment of migraine, the onset of pain relief with these products tends to be relatively slow and variable due to inconsistent systemic absorption via oral and nasal routes of administration. Published studies cite that recurrence of migraine, or the recurrence within 24 hours of an effectively treated migraine, is a common reason given for dissatisfaction among migraine sufferers.

*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. Additionally, triptans have been shown to be more effective when taken early in a migraine attack; however, migraine sufferers often wait to treat or are unable to treat early and may not fully benefit from triptan therapy.

*Side effects:* Triptans may produce sensations of chest tightness, chest pressure and tingling, often referred to as triptan sensations. 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 also has had its own limitations, including the following:

*Inconvenient and inconsistent dosing:* DHE has been available predominantly for administration intravenously and nasally. 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 congestion or irritation of the nasal membrane.

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



## **Table of Contents**

### ***Our Potential Solution: LEVADEX***

Based on our Phase 3 FREEDOM-301 clinical trial, we believe that LEVADEX may provide patients with the following benefits when compared to existing migraine therapies:

*Rapid onset:* In our Phase 3 clinical trial, LEVADEX provided significant pain relief at 30 minutes after dosing and pain relief in as early as 10 minutes after dosing for patients with severe migraine pain.

*Long-lasting:* In our Phase 3 clinical trial, LEVADEX provided long-lasting pain relief with low incidence of recurrence, and provided sustained pain relief through 48 hours.

*Efficacy at any time after the start of migraine:* Additional analyses of the Phase 3 clinical trial indicated the potential of LEVADEX to effectively treat at any time during the migraine, including within one hour and after eight hours from the start of migraine.

*Broadly efficacious:* Based on historical DHE use in migraine, LEVADEX 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 LEVADEX has the potential to treat a broad spectrum of migraine, including migraine subpopulations that are often difficult to treat, such as menstrual migraine, morning migraine, migraine with allodynia, migraine associated with severe pain and migraine with nausea and vomiting.

*Low incidence of side effects:* In our Phase 3 clinical trial, LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at 6% compared with 2% for placebo. The next most common adverse event was nausea at 5%, compared with 2% for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort or chest pain, were rare and comparable to placebo.

*Convenient and consistent delivery:* LEVADEX is non-injectable and designed to be easy to use, which may result in increased patient comfort and compliance. The clinical trial was performed in the home, without clinical supervision and with minimal training. In a previous trial, dose-to-dose variability was comparable to solid oral dosage forms.

### ***LEVADEX Clinical Development Program***

We completed our LEVADEX clinical development program in 2010, and in May 2011 we submitted our NDA to the FDA for our LEVADEX orally inhaled migraine drug for the potential acute treatment of migraine in adults. The FDA reviewed our NDA and on March 26, 2012, we received a Complete Response letter. In the Complete Response letter, the FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter. Our comprehensive clinical development program for LEVADEX evaluated the efficacy, safety, PK and PD of LEVADEX in approximately 1,000 patients. In all of our clinical trials conducted for LEVADEX, no drug related serious adverse events have been reported.

*Phase 3 Clinical Program.* We evaluated the safety and efficacy of LEVADEX as a potential acute treatment for migraine in a Phase 3 multi-center, randomized, double-blind, placebo-controlled or FREEDOM 301 trial followed by a 12-month open-label safety assessment. In this trial, patients were randomized to either LEVADEX or placebo during the efficacy portion of the trial.

In May 2009, we announced top-line results from the efficacy portion of our Phase 3 FREEDOM-301 clinical trial. We announced that the clinical trial met its four primary endpoints, pain relief and being nausea, phonophobia and photophobia free as reported two hours after dosing when LEVADEX was compared to placebo. Additional endpoints showed that LEVADEX provided rapid and sustained pain relief for up to 48 hours after dosing.





## **Table of Contents**

Patients taking LEVADEX therapy had statistically significant improvement at two hours compared to patients on placebo for each of the primary endpoints:

Pain relief: 58.7% of patients who received LEVADEX compared with 34.5% for placebo ( $p < 0.0001$ );

Phonophobia free: 52.9% of patients who received LEVADEX compared with 33.8% for placebo ( $p < 0.0001$ );

Photophobia free: 46.6% of patients who received LEVADEX compared with 27.2% for placebo ( $p < 0.0001$ ); and

Nausea free: 67.1% of patients who received LEVADEX compared with 58.7% for placebo ( $p = 0.02$ ).

A total of 792 patients were included in the primary data analysis as specified in the protocol of the FREEDOM-301 study. The patient population studied had more severe migraine pain than expected, with 46% reporting severe pain and 54% reporting moderate pain prior to administration of the study drug.

Results from additional pre-defined analyses include:

LEVADEX therapy achieved statistically significant onset of pain relief at 30 minutes after dosing ( $p = 0.03$ );

While not statistically significant, 50% more of the patients receiving LEVADEX therapy than the patients receiving placebo reported pain relief at 10 minutes;

LEVADEX therapy achieved statistically significant sustained pain relief from two to 24 hours ( $p < 0.0001$ ), as well as two to 48 hours ( $p < 0.0001$ , when unadjusted for multiplicity);

LEVADEX therapy achieved statistically significant pain freedom (pain symptom score = 0) as early as 30 minutes ( $p = 0.002$ , when unadjusted for multiplicity); and

LEVADEX therapy achieved sustained pain freedom from two to 24 hours, as well as two to 48 hours ( $p < 0.0001$  for both time points, when unadjusted for multiplicity).

LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at 6%, with 2% of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at 5%, compared with 2% for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort (1%) or chest pain (0%), were rare and comparable to placebo. There were no decreases in lung function, as measured by spirometry, between the active and placebo groups. There were no drug-related serious adverse events reported in the trial. These data were presented in September 2009 in a late-breaking session of the 14<sup>th</sup> Congress of the International Headache Society and the efficacy data was published in the peer-reviewed journal *Headache* in April 2011.

We have also presented additional post-hoc analyses of data from this Phase 3 trial showing the potential of LEVADEX to be effective in acute treatment of migraine as well as a broad spectrum of migraine, including migraine subpopulations that are often resistant to current therapies such as triptans, migraine with moderate and severe pain, migraine with nausea and vomiting, migraine with and without aura, morning migraine, menstrually-related migraine and migraine in allodynic patients.

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

A long-term safety extension evaluated overall safety, including pulmonary and cardiovascular safety, of LEVADEX in over 250 patients, including migraine sufferers with asthma, for 12 months. On an ongoing basis, including a six month interim review, a Data Monitoring Committee, or DMC, reviewed data from the safety extension, including results of both pulmonary lung function evaluations using measures such as DLco and FEV<sub>1</sub> and cardiac evaluations using electrocardiograms, echocardiograms and chest X-rays. The DMC is an independent group of clinical trial experts, including physicians, formed to critically review and evaluate patient safety data generated with the objective of ensuring clinical trial patient safety, quality of the data collected and continued scientific validity of the trial design. In December 2010, we announced completion of the LEVADEX open-label safety trial. LEVADEX was well tolerated and no drug-related serious adverse events were reported;

---

**Table of Contents**

and no clinically significant trends were observed for LEVADEX in the evaluation of cardiovascular measurements or pulmonary function.

*Clinical Pharmacology Trials.* A PK trial compared the PK and safety of LEVADEX and intravenous DHE in 23 adult smokers and 24 adult non-smokers. The trial was designed to measure whether the systemic absorption of LEVADEX is higher and exposure to DHE is greater in smokers than in non-smokers. In the trial, the systemic absorption of LEVADEX was not higher and systemic exposure to DHE was not greater in smokers than in non-smokers.

A PD trial evaluated pulmonary artery pressure in approximately 24 healthy volunteers using echocardiograms. The trial compared the acute effects on pulmonary artery pressure of LEVADEX, DHE administered intravenously and placebo. In the trial, there was no statistically significant difference between the LEVADEX and placebo groups in the primary endpoint of pulmonary artery pressure over two hours after administration.

A thorough QT trial in 54 healthy adults compared the acute effects of a supra-therapeutic dose of LEVADEX (approximately three times the anticipated commercial dose), oral moxifloxacin (400 mg) and placebo on the cardiac QT interval as measured by electrocardiograms. Results of the trial showed that a supra-therapeutic dose of LEVADEX does not increase QTc intervals.

A drug-drug interaction trial in 24 healthy volunteers assessed the impact of CYP3A4 inhibition on LEVADEX pharmacokinetics. Results of the trial showed that co-administration of LEVADEX with a potent CYP3A4 inhibitor showed no effects on the plasma levels of DHE or its elimination. Therefore, the potential for potent CYP3A4 inhibitors to enhance or prolong the pharmacological effects of orally inhaled DHE appears to be minimal.

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

The objective of the first Phase 2 clinical trial was to evaluate the efficacy and tolerability of three different doses of LEVADEX in adult migraine patients when self-administered at home. This Phase 2 clinical trial was a randomized, double blind, placebo-controlled trial of three doses of LEVADEX in 86 patients. The clinical trial consisted of two treatment periods. The first treatment period evaluated two doses of LEVADEX, 1.0 mg and 0.5 mg versus placebo and the second treatment period re-randomized responders in the first treatment period to evaluate a lower dose, 0.25 mg versus placebo. In the first treatment period, the 0.5 mg dose of LEVADEX showed pain relief in 32% of the patients at ten minutes ( $p = 0.019$ ), pain relief in 72% of the patients at two hours, the clinical trial's primary endpoint ( $p = 0.019$ ), and sustained pain relief in 43% of the patients at 24 hours ( $p = 0.066$ ) in a treatment received population. Unlike IV DHE, which is generally administered with an anti-nausea medication, LEVADEX was administered by itself and showed no statistically significant drug related increase in nausea. LEVADEX was also shown in the clinical trial to be well tolerated, with no serious adverse events reported. In the second treatment period, 35 subjects were randomized to treat a second subsequent migraine with a 0.25 mg dose versus placebo. No significant benefit was seen with this lower dose when compared to placebo.

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

---

## **Table of Contents**

rate, blood pressure, respiratory rate or mean IgE levels, a measure of systemic immune response, or the body's defenses reacting to a foreign substance.

We believe that, based on our PK and receptor binding research, administration of LEVADEX via the lung may provide an opportunity to retain the efficacy attributes seen with IV DHE while minimizing the potential side effects often seen during IV DHE administration. PK data suggest that LEVADEX closely mimics the blood levels and the time to maximum drug concentration seen with effective doses of DHE administered intravenously. However, unlike IV administration of DHE, we do not expect LEVADEX to cause significant treatment related nausea which may be a factor that has limited the usage of IV DHE outside the headache clinic or hospital. In the FREEDOM 301 trial the incidence of treatment related nausea was low at 5% compared with 2% for placebo. In our Phase 1 trial comparing IV DHE to LEVADEX, the blood levels of drug were similar. However, the maximum drug concentration for inhaled DHE administered with our TEMPO inhaler was approximately 20 fold lower than that for IV DHE, which we believe in part accounts for the low incidence of drug-induced nausea observed in our clinical trials to date.

In addition, we have conducted pre-clinical animal studies to evaluate lung toxicity and coronary vascular effects of our proprietary formulation of DHE. In our six month chronic inhalation toxicity assessment of DHE, where animals were exposed to up to 1.08 mg/kg (more than 46 times the maximum potential recommended daily dose of LEVADEX, if approved) of DHE per day for six months, there was no significant respiratory tract toxicity observed. In another pre-clinical study designed to evaluate cardiovascular parameters, we observed no significant differences in coronary vascular effects comparing inhaled DHE to IV DHE.

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

### ***Other Potential Uses and Indications for LEVADEX***

Through our collaboration with Allergan, we and Allergan have agreed, following potential approval of LEVADEX for the acute treatment of migraine in adults, to jointly develop and fund LEVADEX for the treatment of pediatric migraine and for another additional indication to be determined jointly by both companies.

Furthermore, based on key LEVADEX attributes observed to date, including fast onset of action, long duration of effect as well as historical uses for DHE, developing additional indications for LEVADEX may represent significant opportunities. We believe LEVADEX may have the potential to treat additional migraine indications such as cluster headache, menstrual migraine, chronic migraine, chronic daily headache, medication over-use headache and status migrainosus.

We believe there is opportunity to develop LEVADEX for potential use outside of the U.S. While migraine is a major public health problem affecting approximately 12% of the population in the U.S., it also affects approximately 15% of the population in Europe. Based on the accumulated nonclinical and clinical data to date, we believe there may be significant commercial opportunities for LEVADEX outside of the U.S.

### ***LEVADEX Commercialization Strategy***

If LEVADEX is approved, with Allergan we will market and co-promote LEVADEX to neurologists and pain specialists in the U.S. Specifically, we will build a 50-person MAP Pharmaceuticals field sales force targeting neurologists and pain specialists that will be complemented by Allergan, which will leverage its existing U.S. sales force dedicated to headache specialists using BOTOX for Chronic Migraine.

## **Table of Contents**

### ***Neurology Pipeline***

We apply our proprietary technologies to optimize drugs for pulmonary delivery as a non-invasive method of quickly and safely administering drugs to the Central Nervous System (CNS). Administration of drugs via the respiratory tract is a non-invasive method which can achieve rapid onset of action in the CNS, without the elevated systemic doses required by oral or other administration routes to overcome first pass metabolism. Thus systemic doses can be lowered to minimize side effects. 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.

We are exploring options to advance and expand our neurology product pipeline by leveraging our technologies and our expertise in neurology, aerosol medicine and delivery/formulation technology to develop additional neurological product candidates offering unique features and benefits. Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies.

We have proprietary product candidates in development that address large market opportunities. Our strategy is to commercialize and develop differentiated neurology product candidates that can address significant unmet medical needs and overcome limitations of existing products. Our goal is to submit an IND in 2012 and another IND in 2013. We are currently developing two early stage, pre-clinical product candidates, including one in Parkinson's disease and another in epilepsy.

*Parkinson's disease.* Parkinson's disease (PD) is a progressive, neurodegenerative condition characterized by slowed ability to start and continue movements, muscular rigidity, tremors or shaking and difficulty with balance. It is the second most commonly diagnosed neurodegenerative disease in the U.S. after Alzheimer's disease. It is estimated that more than 1.5 million people in the U.S. have PD, with 70,000 new cases diagnosed each year. Dopamine is naturally produced by the body and it helps regulate the body's movement. A deficiency in dopamine-producing nerve cells in the brain results in PD. Currently there is no cure for PD, but there are some medications that can provide relief from the symptoms. In patients with moderate to severe PD, levodopa (L-dopa) and dopamine agonists are the main therapy used as combination therapy to mimic the role or replenish dopamine in the brain.

Our pre-clinical PD product candidate is an orally inhaled dopaminergic agonist that we are developing as a potential supplemental therapy for PD patients who are not adequately controlled by their standard maintenance therapy. Even with standard maintenance therapy, a common problem for many patients is on-off fluctuations which can occur as the maintenance medication wears off, or as the disease progresses and the maintenance dose is inadequate. Patients cease to experience benefits of treatment during this period until their next scheduled maintenance dose. There are orally administered and injectable medicines available today that are effective in helping during these off periods. The oral therapies may take a long time to provide benefit, and have highly variable absorption and significant drug and food interactions. The injectables require co-administration of antiemetics due to the high prevalence of nausea. The existing therapies can result in tremors, shaking, nausea and other side effects. We believe that our product candidate may have the potential to rapidly and conveniently provide consistent symptomatic control during these off periods.

*Epilepsy.* Epilepsy is a neurodegenerative disease characterized by seizures that affects approximately 50 million people worldwide and almost three million people in the U.S. It strikes most often among the very young and the very old, although anyone can develop epilepsy at any age. Epilepsy affects greater than 300,000 children under the age of 15 with greater than 90,000 who have seizures that are not adequately treated. As the elderly population in the U.S. continues to increase, the number of epilepsy cases continues to climb with currently more than 570,000 adults age 65 or over diagnosed with epilepsy. Epileptic seizures are usually controlled, but not cured, with antiepileptic drugs (AEDs). However, over 25% of people with epilepsy do not have seizure control even with the best available therapies and are therefore at risk for serious problems

## **Table of Contents**

associated with uncontrolled epileptic seizures. The primary goals of therapy are cessation of the seizure and prevention of recurrence.

Diastat, a formulation of diazepam indicated for rectal administration, is currently the only FDA-approved AED to treat acute repetitive seizures. The use of intramuscular, nasal and oral benzodiazepines, are used off-label for treatment of seizures; however, these older therapies often have slow and highly variable time to onset of action. To achieve therapeutic thresholds in the CNS using these routes, high systemic dosing levels are required, and may result in over-sedation.

Our pre-clinical epilepsy product candidate is a gamma-aminobutyric acid (GABA) receptor agonist that we are developing as a supplemental therapy used to quickly abort intermittent bouts of increased seizures among patients who are not adequately managed on long-term anti-epileptic medication. We believe that our drug candidate may present an advantage over these current therapies by enabling the patient or a caregiver to deliver therapy to abort follow on seizures.

## **Our Technology**

*Overview.* We take an integrated approach to innovation in medicine by focusing not only on enhancing a drug's pharmacological profile, thereby improving its efficacy and safety, but also on the best ways to administer the drug and to target the therapy to the affected area in order to improve its performance. We select therapeutic agents that target specific receptor activities to create drug products with potentially enhanced efficacy and safety. We often select drugs that have a history of safety and efficacy, but that have identified shortcomings, such as narrow therapeutic window. Then, we apply proprietary particle creation and formulation technologies to produce dosage forms that are designed to achieve a particular, repeatable pharmacokinetic profile. Finally, our innovative delivery systems are designed to be simple and convenient to administer and to optimize the delivery efficiency and consistency. We develop, engineer and manufacture aerosol delivery devices, including our TEMPO inhaler, which have the potential to provide greater deposition in the lung and provide consistent dosing. Our drug formulation and delivery technologies are covered by over 15 issued U.S. patents and over 25 U.S. patent applications that we own or have licensed, as well as their foreign counterparts. We believe that the combination of our various drug particle creation, formulation, delivery and targeting technologies add up to a significant competitive advantage in bringing new therapies to market to address areas of unmet need in neurology.

*Pharmacological Profiling.* Our aerosol delivery and pharmacological profiling technology combines our knowledge of aerosol science and pharmaceutical technology, and enables us to create inhaled drug products with potentially enhanced pharmacological profiles relative to the parent drugs. Starting with the bulk drug substance, we develop particles with 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 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, if needed, that are already in wide use and regarded as safe, that result in favorable absorption, metabolic and 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.

*Proven Drugs.* We focus our product development on 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 or foreign agencies for other sponsors and in other dosage forms and

## Table of Contents

formulations. As a result, we may seek FDA marketing approval of our product candidates under Section 505(b)(2) of the FDCA, which, if available to us, would allow the 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.

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

One of our key technologies is the generation of particles by supercritical fluid, or SCF, crystallization. SCF gives us the ability to create very small particles ranging from 100 nanometers to 10 microns in diameter with highly precise particle size distributions. The particles have uniform surfaces with few discontinuities or irregularities that provide enhanced aerosol performance. They are also stable for long storage periods without refrigeration, and require minimal or no excipients that can increase the potential for local toxicity or inflammatory response.

*Formulation.* 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.

*Delivery Technologies.* Our technologies also consist of the development and manufacturing of aerosol delivery platforms, including our TEMPO inhaler. The TEMPO inhaler is a proprietary, next generation pressurized metered dose inhaler, or MDI, that dispenses drug automatically when the patient inhales and has high consistency and efficiency compared to other inhalers.

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

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

*Automatic, optimal release of therapy:* Our triggering technology is tuned for each particular drug so that drug release is synchronized to a specified point in the breathing cycle to allow the released drug to reach the targeted area of the respiratory tract. For example, data from a scintigraphy study showed that

## **Table of Contents**

the TEMPO inhaler deposited 75% less of a corticosteroid in the mouth and throat and delivered three times as much drug to the lungs as a conventional MDI.

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

*Dose consistency:* Results from the TEMPO inhaler performance data along with results from our clinical trials indicate that the TEMPO inhaler's dose-to-dose consistency is comparable to IV dosing. The TEMPO inhaler also includes a dose counter to display how many doses remain available for use. The dose counter can prevent dispensing of additional doses after a maximum number of doses have been delivered.

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

We have conducted clinical trials with three clinical product candidates which utilize our TEMPO inhaler: LEVADEX for the potential treatment of migraine, MAP0005 for the potential treatment of asthma and chronic obstructive pulmonary disease, or COPD, and MAP0001 for the potential treatment of diabetes.

### ***Other Product Technologies***

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

*Combination Particle Technology:* We have applied our proprietary particle formulation technologies to deliver the optimal ratio of multiple drugs in a reproducible and consistent manner. We can combine two or more drugs together into a single micron scale inhalable 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 combination product candidates in diverse indications via inhalation and other routes of delivery.

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

*Nebulized Corticosteroid Particle Technology:* We have expertise in the formulation and administration of nebulized corticosteroids for the treatment of pediatric asthma. We have created novel versions of budesonide that are designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide. Conventional nebulized budesonide is an inhaled corticosteroid approved by the FDA for treating asthma in children from 12 months up to eight years of age. We have developed novel morphologies of corticosteroid particles which may allow for faster delivery and efficacy at a lower dose, which together may offer improved safety, compliance and convenience.

### **Our Strategy**

Key elements of our strategy include:

*Obtain regulatory approval for our most advanced product candidate, LEVADEX:* In May 2011, we submitted an NDA to the FDA for our LEVADEX orally inhaled migraine drug for the potential acute





---

## **Table of Contents**

treatment of migraine in adults. The FDA reviewed our NDA and on March 26, 2012, we received a Complete Response letter. We currently are working to address the issues identified in the Complete Response letter.

*Build a specialized sales force to commercialize LEVADEX to neurologists and pain specialists in the U.S.:* Our goal is to build a sales force in the U.S. to market and sell our products, if approved, to neurologists and pain specialists.

*Expand the market opportunity for LEVADEX:* In order to expand the commercial opportunity for LEVADEX, we may develop additional follow-on indications for LEVADEX and develop partnerships with pharmaceutical companies to market and sell to additional physicians including primary care physicians. Outside the U.S., 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.

*Advance and expand our neurology product pipeline, by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional potential product candidates offering unique features and benefits:* We intend to focus our pipeline development initially on products with established safety and efficacy records, but whose market potential has been limited by safety, relative efficacy and patient compliance. We believe that we can overcome these limitations by leveraging our technologies. These technologies underpin our competitive advantage in developing multiple, high-value products with clearly defined patient benefits. In addition, we may in-license additional product candidates to be marketed to the same neurology channel.

### **Collaborations and License Agreements**

#### ***Allergan***

On January 28, 2011, we entered into a Collaboration Agreement (the Collaboration Agreement ) and a Co-Promotion Agreement (the Co-Promotion Agreement, and together with the Collaboration Agreement, the Allergan Agreements ) with Allergan, Inc., Allergan USA, Inc. and Allergan Sales, LLC (collectively, Allergan ). Pursuant to the terms of the Allergan Agreements, we have granted Allergan a co-exclusive license to market and co-promote LEVADEX, our proprietary novel migraine drug for delivery by inhalation, to neurologists and pain specialists in the U.S. in collaboration with us. In February 2011, we received a \$60.0 million up-front payment from Allergan. We are responsible for obtaining NDA approval, and retain ownership of the NDA.

In July 2011, Allergan exercised its option to expand the Collaboration Agreement to include Canada for neurologists and pain specialists. Under the Allergan Agreements, we retain the right to market and co-promote LEVADEX to other physicians within the U.S. and Canada and also retain all rights to LEVADEX in all other countries. We and Allergan will each provide sales representatives and other sales support for such marketing and promotional efforts. The Allergan Agreements specify minimum annual sales detail requirements to be provided by each party, and establish maximum annual amounts of detailing costs that each party will be obligated to incur pursuant to a commercialization plan.

In August 2011, the FDA accepted for filing our LEVADEX NDA which triggered a milestone payment of \$20.0 million from Allergan which we received in September 2011. In addition to the \$20.0 million milestone described above, under the terms of the Collaboration Agreement, we may also receive up to an additional \$77.0 million in milestone payments, including a \$50.0 million milestone for the first commercial sale associated with the initial indication (the acute treatment of migraine), up to \$25.0 million in milestones for the achievement of certain FDA-approved product labeling in the U.S. and a \$2.0 million milestone for regulatory approval of the initial indication for LEVADEX in Canada.

The parties will collaborate in the development of LEVADEX for the treatment of pediatric migraine and for at least one other indication. We may develop LEVADEX for certain other indications independently of the collaboration if Allergan does not agree to develop LEVADEX for such indications pursuant to the Allergan

## **Table of Contents**

Agreements. We will be responsible for manufacturing and distributing LEVADEX, and anticipate booking product revenues from sales of LEVADEX resulting from the parties' collaboration.

The parties will share profits and losses resulting from the collaboration equally. We are solely responsible for payment of all remaining costs of obtaining regulatory approval of LEVADEX for the acute treatment of migraine in adults, except that if the FDA notifies us that additional development or manufacturing activities costing in excess of a certain threshold amount will be required for such regulatory approval, the parties will share any such excess costs. The parties generally will share equally all other costs of developing LEVADEX under the Allergan Agreements, except that neither party shall be obligated for more than a certain threshold amount in a given year, or for more than a certain threshold amount in the aggregate, for development or manufacturing costs or expenses incurred by us for such activities.

The Collaboration Agreement may be terminated (i) by Allergan, at will, after first commercial sale of LEVADEX in the U.S., upon 180 days prior written notice, (ii) by Allergan, upon written notice to us, if we receive a complete response letter or equivalent communication from the FDA that Allergan determines will extend potential approval beyond a certain date or requires a certain minimum level of additional investment, (iii) by us, upon written notice to Allergan, if Allergan commercializes a competing product in the U.S. or Canada and (iv) by us, upon written notice to Allergan, if Allergan challenges or opposes patent rights licensed to Allergan pursuant to the Collaboration Agreement. Additionally, either party may terminate the Collaboration Agreement in the event of an uncured material breach. The Co-Promotion Agreement will terminate upon termination of the Collaboration Agreement.

### ***Nektar Therapeutics***

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

Our obligation to pay royalties to Nektar is based on net sales of products, and will continue, on a country-by-country basis, until the longer of expiration of Nektar patents covering the product, ten years after the first commercial sale of the product, or the date that Nektar's know-how becomes known to the general public.

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.

### ***Exemplar Pharmaceuticals***

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

## **Table of Contents**

Exemplar agreed to convert its manufacturing facility into a Good Manufacturing Practices, or GMP, contract manufacturing facility suitable for the commercial production of the product prior to or when Exemplar 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 certain period thereafter Exemplar will manufacture and supply from its manufacturing facility all such filled canisters as we require to support development and commercialization. If Exemplar 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 Exemplar does not have the capability to manufacture the product in accordance with the warranty or in sufficient quantities.

## **Intellectual Property**

We protect our technology through the use of patents, trade secrets and proprietary know-how. We own or in-license nine issued U.S. patents, and over ten U.S. patent applications, as well as their foreign counterparts, which relate to our most advanced product candidate LEVADEX. The patents and patent applications that may issue that we own or in-license, which we rely on for LEVADEX, expire between 2017 and 2030. Our patent and patent applications relating to LEVADEX include claims covering:

TEMPO inhaler devices and components;

various formulations of the LEVADEX active ingredient;

the processing of the LEVADEX active ingredient;

stabilization of the formulation;

pharmacokinetics of the active ingredient delivered by the inhalation system; and

the treatment of migraine via delivery of the formulation to the lung.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We have rights to several third-party proprietary processing and manufacturing technologies related to our product candidates. See the section above titled "Collaborations and License Agreements." We rely on such third parties to protect the intellectual property we license, and we do not and have not had any control over the filing or prosecution of patent applications. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Our enforcement of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

## **Manufacturing**

All of our manufacturing processes, which comply with current good manufacturing practices, or cGMP, are outsourced to third parties with oversight by our internal managers. We have limited cGMP manufacturing and commercial supply 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 LEVADEX and for any other potential products for which we retain significant development and

commercialization rights.

The drug substance of LEVADEX has been manufactured by a contract manufacturing organization, or CMO, located in Europe. Our CMO has extensive experience manufacturing bulk drug under cGMP and has the

---

## **Table of Contents**

capacity to manufacture at commercial scale. We are exclusive licensees of the manufacturing process for production of LEVADEX final drug substance. Under our worldwide license from Nektar, we have enabled another CMO to manufacture clinical and commercial supply of the final drug substance to be used in the development and commercialization of LEVADEX. The TEMPO inhaler is manufactured by third-party CMOs. The plastic inhaler component manufacture and assembly, valve manufacture and canister fill are each performed by specific third-party CMOs.

### **Competition**

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

If approved for the acute treatment of migraine, we anticipate that LEVADEX would compete against other marketed migraine therapies for the acute treatment of migraine and may compete with products currently under development by other companies.

In 2011, there were approximately 13 million migraine-specific prescriptions written for the acute treatment of migraine, generating approximately \$1.7 billion in revenues in the U.S. The majority of the prescriptions written were in the triptan class, and the leading branded agent, Maxalt, generated approximately \$450 million in revenues in the U.S. However, in 2008 when the leading migraine-specific agent, Imitrex, became generic, the total market for migraine-specific prescriptions generated approximately \$2.5 billion in revenues in the U.S. There are at least six other branded triptan therapies being sold by pharmaceutical companies. Alternative formulations of triptans are available that may have faster onset of action than solid oral dosage forms. In April 2008, GlaxoSmithKline's Treximet, a combination oral formulation of sumatriptan and naproxen sodium, was approved by the FDA for the acute treatment of migraine. In July 2009, Zogenix, Inc.'s Sumavel DosePro needle-free sumatriptan was approved by the FDA for the acute treatment of migraine and cluster headache. Alternative formulations of DHE include Migranal, which is nasally delivered and which may become generically available prior to any commercial introduction of LEVADEX. In addition to marketed migraine therapies, there are other product candidates under development. In October 2010, Allergan's BOTOX injectable onabotulinumtoxinA was approved by the FDA for the treatment of chronic migraine, a different indication than migraine.

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

### **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 FDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable FDA or other requirements may result

## **Table of Contents**

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 U.S. All applications for FDA approval must contain, among other things, information relating to safety and efficacy, pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control.

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

A new drug approval by the FDA is generally required before a drug may be marketed in the U.S. 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 U.S.;

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.

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

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

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





---

## **Table of Contents**

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

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

*Phase 4:* These are clinical trials conducted after a drug has been approved. In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post approval trials are typically referred to as Phase 4 clinical trials.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive manufacturing information. Once the NDA 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 minor improvement over existing marketed therapies. Standard Review NDAs have a goal of being completed within a 10-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 pre-clinical or clinical data and/or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and FDA may interpret data differently than we do and may decide the clinical data in the NDA do not meet the criteria for NDA approval. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials and surveillance programs, to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these postmarketing commitments. Drugs may be marketed only for approved indications and in accordance with the provisions of the approved labeling. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

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

One of the paths to FDA approval for new formulations of a drug previously approved by the FDA, is 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

## **Table of Contents**

permits the filing of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness based on certain pre-clinical or clinical trials conducted for an approved product. The FDA may also require companies to perform additional clinical trials 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 of the approved product, 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 FDA findings of safety and efficacy 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.

### ***International Regulation***

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

For example, 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.

---

## **Table of Contents**

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

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

Although none of our product candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private health care insurance companies and managed care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. 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 U.S. 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 platforms or drug therapies before they will reimburse health care providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

### ***Manufacturing Requirements***

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

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

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote prescription pharmaceuticals, which include, among other things, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement

## **Table of Contents**

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, 2011, we had 116 full-time employees. Of the full-time employees, 77 were engaged in research and development related activities, and 39 were engaged in sales, general and administrative activities. We plan to expand our commercial infrastructure in preparation of the potential launch of our LEVADEX product candidate. To support this growth, we will need to expand managerial, operations, development, regulatory, sales, marketing, finance and other functions. None of our employees are represented by a labor union, and we consider our employee relations to be good.

## **Financial Information about Geographic Areas**

Not applicable.

## **Available Information**

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is <http://www.sec.gov>.

Our internet address is [www.mappharma.com](http://www.mappharma.com). We make available free of charge on our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such reports are filed with or furnished to the SEC. Our Code of Business Conduct and Ethics can also be found on our website.

Our principal executive offices are located at 2400 Bayshore Parkway, Suite 200, Mountain View, California, 94043. Our telephone number is (650) 386-3100.

---

**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 may 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 on a sustained basis in the foreseeable future. We have incurred significant net losses in each year since our inception, including net losses of approximately \$32.9 million, \$54.7 million and \$9.0 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, we had a deficit accumulated during the development stage of approximately \$272.5 million. We have devoted most of our financial resources to research and development, including our pre-clinical development activities, clinical trials and manufacturing-related activities. We have not obtained regulatory approval for, or commercialized any product candidate and have therefore not generated any product revenues. In that regard, we expect to incur additional expenses as we continue to pursue our new drug application, or NDA, for LEVADEX, our most advanced product candidate, with the U.S. Food and Drug Administration, or the FDA. In addition, if we are required by the FDA to perform studies in addition to those we have conducted, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We expect an increase in our expenses associated with our manufacturing work and with preparing for commercialization. In addition, we expect to continue to incur costs to support operations as a public company. As a result, we may continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to achieve or maintain profitability. We have financed our operations primarily through the sale of equity securities, collaboration payments 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 additional strategic partnerships, including with respect to promotion of LEVADEX to additional physicians including primary care physicians. On January 28, 2011, we entered into a collaboration agreement with Allergan pursuant to which Allergan will co-promote LEVADEX with us in the United States to neurologists and pain specialists. In addition to the \$80.0 million in upfront and milestone payments already received from Allergan, we are eligible to receive additional payments upon achievement of regulatory milestones and first commercial sale. If we do not meet these milestones, we will not receive additional payments and, under certain circumstances, Allergan may terminate our collaboration. If we are unable to develop and commercialize our other product candidates, including pursuant to strategic partnerships, 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, undertaking pre-clinical studies, clinical trials and manufacturing-related activities of our product

**Table of Contents**

candidates and preparing for the potential commercialization of our initial product candidate, LEVADEX, if approved. 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 and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, among others: our ability to obtain additional funding to develop our product candidates;

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

the need to obtain regulatory approval of our most advanced product candidate, LEVADEX for the potential acute treatment of migraine;

potential risks related to any collaborations we may enter into for our product candidates, including our current collaboration with Allergan for LEVADEX;

our ability to receive regulatory approval for or commercialize our LEVADEX product candidate, as well as future product candidates;

any delays in regulatory review and approval of our LEVADEX product candidate or future product candidates, including any requirements to perform additional preclinical or clinical trials;

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

the success of clinical trials of our LEVADEX product candidate or future product candidates;

delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;

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

our ability, and our partners' ability, to commercialize our products including establishing an effective sales and marketing infrastructure;

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

competition from existing products or new products that may emerge;

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

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

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

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

regulatory difficulties and post-market requirements relating to products that have already received regulatory approval;

our ability to obtain FDA approval of the proposed product names for our product candidates without delay;

practice 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;

**Table of Contents**

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

costs related to and outcomes of potential intellectual property litigation;

compliance with obligations under intellectual property licenses with third parties;

our need to transform our company by adding commercial expertise;

our ability to manage future growth;

our ability to remediate a material weakness in our internal controls over financial reporting and risks related to that material weakness; and

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

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 and an effective sales and marketing infrastructure, is expensive. While we have completed our clinical development program for LEVADEX for the acute treatment of migraine in adults, we expect to have continued expenses in connection with our ongoing activities, particularly as we seek to obtain approval of our NDA for LEVADEX, our most advanced product candidate, for the acute treatment of migraine in adults. On March 26, 2012, we received a Complete Response letter from the FDA. FDA issues a Complete Response letter to an applicant to communicate the Agency's decision that an NDA will not be approved in its current form. In the Complete Response letter, the FDA described the reasons it was unable to approve our NDA and identified issues that the company needs to address in order to obtain FDA approval for LEVADEX. Specifically, FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter. In addition, if we are required by the FDA to perform studies in addition to those we have conducted, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least 12 months. We will need substantial additional capital in the future in order to commercialize LEVADEX and to fund the development and commercialization of future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, including our collaboration with Allergan. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

If adequate funds are not available, we may be required to delay or reduce the scope of our commercialization efforts or delay, reduce the scope of or eliminate one or more of our research or development programs. To the extent that we raise additional funds by issuing equity securities,



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

our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or to grant licenses on terms that may not be

## Table of Contents

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 costs and timing of regulatory approval including any potential delays that may occur;

the cost and timing of commercial-scale manufacturing and distribution activities;

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

rate of market adoption of our product candidates for which we obtain regulatory approval.

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

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

the effect of competing technological and market developments; and.

the terms and timing of any collaboration, licensing or other arrangements that we may establish, including our current collaboration agreement with Allergan.

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

*We are largely dependent on the success of one product candidate, and we cannot be certain that this product candidate will receive regulatory approval.*

We have invested a significant portion of our efforts and financial resources in the development of LEVADEX and our Unit Dose Budesonide, or UDB, product candidate. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in either dose evaluated when compared to placebo. On July 8, 2009, we received a notice of termination of our license agreement with AstraZeneca AB, or the AstraZeneca Agreement, related to our UDB product candidate. Following the termination of the AstraZeneca Agreement, we suspended development of UDB. We are now largely dependent on the success of one product candidate, LEVADEX, for which we have completed a Phase 3 clinical development program and the FDA currently is reviewing our NDA for the acute treatment of migraine in adults. Our ability to generate product revenue is dependent on the successful regulatory approval and commercialization of this product candidate. On March 26, 2012, we received a Complete Response letter, in which the FDA described the reasons it was unable to approve our NDA and identified issues that the Company needs to address in order to obtain FDA approval of LEVADEX. Specifically, the FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter. We may have inadequate financial or other resources to advance LEVADEX through the NDA process, depending on the

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

requirements of the FDA. In May 2009, we announced top-line results from the efficacy portion of our first Phase 3 trial of LEVADEX, indicating that the trial met all its co-primary endpoints when LEVADEX was compared to placebo. A long-term safety extension of the trial has also been completed and no drug-related serious adverse events were reported in

---

**Table of Contents**

the trial. Although we had planned to initiate a second Phase 3 efficacy study in the first quarter of 2010, we have been informed by the FDA that a second pivotal efficacy study is not required for submission of our NDA if the top-line efficacy results we submitted in 2009 are confirmed during the NDA review. We have completed a pharmacokinetics trial in 23 adult smokers comparing them to 24 adult non-smokers. The trial was designed to measure whether the systemic absorption of LEVADEX is higher and exposure to dihydroergotamine mesylate, or DHE, is greater in smokers than in non-smokers. In the trial, the systemic absorption of LEVADEX was not higher and systemic exposure to DHE was not greater in smokers than in non-smokers. We have completed a pharmacodynamics trial evaluating pulmonary artery pressure in approximately 24 healthy volunteers using echocardiograms. The trial compared the acute effects on pulmonary artery pressure of LEVADEX, DHE administered intravenously and placebo. In the trial, there was no statistically significant difference between the LEVADEX and placebo groups in the primary endpoint of pulmonary artery pressure over two hours after administration. We have completed a thorough QT trial in which LEVADEX did not increase QTc intervals as measured by electrocardiograms. We also completed a drug-drug interaction trial in which co-administration of LEVADEX with a potent CYP3A4 inhibitor showed no effects on the plasma levels of DHE or its elimination. Our clinical development program for LEVADEX may not lead to regulatory approval from the FDA and similar foreign regulatory agencies if we fail to demonstrate that the product candidate is safe and effective, and we may therefore fail to commercialize LEVADEX. Any failure to obtain regulatory approval of LEVADEX would have a material and adverse impact on our business.

With the suspension of development for our UDB product candidate, LEVADEX is our only current late stage product candidate. Our drug development efforts may not produce any other proprietary product candidates. We cannot be certain that we will be able to acquire or in-license other product candidates or develop other product candidates. Our failure to develop product candidates will limit our ability to generate additional revenue.

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 an NDA from the FDA for each product candidate. We have not received marketing approval for any of our product candidates in any country. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. Markets outside of the United States also have requirements for approval of drug candidates which we must comply with prior to marketing.

*We have entered into a collaboration arrangement with Allergan, pursuant to which Allergan will commercialize LEVADEX, with us, to neurologists and pain specialists in the United States, following regulatory approval of LEVADEX. We may not fully realize the potential benefits of our collaboration with Allergan which may lead to an inability to obtain significant sales within the neurology and pain specialist segment of the migraine market and we may not be able to commercialize LEVADEX to primary care physicians.*

We have entered into a collaboration agreement with Allergan targeting the neurology and pain specialist segment of the United States and Canada markets. We believe that adoption of LEVADEX by neurologists and pain specialists, who regularly treat migraine patients, will help to lead to broader adoption in the United States market. Our dependence on Allergan to help us to commercialize LEVADEX in this market segment and Allergan's performance under our collaboration agreement may not lead to physician uptake in this market and we may not be able to successfully commercialize LEVADEX in the neurology and pain specialist market. Our profits from the collaboration, if any, will be shared equally with Allergan and this arrangement may limit our overall profits and financial performance. While we believe that neurologists and pain specialists, because they treat migraine patients, may be early prescribers of LEVADEX and drive market adoption in the primary care physician segment of the market, our ability to enter into a partnership targeting primary care physicians may have an effect on the overall sales of LEVADEX. If we are unable to enter into a commercial partnership

## **Table of Contents**

targeting primary care physicians, we may be unable to commercialize LEVADEX to primary care physicians on our own, and we may not realize significant revenues from product sales relating to that segment.

***We may enter into additional collaborations with third parties to develop and commercialize our product candidates, including LEVADEX. These collaborations may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.***

We may enter into additional collaborations with third parties to develop and commercialize our product candidates, including LEVADEX. If LEVADEX is approved, we plan to jointly develop and fund research and development for two additional LEVADEX indications together with our partner Allergan. In addition, we may enter into a collaboration with a third party in the United States of America to commercialize LEVADEX to additional physicians including primary care physicians and/or to develop or commercialize LEVADEX outside the United States of America. Our dependence on current and future partners for development and commercialization of our product candidates will subject us to a number of risks, including:

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

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

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

partners may experience financial difficulties;

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

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

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

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

***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, including review of pre-clinical data, clinical data and inspection of facilities and processes, including those relating to clinical and manufacturing activities. Any delays in the regulatory review or approval of our product candidates in development would delay market launch, increase our cash requirements and result in additional operating losses. The FDA reviewed our NDA for LEVADEX and on March 26, 2012, we received a Complete Response letter. FDA

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

issues a Complete Response letter to an applicant to communicate the Agency's decision that an NDA will not be approved in its current form. In the Complete Response letter, the FDA described the reasons it was unable to approve our NDA and identified issues that the Company needs to address in order to obtain FDA approval for LEVADEX. Specifically, the FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated

## **Table of Contents**

that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter.

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

Data obtained from pre-clinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our products. In addition, as a routine part of the evaluation of any potential drug, clinical studies are generally conducted to assess the potential for drug-drug interactions that could impact potential product safety. We conducted a drug-drug interaction trial in which co-administration of LEVADEX with a potent CYP3A4 inhibitor showed no effects on the plasma levels of DHE or its elimination. 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.

***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 receive FDA marketing approval of our product candidates under Section 505(b)(2) of the FDCA. Section 505(b)(2), if applicable to us, would allow an NDA we file with the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the overall scope of work we must do ourselves. If we are unable to rely on Section 505(b)(2), we would also have to conduct more clinical trials than we had anticipated, and the development program for our product candidates would be longer than we expected.

---

**Table of Contents**

***If clinical trials of our LEVADEX product candidate 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 LEVADEX 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. In such cases, we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing, or we may decide not to pursue further development of a product candidate, such as the case of our UDB product candidate, where top-line results of our Phase 3 clinical trial indicated that the trial failed to meet the primary endpoints. Subsequently we suspended development of UDB. 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 our inability to obtain 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 and regulatory approval. 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 LEVADEX or any other product candidates would prevent regulatory approval and, ultimately, the commercialization of that product candidate.

***Because the results of prior clinical trials are not necessarily predictive of future results, LEVADEX or any other product candidate advanced into clinical trials may not have favorable results in subsequent clinical trials or receive regulatory approval.***

Success in pre-clinical studies and clinical trials does not ensure that subsequent 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 prior clinical trials.

The data collected from our clinical trials may not be adequate to support regulatory approval of LEVADEX or any of our other product candidates. In May 2009, we announced top-line results from the efficacy portion of our Phase 3 trial of LEVADEX, indicating that the trial met all four of its co-primary endpoints when LEVADEX was compared to placebo. We have completed a long-term safety extension of this Phase 3 trial, and no drug-related serious adverse events were reported in the trial. In July 2010, we announced that in a pharmacokinetics trial of LEVADEX, systemic absorption of LEVADEX was not higher and systemic exposure to DHE was not greater in smokers than in non-smokers. In September 2010, we reported results from a pharmacodynamics trial comparing the acute effects on pulmonary artery pressure of LEVADEX, DHE administered intravenously and placebo. In the trial, there was no statistically significant difference between the LEVADEX and placebo groups in the primary endpoint of pulmonary artery pressure over two hours after administration. In November 2010, we announced that in a thorough QT trial, a supra-therapeutic dose of LEVADEX did not increase QTc intervals. We also completed a drug-drug interaction trial in which co-administration of LEVADEX with a potent CYP3A4 inhibitor showed no effects on the plasma levels of DHE or its elimination. Even if we obtain regulatory approval of a product candidate, the FDA may require continuing



## **Table of Contents**

evaluation and study of our product through clinical trials as a condition of any approval. Despite the results reported in prior clinical trials for our product candidates, we do not know whether subsequent clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. For example, after receiving positive data from a previous Phase 2 trial, in February 2009 we announced top-line results from our Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints in either dose evaluated when compared to placebo. Subsequently, we suspended development of UDB.

***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. While we have completed clinical development for our LEVADEX product candidate for the acute treatment of migraine in adults, we may be requested by the FDA to conduct additional clinical trials. In addition we will need to conduct clinical trials for future product candidates. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may be required to withdraw from our clinical trial as a result of changing standards of care or may become ineligible to participate in clinical studies. The commencement, enrollment and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

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

obtaining regulatory approval to commence a clinical trial;

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

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

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

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

collecting, analyzing and reporting final data from the clinical trials.

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

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

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

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

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

We have completed a Phase 3 clinical program to support our NDA for LEVADEX. In October 2009, we submitted our top-line efficacy results for the double-blind efficacy portion of our pivotal Phase 3 study. We also have completed the long-term safety extension of our pivotal Phase 3 trial, a pharmacokinetics trial in healthy

---

**Table of Contents**

adult smokers and non-smokers, a pharmacodynamics trial measuring pulmonary artery pressure in healthy adults, a thorough QT trial and a drug-drug interaction trial in support of our NDA for LEVADEX. FDA communicated its agreement with the design, execution, and analyses for our pivotal Phase 3 trial, which we submitted to the FDA under the Special Protocol Assessment, or SPA, process and modified as suggested by FDA. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. In March 2010, we held a pre-NDA meeting with the FDA to discuss the clinical portion of our anticipated NDA filing. The FDA's minutes of that meeting state that, while the FDA did not have a record of a formal SPA, the FDA concurred with the selection of our co-primary endpoints and confirmed that a second pivotal efficacy study was not necessary if top-line efficacy results were confirmed during the NDA review. We believe that our prior written correspondence and interactions with the FDA under the SPA process constitute an SPA with the agency. The FDA may take a different view and could request additional safety and efficacy studies without having to identify a substantial scientific issue with our Phase 3 trial that is essential to determining the safety and efficacy of LEVADEX. If we are required to conduct additional clinical trials or other testing of our LEVADEX product candidate beyond those that we currently contemplate, we may be delayed in obtaining, or may not be able to obtain, marketing approval for this product candidate. We may not be able to obtain approval for indications that are as broad as intended or we may obtain approval for indications different than those indications for which we seek approval. Furthermore we may not be able to obtain approval for any of our other product candidates.

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

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

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

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

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

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

lower demonstrated efficacy and a less favorable safety or tolerability profile compared to other products;

device-related difficulties associated with our TEMPO inhaler;

prevalence and severity of adverse effects;

our failure to establish an effective sales and marketing infrastructure;

---

**Table of Contents**

ineffective marketing and distribution efforts by us or our collaborators;

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

our ability to manufacture sufficient inventory and supply wholesale distributors;

lack of cost-effectiveness;

timing of market introduction and perceived effectiveness of competitive products;

availability of alternative therapies, including generics, at similar or lower costs;

extent of a Risk Evaluation and Mitigation Strategies, or REMS, program, if any;

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

potential product liability claims.

Our and our partners' ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our and our partners' ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Inhaled versions of certain previously approved drugs have suffered commercial failure, including inhaled insulin. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our and our partners' efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

***We have never marketed a drug before, and if we are unable to establish, or access an effective and specialized 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 specialized sales force in the United States. We have entered into a collaboration with Allergan pursuant to which we will co-promote LEVADEX to neurologists and pain specialists in the United States, following potential FDA approval of LEVADEX. We currently do not have significant internal sales, distribution and marketing capabilities. The development of a sales and marketing infrastructure for our domestic operations will require substantial resources and additional personnel with sales, distribution and marketing experience whom we do not currently employ, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay of any product launch. Many of these costs are being incurred in advance of notice to us that any of our product candidates has been approved. For example, in order to commercialize LEVADEX, we will need to hire, train and deploy a specialized sales force and marketing capabilities in the United States directed at high prescribers, including specialists such as neurologists and pain specialists. We may not be able to hire a specialized 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 neurology. If we are unable to establish our specialized sales force and marketing capability for our most advanced product candidate, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

We will also need to expend significant time and resources to train any sales force that we do hire to be credible and persuasive in discussing LEVADEX with these specialists. We will also need to train our sales force to ensure that a consistent and appropriate message about LEVADEX is being delivered to our potential customers. In addition, if we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of

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

LEVADEX and its proper administration, our efforts to successfully commercialize LEVADEX could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

## **Table of Contents**

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

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

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods for 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, pursuant to currently proposed healthcare reforms or otherwise. 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.

*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, extent of adverse side effects, time to market, pricing and reimbursement, and convenience of treatment procedures. One or more of our competitors may develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us, obtain approvals for such products from the FDA more rapidly than us or develop products based upon the principles underlying our proprietary technologies earlier than 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



---

## **Table of Contents**

sales and marketing resources and experience.

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

***The migraine market is extremely competitive which may negatively impact our ability to commercialize LEVADEX.***

If approved for the acute treatment of migraine, we anticipate that LEVADEX would compete against other marketed migraine therapies and may compete with products currently under development by both large and small companies. In 2011, there were approximately 13 million migraine-specific prescriptions written for the acute treatment of migraine, generating approximately \$1.7 billion in revenues in the U.S. The majority of the prescriptions written were in the triptan class, and the leading branded agent, Maxalt, generated approximately \$450 million in revenues in the U.S. However, in 2008 when the leading migraine-specific agent, Imitrex, became generic, the total market for migraine-specific prescriptions generated approximately \$2.5 billion in revenues in the U.S. There are at least six other branded triptan therapies being sold by pharmaceutical companies. Alternative formulations of triptans are available that may have faster onset of action than solid oral dosage forms. In April 2008, GlaxoSmithKline's Treximet, a combination oral formulation of sumatriptan and naproxen sodium, was approved by the FDA for the acute treatment of migraine. In July 2009, Zogenix, Inc.'s Sumavel DosePro needle-free sumatriptan was approved by the FDA for the acute treatment of migraine and cluster headache. Alternative formulations of dihydroergotamine, or DHE, include Migranal, which is nasally delivered, and which may become generically available prior to any commercial introduction of LEVADEX. In addition to the marketed migraine therapeutics, there may be product candidates under development by companies that could potentially be used for the acute treatment of migraine and compete with LEVADEX. In October 2010, Allergan, Inc.'s BOTOX botulinum toxin was approved by the FDA for the treatment of chronic migraine, a different indication than the acute treatment of migraine.

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

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

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

## **Table of Contents**

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 subject to more restricted use or to be taken off the market.***

If our most advanced product candidate, LEVADEX, or any other product candidate, 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, contraindications 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, change the labeling of the product or conduct a Risk Evaluation and Mitigation Strategies, or REMS, program;

we may have limitations on how we promote our drugs;

sales of products may decrease significantly;

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

our reputation may suffer.

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

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

Even if we obtain U.S. regulatory approval for LEVADEX, the FDA may still impose significant restrictions on its 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. In addition, the FDA could condition any approval of LEVADEX on our implementation of a post-approval risk management plan. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to provide adequate oversight of the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. 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 LEVADEX or any other product candidates may include a restriction on the term of its use, such as a black box warning, 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 LEVADEX labeling to carry this contraindication.

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

Our product candidates will also be subject to ongoing FDA requirements for the current Good Manufacturing Practices, or cGMP, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products,

## **Table of Contents**

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 requesting withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, or fail to be made in compliance with applicable regulatory requirements such as cGMP, a regulatory agency may:

issue warning letters or untitled letters identifying violations;

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 review of pending NDAs or approval of new products;

suspend any ongoing clinical trials;

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

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

seize or detain products or require a product recall.

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

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

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

Government agencies issue regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health/science foundations and organizations involved in various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage, dosage, route of administration and use of related or competing therapies. 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.***

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

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if any, 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

## **Table of Contents**

we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our product candidates;

loss of revenues;

the inability to commercialize our product candidates;

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; and

impairment of our business reputation.

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

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

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals, including employees, to hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use of these materials and our liability may exceed our total assets. We maintain limited 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

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

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.

---

## **Table of Contents**

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

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

We have a collaboration agreement with Allergan to commercialize LEVADEX to neurologists and pain specialists in the United States and Canada. We may establish additional marketing, sales and distribution collaborations with third parties where appropriate. For example, if we choose to expand the marketing and sales of LEVADEX to additional physicians including primary care physicians beyond neurologists and pain specialists, we may establish partnerships with other companies to maximize the potential of the commercialization opportunity. Outside the United States and Canada, we may establish commercial partnerships for LEVADEX in order to effectively reach target markets in order to maximize its commercial opportunities. We expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize LEVADEX to primary care physicians or outside the United States and Canada. 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 LEVADEX.

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

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

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, quality assurance and hazardous materials handling;

the possible breach of the manufacturing and quality 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 of required approvals or commercialization of our products, could prevent us from commercializing our product candidates successfully, could cause the suspension of initiation or completion of clinical trials and regulatory submissions, and could lead to higher product costs.



---

**Table of Contents**

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. We have received a Complete Response letter in which the FDA described the reasons it was unable to approve our NDA and identified issues that the Company needs to address in order to obtain FDA approval for LEVADEX. Specifically, FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter.

***We will rely on third parties to perform many essential services for LEVADEX and any other products that we commercialize, including services related to warehousing and inventory control, distribution, customer service, accounts receivable management, cash collection and adverse event reporting, and if such third parties fail to perform as expected or to comply with legal and regulatory requirements, our efforts to commercialize LEVADEX or any other products may be significantly impacted and we may be subject to regulatory sanctions.***

We intend to rely on third-party service providers to perform a variety of functions related to the sale and distribution of LEVADEX, key aspects of which are out of our direct control. The services provided by these third parties include warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection. As a result, most of our inventory will be stored at a single warehouse maintained by one such service provider. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or if our products encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we have engaged third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding LEVADEX and related services. If the quality or accuracy of the data maintained or services performed by these third parties is insufficient, we could be subject to regulatory sanctions.

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

We may not be able to establish or maintain collaborations around our product candidates, which may adversely affect our ability to develop and commercialize our product candidates. We have entered into a collaboration agreement and co-promotion agreement with Allergan pursuant to which Allergan will co-promote LEVADEX to neurologists and pain specialists in the United States, following potential FDA product approval, and will share expenses relating to the commercialization of LEVADEX. Under certain circumstances, Allergan has the right to terminate these agreements. If Allergan terminates our agreement, we would not receive milestones due after the termination date, and we would be responsible for commercialization expenses previously shared with Allergan. Also in the event of a termination by Allergan, we may have difficulty commercializing LEVADEX to neurologists and pain specialists, as we have no experience marketing pharmaceutical products on our own. In July 2009, we received a notice of termination of our AstraZeneca Agreement related to our UDB product candidate. Our AstraZeneca Agreement provided that AstraZeneca could terminate the agreement in the event that the primary endpoints of our Phase 3 clinical trial of UDB were not met. Following the termination of the AstraZeneca Agreement, we suspended development of UDB. In addition, our earlier stage product portfolio includes next generation budesonide, MAP0005 for the potential treatment of asthma and COPD and MAP0001 for the potential treatment of diabetes. We have no current intention to further

## **Table of Contents**

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 product candidates. We expect to face competition in seeking appropriate partners. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, if any. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may not be successful. If we seek partners to help develop next generation budesonide, MAP0005 and MAP0001, but are unable to reach agreements with suitable partners, we may fail to commercialize such products.

### **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 from a third-party. 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 compositions or formulations 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 issued patents or pending patent applications;

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

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

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



## Table of Contents

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

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

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

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

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

If we or our partners choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop a third 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 prevent the other party's activities 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. We are aware that claims in patents owned by others may relate to our business and technologies. 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. If we are sued for patent infringement, there is a risk that a court 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 patent rights. 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.

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

## **Table of Contents**

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 by others covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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

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

We are a party to a license agreement with Nektar Therapeutics UK Limited, pursuant to which we license the use of key intellectual property, including intellectual property relating to our most advanced product candidate, LEVADEX. 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 candidate, 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, Managing Growth and Accounting Matters**

***We need to transform our company by adding commercial expertise.***

From inception to date, we have focused on research and development, including our pre-clinical development activities, clinical trials, manufacturing-related activities and the preparation of our NDA for LEVADEX. In connection with the potential commercialization of LEVADEX, if approved, we will need to add personnel with expertise in new areas for our company, such as sales, marketing and distribution, and to have our existing employees learn additional skills to support our commercialization efforts. We may not be able to attract or retain qualified employees with sales, marketing and distribution experience, due to competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Silicon Valley region of California. In addition, we will need to integrate employees with sales, marketing and distribution expertise into our company, which to date has focused predominantly on research and development activities. If we are not able to attract and retain necessary personnel, we may experience constraints that will significantly impede the achievement of our commercialization strategy.

---

**Table of Contents**

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

As December 31, 2011, we had 116 full-time employees. If LEVADEX is approved, we will need to expand our managerial, operational, administrative and other resources in order to commercialize our product candidates, manage and fund our operations and continue our development activities. To support this growth, we intend 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 development program for LEVADEX, including manufacturing and regulatory activities in support of the NDA process with the FDA, and potential approval from the FDA;

begin activities related to commercialization, and effectively hire, train and manage a sales force, who will have no prior experience with our company or LEVADEX, and establish appropriate systems, policies and infrastructure to support our commercial organization; 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, commercial, scientific and clinical personnel in the future due to competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Silicon Valley region of California. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

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

*Our management's determination that there was a material weakness in our internal control over financial reporting could have a material adverse impact on us.*

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that

## **Table of Contents**

fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, management's assessment of our internal controls over financial reporting.

In Item 9A of this report, management determined that there was a material weakness in our internal control over the evaluation of, and accounting for, a complex multiple element arrangement, in this case timing of recognition of revenue related to an upfront payment from Allergan, which timing had no impact on the Company's cash position, total assets or operating expenses. As a result, our internal control over financial reporting was not effective as of the end of the period covered by this report. Due to this material weakness, our principal executive officer and principal financial officer also concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report. Consequently, and pending our remediation of the matters that caused the control deficiencies underlying the material weaknesses, our business and results of operations could be harmed, we may be unable to report properly or timely the results of our operations, and investors may lose faith in the reliability of our financial statements. Accordingly, the price of our securities may be adversely and materially impacted.

The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify any additional material weaknesses in our internal controls in the future.

### **Risks Relating to Owning 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 conditions and operating results;

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

actions and decisions by our collaborators or partners;

status and/or results of our clinical trials;

results of clinical trials of our competitors' products;

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

rate of prescription growth for LEVADEX, if approved, and how that growth compares to analyst expectations;

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

competition from existing products, new products or generics that may emerge;

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

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

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

market conditions for biopharmaceutical stocks in general; and

general economic and market conditions.



## **Table of Contents**

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

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

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

Persons who were our stockholders prior to the sale of shares in our IPO continue to hold a large number of shares of our common stock that they are now able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a large 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 large 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 or plan to register all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers may establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

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

As a public company, we will continue to incur significant legal, accounting and other expenses to comply with the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the Securities and Exchange Commission and by the NASDAQ Global Market. In addition, any changes in such regulations will result in increased costs to us as we respond to these requirements. For example, we must use certain required internal controls and disclosure controls and procedures, as required by Section 404 of the Sarbanes-Oxley Act of 2002. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. In addition, we will continue to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and related regulations implemented by the Securities and Exchange Commission and The NASDAQ Global Market, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We are currently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We will continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from potentially revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by

## **Table of Contents**

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 cash and future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

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

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**Table of Contents**

**ITEM 2. PROPERTIES**

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

<b>Location</b>	<b>Approximate Square Feet</b>	<b>Operation</b>	<b>Expiration</b>
2400 Bayshore Parkway, Mountain View, CA 94043	43,000	Office and Laboratory	Lease expires in June 2013, with four consecutive options to extend the expiration of the lease for periods of six months each.
2450 Bayshore Parkway, Mountain View, CA 94043	8,000	Office	Lease expires in June 2013.

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

**ITEM 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceeding.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

**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 (and since January 3, 2012, on the NASDAQ Global Select 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>High</b>	<b>Low</b>
<b>Year Ended December 31, 2011:</b>		
First Quarter	\$ 16.94	\$ 13.69
Second Quarter	\$ 17.35	\$ 12.93
Third Quarter	\$ 16.44	\$ 10.54
Fourth Quarter	\$ 16.19	\$ 11.95
<b>Year Ended December 31, 2010:</b>		
First Quarter	\$ 17.83	\$ 9.34
Second Quarter	\$ 18.97	\$ 11.32
Third Quarter	\$ 15.49	\$ 10.61
Fourth Quarter	\$ 16.98	\$ 13.95
<b>Holders of Record</b>		

As of March 26, 2012, there were approximately 35 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 SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of MAP Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph shows a comparison from October 5, 2007 (the date our common stock commenced trading on the NASDAQ Global Market) through December 31, 2011 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.

	10/5/07	12/31/07	3/31/08	6/30/08	9/30/08	12/31/08	3/31/09	6/30/09	9/30/09	12/31/09
MAP Pharmaceuticals, Inc.	100.00	131.16	104.64	77.38	75.81	52.28	15.73	91.54	78.35	71.39
NASDAQ Composite	100.00	97.74	83.86	84.36	75.56	58.19	56.38	67.76	78.60	84.38
NASDAQ Biotechnology	100.00	93.40	91.01	92.72	95.36	87.98	81.98	89.10	98.69	100.25

	3/31/10	6/30/10	9/30/10	12/31/10	3/31/11	6/30/11	9/30/11	12/31/11
MAP Pharmaceuticals, Inc.	119.03	98.05	114.61	125.39	103.30	119.63	109.51	98.65
NASDAQ Composite	89.25	78.83	88.73	99.36	104.39	104.25	90.72	98.22
NASDAQ Biotechnology	109.63	92.69	101.03	106.76	112.01	119.10	102.80	113.45

**Unregistered Sales of Equity Securities and Uses of Proceeds**

There were no sales of unregistered equity securities by us for the fiscal period ended December 31, 2011.

**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. The consolidated statements of operations data for the years ended December 31, 2011, 2010, 2009 and for the period from July 3, 2003 (date of inception) through December 31, 2011, and the consolidated balance sheet data as of December 31, 2011 and 2010, are derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2008 and 2007, and the consolidated balance sheet data as of December 31, 2009, 2008 and 2007, 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, 2011
	2011	2010	2009	2008	2007	
(in thousands, except per share data)						
<b>Consolidated Statement of Operations Data:</b>						
Collaboration revenue	\$ 23,069	\$	\$ 54,166	\$	\$	\$ 77,235
Operating expenses						
Research and development	33,663	37,775	47,996	59,277	31,362	251,132
Sales, general and administrative	22,060	15,713	13,139	13,417	9,567	84,974
Total operating expenses	55,723	53,488	61,135	72,694	40,929	336,106
Loss from operations	(32,654)	(53,488)	(6,969)	(72,694)	(40,929)	(258,871)
Interest income	63	37	119	2,103	2,775	6,468
Interest expense	(316)	(1,242)	(2,118)	(2,056)	(1,343)	(7,309)
Other income (expense), net	(32)	20	(29)	(281)	(563)	(774)
Net loss	\$ (32,939)	\$ (54,673)	\$ (8,997)	\$ (72,928)	\$ (40,060)	\$ (260,486)
Net loss attributed to common stockholders	\$ (32,939)	\$ (54,673)	\$ (8,997)	\$ (72,928)	\$ (45,635)	\$ (274,411)
Net loss per share attributed to common stockholders - Basic and diluted	\$ (1.08)	\$ (2.01)	\$ (0.41)	\$ (3.58)	\$ (8.28)	
Weighted average shares outstanding used in calculating net loss per share attributed to common stockholders - Basic and diluted	30,377	27,261	22,195	20,350	5,510	

	As of Year Ended December 31,				
	2011	2010	2009	2008	2007
(in thousands)					
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 98,816	\$ 76,007	\$ 65,776	\$ 44,710	\$ 94,990
Working capital	86,073	56,630	44,629	22,091	83,337
Total assets	107,338	82,794	70,996	50,860	100,695
Long-term debt, net of current portion			7,337	14,229	6,357
Deficit accumulated during the development stage	(272,503)	(239,564)	(184,891)	(175,894)	(102,966)
Total stockholders' equity	39,552	62,656	41,802	13,147	81,606



---

## **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**

Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. We are developing proprietary product candidates that address large market opportunities in the field of neurology.

Our strategy is to commercialize and develop differentiated neurology product candidates that can address significant unmet medical needs and overcome limitations of existing products. Key elements of our strategy include:

Obtain regulatory approval for our most advanced product candidate, LEVADEX<sup>®</sup> orally inhaled migraine drug, for the potential acute treatment of migraine in adults;

Build a specialized sales force to commercialize LEVADEX to neurologists and pain specialists in the United States (U.S.);

Expand the market opportunity for LEVADEX; and

Advance and expand our neurology product pipeline by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional potential product candidates offering unique features and benefits.

Our current focus is to advance our lead product candidate, LEVADEX, formerly known as MAP0004, a proprietary orally inhaled version of dihydroergotamine mesylate, or DHE, for the potential acute treatment of migraine. We are in the development stage and since our inception, we have devoted substantially all of our efforts to research and development, raising capital and recruiting personnel. We completed clinical development for LEVADEX in 2010 and in May 2011 we submitted our New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA. The FDA reviewed our NDA and on March 26, 2012, we received a Complete Response letter. In the Complete Response letter, the FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX, FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter. In collaboration with Allergan, Inc., we plan to commercialize LEVADEX directly to neurologists and pain specialists in the U.S. and Canada, if approved. We are also evaluating options to commercialize LEVADEX to additional physicians in the U.S. and Canada and to physicians in markets outside the U.S. and Canada.

#### **Our Lead Product Candidate LEVADEX**

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. Migraines 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 approximately 12% of the population in the U.S. and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people





## **Table of Contents**

in the U.S. suffer from migraine. Migraine is more common in women, with about 18% of women affected and 6% of men. Migraine prevalence is highest during the peak productive ages of 25 to 55, which results in high costs to employers and managed care organizations.

Migraine is listed in the top 20 causes of disabling conditions and in the top four neurologic disabling conditions by the World Health Organization, or WHO. Related disability from migraine is substantial, with over 90% of sufferers experiencing functional impairment with their migraine that can disrupt every aspect of day to day life, including work, school, family and social relationships. More than half of the sufferers report severe impairment or the need for bed rest as a result of their migraines, according to published surveys. The economic burden of migraine remains substantial despite existing treatments with patients losing four to six work days each year due to migraine. The combination of direct and indirect costs of migraine in the U.S. is estimated at over \$20 billion annually.

In 2011, there were approximately 13 million migraine-specific prescriptions written for the acute treatment of migraine, generating approximately \$1.7 billion in revenues in the U.S. The majority of the prescriptions written were in the triptan class, and the leading branded agent, Maxalt, generated approximately \$450 million in revenues in the U.S. However, in 2008 when the leading migraine-specific agent, Imitrex, became generic, the total market for migraine-specific prescriptions generated approximately \$2.5 billion in revenues in the U.S.

LEVADEX is an easy to use, at-home therapy in development that patients self-administer using our proprietary hand-held TEMPO® inhaler. We have designed LEVADEX to provide faster onset and longer-lasting migraine relief than triptans, the class of drugs most often prescribed for treating migraine. DHE currently is available as an intravenous, or IV, therapy which has been used in clinical settings for over 50 years for the safe and effective treatment of migraine, particularly forms of migraine that are severe or do not respond to triptans or other therapies. We believe LEVADEX has the potential to be suitable as a first-line therapy for some migraine patients.

The LEVADEX clinical development program was a comprehensive program under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, that evaluated the efficacy, safety, pharmacokinetics and pharmacodynamics of LEVADEX in approximately 1,000 patients across nine trials. In our clinical trials conducted for LEVADEX, no drug-related serious adverse events have been reported.

In the efficacy portion of our pivotal Phase 3 FREEDOM-301 clinical trial, LEVADEX met all four primary endpoints, showing statistically significant improvement in pain relief ( $p < 0.0001$ ), freedom from phonophobia (sensitivity to sound) ( $p < 0.0001$ ), freedom from photophobia (sensitivity to light) ( $p < 0.0001$ ) and freedom from nausea ( $p = 0.02$ ) as reported two hours after dosing. Additional endpoints showed that LEVADEX provided rapid pain relief in 30 minutes and sustained pain relief for up to 48 hours after dosing. LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at 6%, with 2% of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at 5%, compared with 2% for placebo. We completed a 12 month open-label safety extension of our FREEDOM 301 trial, which evaluated lung function and cardiovascular parameters, during which approximately 9,500 headaches were treated and over 250 subjects completed 12 months of exposure. There were no mean decreases in lung function, as measured by spirometry, between the LEVADEX and placebo groups. There were no drug-related serious adverse events reported in the trial.

We also have completed additional clinical pharmacology trials that include a pharmacokinetic (PK) trial in smokers, a pharmacodynamics (PD) trial evaluating pulmonary artery pressure using echocardiogram, a thorough QT trial, a PK trial in asthmatics and a drug-drug interaction trial.

---

## **Table of Contents**

### **Neurology Pipeline**

We are exploring options to advance and expand our neurology product pipeline by leveraging our technologies and our extensive scientific expertise in aerosol science and pharmaceutical technology to develop additional neurological product candidates offering unique features and benefits.

Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. Our strategy is to develop differentiated neurology products that address large market opportunities with significant unmet medical needs. We intend to commercialize potential future products through the sales force we intend to build upon the potential commercialization of LEVADEX. Our goal is to submit an Investigational New Drug Application, or IND, in 2012 and another IND in 2013. We are currently developing two early stage, pre-clinical product candidates, including one in Parkinson's disease and another in epilepsy.

### **Allergan Collaboration**

On January 28, 2011, we entered into a Collaboration Agreement, or the Collaboration Agreement, and a Co-Promotion Agreement, or the Co-Promotion Agreement, and together with the Collaboration Agreement, the Allergan Agreements, with Allergan, Inc., Allergan USA, Inc. and Allergan Sales, LLC, or collectively, Allergan. Pursuant to the terms of the Allergan Agreements, we have granted Allergan a co-exclusive license, or the Allergan License, to market and co-promote LEVADEX, our proprietary novel migraine therapy for delivery by inhalation, to neurologists and pain specialists in the United States in collaboration with us. In July 2011, Allergan exercised its option to expand the Collaboration Agreement to include Canada for neurologists and pain specialists. Under the Allergan Agreements, we retain the right to market and co-promote LEVADEX to other physicians within the United States and Canada and also retain all rights to LEVADEX in all other countries. We and Allergan will each provide sales representatives and other sales support for such marketing and promotional efforts. The Allergan Agreements specify minimum annual sales detail requirements to be provided by each party, and establish maximum annual amounts of detailing costs that each party will be obligated to incur pursuant to a commercialization plan. The parties will collaborate in the development of LEVADEX for the treatment of migraine and for at least one other indication. We may develop LEVADEX for certain other indications independently of the collaboration if Allergan does not agree to develop LEVADEX for such indications pursuant to the Allergan Agreements. We will be responsible for manufacturing and distributing LEVADEX, and anticipate booking product revenues from sales of LEVADEX resulting from the parties' collaboration. The parties will share profits and losses resulting from the collaboration equally. We will be solely responsible for payment of all remaining costs of obtaining regulatory approval of LEVADEX for the acute treatment of migraine in adults, except that if the FDA notifies us that additional development or manufacturing activities costing in excess of a certain threshold amount will be required for such regulatory approval, the parties will share any such excess costs. The parties generally will share equally all other costs of developing LEVADEX under the Allergan Agreements, except that neither party shall be obligated for more than a certain threshold amount in a given year, or for more than a certain threshold amount in the aggregate, for development or manufacturing costs or expenses incurred by us for such activities.

In February 2011, Allergan paid us an upfront payment of \$60.0 million, out of which we recognized \$3.1 million as collaboration revenue for the year ended December 31, 2011 and deferred the remaining \$56.9 million, which will be amortized as collaboration revenue through the end date of the deliverable under the Collaboration Agreement with the longest term. Our participation in joint committees with Allergan has the longest obligation period, requiring our participation throughout the term of the Collaboration Agreement. The term of the Collaboration Agreement is the later of (a) December 31, 2025, and (b) the date that our last patent right covering LEVADEX in the United States expires. The date that our last patent right covering LEVADEX in the United States expires is 2028. As a result, we will amortize the remaining \$56.9 million of the initial \$60.0 million through 2028.

During the third quarter ended September 30, 2011, the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of the Allergan Agreements, Allergan paid us a milestone payment of \$20.0 million.

## **Table of Contents**

We have determined that the achievement of this milestone was substantive and we recorded the \$20.0 million as collaboration revenue on our consolidated statements of operations for the year ended December 31, 2011.

In addition to the \$20.0 million milestone described above, under the terms of the Collaboration Agreement, we may also receive up to an additional \$77.0 million in milestone payments, including \$50.0 million for the first commercial sale of LEVADEX associated with the initial indication (the acute treatment of migraine), up to \$25.0 million for the achievement of certain FDA-approved product labeling in the United States and \$2.0 million for regulatory approval of the initial indication for LEVADEX in Canada.

Sales, general and administrative expenses for the year ended December 31, 2011, as well as for the cumulative period from July 3, 2003 (date of inception) to December 31, 2011, were net of \$1.4 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements.

## **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 revenues and 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.

### ***Revenue Recognition***

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Collaboration revenue, which is earned under license agreements with third parties, may include nonrefundable license fees, cost reimbursements and contingent milestones.

Before January 1, 2011, we evaluated license arrangements with multiple elements in accordance with Accounting Standards Codification, or ASC, 605-25 *Revenue Recognition - Multiple-Element Arrangements*. In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2009-13 *Revenue Arrangements with Multiple Deliverables*, or ASU 2009-13, which amended the accounting standards for certain multiple element revenue arrangements to:

provide updated guidance on whether multiple elements exist, how the elements in an arrangement should be separated, and how the arrangement consideration should be allocated to the separate elements;

require an entity to allocate arrangement consideration to each element based on a selling price hierarchy, also called the relative selling price method, where the selling price for an element is based on vendor-specific objective evidence ( VSOE ), if available; third-party evidence ( TPE ), if available and VSOE is not available; or the best estimate of selling price ( ESP ), if neither VSOE nor TPE is available; and

eliminate the use of the residual method and require an entity to allocate arrangement consideration using the selling price hierarchy. The revenue allocated to each element is then recognized when the basic revenue recognition criteria are met for that element.



## **Table of Contents**

On January 1, 2011, we adopted ASU 2009-13 on a prospective basis. The new accounting standard for revenue recognition, if applied in the same manner to the year ended December 31, 2010, would not have any impact to total revenue and deferred revenue for that fiscal year as we did not have any collaboration revenue in fiscal 2010 or any deferred revenue as of December 31, 2010. The new accounting guidance for revenue recognition is not expected to have a significant effect on total net revenue in periods after initial adoption, although the impact on the timing of revenue will vary depending on the evaluation of the elements of any new arrangements.

VSOE is based on the price charged when the element is sold separately and is the price actually charged for that deliverable. We typically are not able to establish VSOE for the elements of a license arrangement because each arrangement is unique, an arrangement typically consists of multiple elements and we have limited history of entering into license arrangements.

When VSOE cannot be established, we attempt to establish the selling price of the elements of a license arrangement based on TPE. TPE is determined based on a competitor's price for similar deliverables when sold separately. We typically are not able to determine TPE for license arrangements, as they contain a significant level of differentiation such that the comparable pricing of a competitor's license arrangement with similar functionality cannot be obtained, and we are therefore unable to reliably determine what a similar competitor's license arrangement's selling price would be on a standalone basis.

When we are unable to establish the selling price of an element using VSOE or TPE, we use the ESP in our allocation of the upfront payment. The objective of the ESP is to determine the price at which we would transact a sale if the element of the license arrangement were sold on a standalone basis.

Our process for determining ESPs involves management's judgment. Our process considers multiple factors such as discounted cash flows, estimated direct expenses and other costs and available data, which may vary over time, depending upon the circumstances, and relate to each deliverable. If the estimated obligation period of one or more deliverables should change, the future amortization of the revenue would also change. We regularly review ESP and maintain internal controls over the establishment and updates of the estimates.

The Allergan Agreements entered into in February 2011 contain multiple elements, including a license to commercialize our product candidate, regulatory approval and manufacturing for our product candidate, and various committee participations. We received an upfront cash payment of \$60.0 million from Allergan upon execution of the Allergan Agreements. In accordance with ASU 2009-13, we evaluated whether there is standalone value for each of the various deliverables. As we have determined that the license and other non-contingent deliverables do not have standalone value, they must be combined with all the remaining deliverables to Allergan because the License could not be deemed to be fully delivered for its intended purpose unless we continue to perform our other obligations under the Collaboration Agreement. Accordingly, they do not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront payment is deferred and will be recognized on a straight-line basis over the term of the Allergan Agreements through 2028, which represents the estimated obligation period.

We recognize a contingent milestone payment as revenue in its entirety upon our achievement of the milestone. A milestone is substantive if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

---

## **Table of Contents**

### ***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, or CROs, in connection with pre-clinical studies;

fees paid to CROs and investigative sites in connection with clinical trials; and

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

Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain number of patients, site initiation and completion of clinical trial milestones. In accruing services fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and status meetings with CROs and review of contractual terms. Our estimates are dependent on the timeliness and accuracy of data provided by our CROs and other vendors.

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

Effective January 1, 2006, we adopted ASC 718 *Compensation – Stock Compensation*, or ASC 718, using the prospective transition method, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. ASC 718 requires companies to estimate the fair value of the stock-based payment awards on the date of grant using an option-pricing model. Our financial statements reflect the impact of ASC 718. We chose the straight-line attribution method for allocating compensation costs and recognize the fair value of each stock option on a straight-line basis over the requisite service period.

For stock option grants and shares from the Employee Stock Purchase Plan, or ESPP, we selected the Black-Scholes valuation model as the most appropriate valuation method. The fair value of these stock options grants and shares from the ESPP is estimated as of the date of grant using the Black-Scholes valuation model. The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of our stock options or shares from the ESPP. The expected stock price volatility of stock options 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 sufficient trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar to us in size, stage of life-cycle and financial leverage. We will continue to analyze the expected stock price volatility of stock options as more historical data for our common stock becomes available. Effective on January 1, 2010, the expected stock price volatility for shares from the ESPP is determined based on our own historical volatilities. The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the historical experience that we have had with stock option grants as well as the expected term of 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 the full term of our stock options. We will continue to analyze the expected term of stock options as more historical data for our common stock becomes available. The expected term for shares from the ESPP is determined based on the length of offering periods for the ESPP. The expected dividend yield of 0% is based on our history and expectation of dividend payouts. We do not anticipate paying any dividends in the near future. We have not paid any dividends, other than a cumulative dividend on our preferred stock paid in connection with our initial public offering, or IPO, in 2007, pursuant to the terms of our certificate of incorporation. Forfeitures are determined based on when awards are ultimately expected to vest. ASC 718 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.

## **Table of Contents**

For restricted stock units, or RSUs, with time-based vesting, the fair value is based on the closing price of our common stock on the date of grant. We measure compensation expense for these RSUs at fair value on the date of grant and recognize the expense over the expected vesting period, after considering the estimated forfeitures

For RSUs with performance-based vesting, the fair value is based on the closing price of our common stock on the date of grant. A probability assessment that performance goals will be achieved is made quarterly. The compensation expense is recognized over the vesting period, and is adjusted periodically for forfeiture rate and any changes to our probability assessment of the number of performance-based RSUs expected to vest as a result of our achievement of the performance goals.

We account for equity instruments issued to non-employees in accordance with ASC 505-50 *Equity- Equity-Based Payments to Non-Employees*. 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.

### ***Net Operating Loss Carryforwards***

At December 31, 2011, we had federal and state net operating loss carryforwards of approximately \$242.4 million and \$231.0 million, respectively. The net operating loss carryforwards expire between 2018 and 2030, 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 \$12.6 million, increased by \$23.3 million, and increased by \$6.4 million during the years ended December 31, 2011, 2010 and 2009, respectively.

As of December 31, 2011, we also had federal and state research and development tax credit carryforwards of approximately \$7.4 million and \$3.9 million, respectively. If not utilized, the federal carryforwards will expire beginning in 2024. 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 ASC 740-10, *Accounting for Uncertainty in Income Taxes*, on January 1, 2007. As of December 31, 2011, we had no unrecognized tax benefits. As of December 31, 2011 we have not recorded any interest or penalties under this pronouncement.

## **Financial Overview**

### ***Collaboration Revenue***

Collaboration revenue, which is earned under agreements with third parties for various activities, may include nonrefundable license fees, cost reimbursements and contingent milestone payments.

Through December 31, 2011, we had recorded approximately \$77.2 million in collaboration revenue since our inception in 2003.

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

Research and development costs include, but are not limited to: (i) expenses incurred under agreements with contract research organizations and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) milestone payments paid to our collaborative partners who work on our processing and supply of clinical trial material; (iii) the cost of manufacturing and supplying clinical trial materials; (iv) payments to contract service organizations, as well as consultants; (v) employee-related expenses, which include salaries and benefits; (vi) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies; and (vii) stock-based compensation expense. All research and development expenses are expensed as incurred.



**Table of Contents**

Conducting a significant amount of research and development is central to our business model. Through December 31, 2011, we had incurred approximately \$251.1 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 later-stage clinical trials. We plan to incur substantial research and development expenses for the foreseeable future in order to complete development of and pursue additional indications for our most advanced product candidate, LEVADEX, and to conduct earlier-stage research and development projects.

The following table summarizes the percentages of our research and development expenses related to our LEVADEX program, our Unit Dose Budesonide, or UDB, program, which has been suspended, and other earlier stage projects for the years ended December 31, 2011, 2010 and 2009, respectively. 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, is not tracked on a project basis and has been allocated based on management estimates.

	Year Ended December 31,			Period from
	2011	2010	2009	July 3, 2003 (Date of Inception) through December 31, 2011
Our product candidates:				
LEVADEX	87%	91%	62%	62%
UDB (suspended)			25%	28%
Other projects	13%	9%	13%	10%
Total	100%	100%	100%	100%

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among other things, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, uncertainty associated with clinical trial enrollment and 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 most advanced product candidate, LEVADEX. We will need substantial additional capital in the future in order to commercialize LEVADEX and to fund the development and commercialization of future product candidates. We may receive additional payments pursuant to the Allergan Agreements.

***Sales, General and Administrative Expenses***

Sales, general and administrative expenses consist primarily of compensation for executive, finance, marketing, legal and administrative personnel, including stock-based compensation. Other sales, general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, other professional services, the cost of market research activities and consulting fees. Costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements are recorded as a reduction of sales, general and administrative expenses.

Through December 31, 2011, we incurred approximately \$85.0 million in sales, general and administrative expenses since our inception in 2003.

**Table of Contents****Results of Operations****Comparison of Years Ended December 31, 2011 and 2010**

	Year Ended December 31,		\$	% Increase/ (Decrease)
	2011	2010	Increase/ (Decrease)	(Decrease)
	(in thousands, except percentages)			
Collaboration revenue	\$ 23,069	\$	\$ 23,069	100%

*Collaboration Revenue.* The increase in collaboration revenue was due to the Allergan Agreements which were effective on January 28, 2011. In February 2011, Allergan paid us an upfront payment of \$60.0 million, out of which we recognized \$3.1 million as collaboration revenue for the year ended December 31, 2011 and deferred the remaining \$56.9 million, which will be amortized as collaboration revenue over the estimated obligation period.

During the third quarter ended September 30, 2011, the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of the Allergan Agreements, we received a milestone payment of \$20.0 million from Allergan. We have determined that the achievement of this milestone was substantive and we recorded the \$20.0 million as collaboration revenue on our consolidated statements of operations for the year ended December 31, 2011.

	Year Ended December 31,		\$	% Increase/ (Decrease)
	2011	2010	Increase/ (Decrease)	(Decrease)
	(in thousands, except percentages)			
Research and development expenses	\$ 33,663	\$ 37,775	\$ (4,112)	(11)%
Sales, general and administrative expenses	22,060	15,713	6,347	40%
Interest income	(63)	(37)	26	70%
Interest expense	316	1,242	(926)	(75)%
Other expense (income), net	32	(20)	52	*

\* Percentage is not meaningful.

*Research and Development Expenses.* The decrease in research and development expenses was due primarily to a decrease of \$5.7 million in expenses related to the LEVADEX program, partially offset by increases of \$0.9 million in personnel-related expenses, including stock-based compensation, primarily due to manufacturing-related headcount in support of commercial readiness activities and \$0.6 million in expenses related to earlier stage research projects.

*Sales, General and Administrative Expenses.* Sales, general and administrative expenses for the year ended December 31, 2011 were net of \$1.4 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements, \$0.7 million of which was received in cash for the year ended December 31, 2011.

The increase in sales, general and administrative expenses was due primarily to an increase of \$3.0 million in personnel-related expenses including stock-based compensation, and an increase of \$2.9 million in professional services, including LEVADEX related market research activities. The increase of \$2.9 million in professional services was net of \$1.4 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements mentioned above.

*Interest Income.* Interest income increased due primarily to an increase in the 12-month average cash and cash equivalents balances, partially offset by a decrease in market interest rates. We expect our interest income to fluctuate in the future due to changes in market interest rates and average cash, cash equivalents and short-term investment balances.

**Table of Contents**

*Interest Expense.* In May 2008, we entered into an agreement to borrow \$20.0 million, or the 2008 Working Capital Loan. The decrease in interest expense was due primarily to lower debt balances related to the 2008 Working Capital Loan. We repaid the 2008 Working Capital Loan in full in October 2011.

**Comparison of Years Ended December 31, 2010 and 2009**

	Year Ended December 31, 2010	Year Ended December 31, 2009 (in thousands, except percentages)	Increase/ (Decrease)	% Increase/ (Decrease)
Collaboration revenue	\$	\$ 54,166	\$ (54,166)	(100)%

*Collaboration Revenue.* Revenues for the year ended December 31, 2010 were \$0, compared to \$54.2 million for the year ended December 31, 2009. Total collaboration revenue recognized under the AstraZeneca Agreement was \$54.2 million for the year ended December 31, 2009 and consists of a \$40.0 million upfront payment and \$14.2 million from reimbursement of qualified development expenses. The AstraZeneca Agreement was terminated in July 2009.

	Year Ended December 31, 2010	Year Ended December 31, 2009 (in thousands, except percentages)	\$ Increase/ (Decrease)	% Increase/ (Decrease)
Research and development expenses	\$ 37,775	\$ 47,996	\$ (10,221)	(21)%
Sales, general and administrative expenses	15,713	13,139	2,574	20%
Interest income	(37)	(119)	(82)	(69)%
Interest expense	1,242	2,118	(876)	(41)%
Other (income) expense, net	(20)	29	49	*

\* Percentage is not meaningful.

*Research and Development Expenses.* The decrease in research and development expenses was due primarily to a decrease of \$8.8 million in clinical and other project expenses to support the UDB Phase 3 clinical program, which was suspended in the third quarter of 2009, and a decrease of \$3.5 million in clinical and other project expenses to support the LEVADEX Phase 3 clinical program. We completed clinical development for LEVADEX in 2010 and we submitted an NDA to the FDA and FDA accepted for filing our NDA in the first half of 2011, with a goal date of March 26, 2012 under the Prescription Drug User Fee Act. The decrease in research and development expenses was partially offset by an increase of \$2.1 million in personnel related expenses, including stock-based compensation.

*Sales, General and Administrative Expenses.* The increase in sales, general and administrative expenses was due primarily to an increase of \$1.3 million in personnel related expenses, including stock-based compensation, an increase of \$0.6 million in professional services and LEVADEX related market research activities and an increase of \$0.5 million in other expenses.

*Interest Income.* The decrease in interest income was due primarily to a decrease in market interest rates in the year ended December 31, 2010 as compared to 2009. We expect our interest income to fluctuate in the future with changes in average investment balances and market interest rates.

*Interest Expense.* The decrease in interest expense was due primarily to lower debt balances related to the 2008 Working Capital Loan. As of December 31, 2011, we had no debt outstanding.

## Table of Contents

### **Liquidity and Capital Resources**

#### *Liquidity*

We have incurred losses since our inception in July 2003 and as of December 31, 2011 we had an accumulated deficit of \$272.5 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we may continue to incur net losses for at least the next several years. We expect to incur increased research and development and sales, general and administrative expenses related to our development and potential commercialization of LEVADEX 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, the issuance of convertible notes and collaboration payments, as follows:

#### Equity

Prior to our IPO in October 2007, we received net proceeds of \$106.7 million from the issuance of convertible notes and convertible preferred stock;

With the completion of our IPO, we received net proceeds of \$62.1 million after deducting expenses and underwriters' discounts and commissions;

In August 2009, we completed a follow-on public offering in which we sold and issued 3,500,000 shares of our common stock at a price of \$9.70 per share. We raised a total of \$34.0 million in gross proceeds or approximately \$31.6 million in net proceeds after deducting expenses and underwriters' discounts and commissions;

In January 2010, we accessed our equity line of credit with Azimuth Opportunity Ltd., or Azimuth, and sold 1,527,695 shares of common stock at a price of approximately \$13.70 per share, less a discount of approximately 4.5% per share, for a net price of approximately \$13.09 per share. The total purchase price for these shares was \$20.0 million or approximately \$19.7 million after deducting the offering expenses;

In October 2010, we completed an equity offering in which we sold a total of 3,450,000 shares of common stock at an offering price of \$14.50 per share. We raised a total of \$50.0 million in gross proceeds, or approximately \$47.0 million in net proceeds after deducting underwriting discounts and commissions and offering expenses;

#### Debt

In September 2006, we entered into a loan facility agreement and borrowed \$10.0 million to finance working capital and a \$1.0 million loan facility to finance equipment purchases. We repaid in full the \$10.0 million working capital loan and the \$1.0 million equipment loan in May 2008 and September 2009, respectively;

In May 2008, we entered into the 2008 Working Capital Loan to borrow \$20.0 million, in order to repay an earlier working capital loan and to support general corporate purposes. We repaid in full the 2008 Working Capital Loan in October 2011;

#### Collaboration

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

In 2009, we received \$54.2 million in an upfront payment and reimbursement of qualified development expenses pursuant to our now terminated collaboration agreement with AstraZeneca AB;

In February 2011, we received a \$60.0 million upfront payment pursuant to the Allergan Agreements;

In August 2011, we received a \$20.0 million milestone payment from Allergan upon the FDA's acceptance for filing of our LEVADEX NDA;

**Table of Contents**

Sales, general and administrative expenses for the year ended December 31, 2011 were net of \$1.4 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements, \$0.7 million of which was received in cash for the year ended December 31, 2011.

As of December 31, 2011, we had approximately \$98.8 million in cash and cash equivalents. Our cash and cash equivalents are held primarily in money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy with a view toward capital preservation and liquidity.

**Cash Flows**

This data should be read in conjunction with our consolidated statements of cash flows.

	As of December 31,	
	2011	2010
	(in thousands)	
Cash and cash equivalents	\$ 98,816	\$ 76,007
Working capital	86,073	56,630
Stockholders' equity	39,552	62,656

A summary of our cash flows is as follows:

	Year Ended December 31,		
	2011	2010	2009
	(in thousands)		
Cash provided by (used in):			
Operating activities	\$ 30,807	\$ (49,363)	\$ (4,008)
Investing activities	\$ (2,844)	(2,080)	11,424
Financing activities	(5,154)	61,674	26,433

*Net cash provided by (used in) operating activities.* We received \$30.8 million of cash from operating activities for the year ended December 31, 2011, compared to cash usage of \$49.4 million for the year ended December 31, 2010. The cash provided by operating activities for the year ended December 31, 2011 was due primarily to a \$60.0 million upfront payment we received from Allergan in February 2011, which resulted in an increase in deferred revenue of \$56.9 million, a \$20.0 million milestone payment we received from Allergan in August 2011 and stock-based compensation of \$7.3 million, partially offset by a net loss of \$32.9 million and a decrease in accrued liabilities of \$2.5 million as a result of paying down expenses related to the LEVADEX Phase 3 clinical program. The increase of cash used for operating activities for the year ended December 31, 2010 as compared to the year ended December 31, 2009 was driven primarily by a net loss of \$54.7 million and a decrease in accrued liabilities of \$2.1 million as a result of paying down expenses related to the LEVADEX Phase 3 clinical program and the UDB program, which was suspended in the third quarter of 2009, partially offset by stock-based compensation of \$6.6 million. Net cash used for operating activities for the year ended December 31, 2009 was due primarily to a loss of \$9.0 million, as a result of revenue recognition of \$54.2 million from the AstraZeneca Agreement, which was terminated in July 2009, together with a decrease in accrued liabilities of \$3.9 million as a result of suspending the development of our UDB product candidate in the third quarter of 2009.

*Net cash provided by (used in) investing activities.* We used \$2.8 million of cash for investing activities for the year ended December 31, 2011, compared to cash usage of \$2.1 million for the year ended December 31, 2010. The usage of cash for both the year ended December 31, 2011 and 2010 was due to purchase of property and equipment. Net cash provided by investing activities of \$11.4 million for the year ended December 31, 2009 was due primarily to sales and maturities of our short-term investments of \$12.7 million.

*Net cash provided by (used in) financing activities.* We used \$5.2 million of cash for financing activities for the year ended December 31, 2011 compared to receiving cash of \$61.7 million for the year ended December 31, 2010. The usage of cash of \$5.2 million for the year ended December 31, 2011 was due primarily to the repayment of the remaining \$7.6 million of outstanding debt in the year ended December 31, 2011, partially

**Table of Contents**

offset by the net proceeds from issuance of common stock through equity plans of \$2.5 million. Net cash provided by financing activities for the year ended December 31, 2010 of \$61.7 million was due primarily to the net proceeds of approximately \$47.0 million from the issuance of our common stock from the equity offering we completed in October 2010, the net proceeds of approximately \$19.7 million from the issuance of our common stock from the drawdown of the equity line of credit with Azimuth completed in January 2010 and the proceeds of \$2.3 million from issuance of common stock through equity plans, partially offset by the repayment of \$7.3 million for the 2008 Working Capital Loan. Net cash provided by financing activities for the year ended December 31, 2009 of \$26.4 million was due primarily to the net proceeds of approximately \$31.6 million from the issuance of our common stock from the equity offering we completed and the proceeds of \$1.2 million from issuance of common stock through equity plans, partially offset by the repayment of \$6.3 million for the 2008 Working Capital Loan.

**Equity Line of Credit**

On November 11, 2009, we entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Azimuth, which provides us with what is sometimes termed an equity line of credit arrangement. Upon the terms and subject to the conditions set forth in the Purchase Agreement, Azimuth is committed to purchase up to \$60.0 million worth of shares of our common stock over the 24-month term of the Purchase Agreement; provided, however, in no event may we sell under the Purchase Agreement more than such number of shares of common stock which is equal to one share less than 20% of our outstanding shares of common stock on the effective date of the Purchase Agreement. From time to time over the term of the Purchase Agreement, and at our sole discretion, we may present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the price per share over ten consecutive trading days or such other period mutually agreed upon by Azimuth and us, with each draw down subject to limitations based on the price of our common stock and a maximum limit of 2.5% of our market capitalization at the time of such draw down, or such other limit of our market capitalization as mutually agreed upon by Azimuth and us.

In January 2010 we accessed our equity line of credit and sold 1,527,695 shares of common stock at a price of approximately \$13.70 per share less a discount of approximately 4.5% per share for a net price of approximately \$13.09 per share. The total purchase price for all these shares was \$20.0 million or approximately \$19.7 million after deducting offering expenses.

On November 29, 2011, we amended the Purchase Agreement to extend the term by up to 24 months past the original expiration date of December 1, 2011. As of December 31, 2011, the remaining aggregate dollar value of shares available for sale under the Purchase Agreement was \$40.0 million.

**Contractual Obligations**

The following table summarizes our contractual obligations as of December 31, 2011 (in thousands):

	2012	Year Ended December 31,		Total
		2013	Thereafter	
Future minimum lease payments(1)	1,672	863		2,535
Total	\$ 1,672	\$ 863	\$	\$ 2,535

(1) The amounts in the table above include the future minimum lease payments for our laboratory and office facilities in Mountain View, California. Please see Note 5. Commitments and Contingencies in Part II, Item 8 of this Form 10-K for additional information. The table above reflects only payment obligations that are fixed and determinable. Milestone payments and royalty payments under our license, supply and service agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur. Amounts and an estimate of significant payments related to licensing and other arrangements not included in the contractual obligations table above are as follows:

## **Table of Contents**

### *Agreement with Allergan*

Under the Collaboration Agreement with Allergan effective January 28, 2011, we are responsible for manufacturing and distributing LEVADEX, and anticipate booking product revenues from sales of LEVADEX resulting from the parties' collaboration. The parties share profits and losses resulting from the collaboration equally. We are solely responsible for payment of all remaining costs of obtaining regulatory approval of LEVADEX for the acute treatment of migraine in adults, except that if the FDA notifies us that additional development or manufacturing activities costing in excess of a certain threshold amount will be required for such regulatory approval, the parties will share any such excess costs. The parties generally share equally all other costs of developing LEVADEX under the Allergan Agreements, except that neither party shall be obligated for more than a certain threshold amount in a given year, or for more than a certain threshold amount in the aggregate, for development or manufacturing costs or expenses incurred by us for such activities. We have agreed to indemnify Allergan against any losses incurred in connection with, among other things, any negligence, recklessness or wrongful intentional acts by us, any breach by us of the Allergan Agreements, the development and commercialization of LEVADEX actually conducted by or for us or our affiliates or sublicensees, allegations that the manufacture, use or commercialization of LEVADEX infringes third party intellectual property rights, or allegations that personal injury or death or property damage was caused by a defect in LEVADEX manufactured by or for us. The Collaboration Agreement may be terminated (i) by Allergan, at will, after first commercial sale of LEVADEX in the United States, upon 180 days' prior written notice, (ii) by Allergan, upon written notice to us, if we receive a complete response letter or equivalent communication from the FDA, that Allergan determines will extend potential approval beyond a certain date or requires a certain minimum level of additional investment, (iii) by us, upon written notice to Allergan, if Allergan commercializes a competing product in the United States or Canada and (iv) by us, upon written notice to Allergan, if Allergan challenges or opposes patent rights licensed to Allergan pursuant to the Collaboration Agreement. Additionally, either party may terminate the Collaboration Agreement in the event of an uncured material breach. The Co-Promotion Agreement will terminate upon termination of the Collaboration Agreement.

### *Operating Capital and Capital Expenditure Requirements*

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

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

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

the cost and timing of establishing commercial infrastructure including sales, marketing, manufacturing and distribution capabilities;

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

the rate of market adoption of our product candidates for which we receive regulatory approval;

delays that may be caused by changing regulatory requirements;

the number of product candidates that we pursue;

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

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



the cost of maintaining adequate working capital;

the extent to which we acquire or invest in businesses, products or technologies; and

the possible costs of litigation.

## **Table of Contents**

We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least 12 months. We will need substantial additional capital in the future in order to complete the development and commercialization of LEVADEX and to fund the development and commercialization of any future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

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.

### **Recent Accounting Pronouncements**

In May 2011 the FASB and International Accounting Standards Board, or IASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04. ASU 2011-04 created a uniform framework for applying fair value measurement principles for companies around the world and clarified existing guidance in US GAAP. ASU 2011-04 is effective for the first reporting annual period beginning after December 15, 2011 and shall be applied prospectively. We will adopt ASU 2011-04 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-04 will have a material impact on our consolidated financial statements.

In June 2011 the FASB issued ASU No. 2011-05, *Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income*, or ASU 2011-05, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. However, the FASB agreed to an indefinite deferral of the reclassification requirement. The adoption of this standard is not expected to have a material impact on our results of operations, cash flows or financial position. We will adopt ASU 2011-05 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-05 will have a material impact on our consolidated financial statements.

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

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

**Table of Contents**

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk is confined to our 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. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and capturing a market rate of return based on our investment policy parameters and market conditions. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of investments in securities of high credit quality.

Our primary exposure to market risk is interest rate related, which is affected by changes in the general level of U.S. interest rates. We currently do not hedge interest rate exposure. Because of the very short term maturity nature 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. We do not have any foreign currency or other derivative financial instruments.

**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>	73
<u>Consolidated Balance Sheets</u>	74
<u>Consolidated Statements of Operations</u>	75
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	76
<u>Consolidated Statements of Cash Flows</u>	78
<u>Notes to Consolidated Financial Statements</u>	79

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

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

In our opinion, the consolidated financial statements listed in the accompanying index, present fairly, in all material respects, the financial position of MAP Pharmaceuticals, Inc. and its subsidiaries (a development stage enterprise) at December 31, 2011 and December 31, 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 and cumulatively for the period from July 3, 2003 (date of inception) to December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) because a material weakness in internal control over financial reporting related to the evaluation of, and accounting for, complex multiple element revenue arrangements existed as of that date. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness referred to above is described in Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. We considered this material weakness in determining the nature, timing, and extent of audit tests applied in our audit of the 2011 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements. The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in management's report referred to above. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 30, 2012

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

	December 31,	
	2011	2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 98,816	\$ 76,007
Accounts receivable	636	
Prepaid expenses and other current assets	763	644
Total current assets	100,215	76,651
Property and equipment, net	6,786	5,803
Other assets	27	30
Restricted investment	310	310
Total assets	\$ 107,338	\$ 82,794
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,860	\$ 2,998
Accrued liabilities	6,933	9,442
Current portion of long-term debt		7,581
Current portion of deferred revenue	3,349	
Total current liabilities	14,142	20,021
Deferred revenue, less current portion	53,581	
Other liabilities	63	117
Total liabilities	67,786	20,138
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock: \$0.01 par value; issuable in series; 5,000,000 shares authorized; none issued or outstanding		
Common stock: \$0.01 par value, 100,000,000 shares authorized; 30,586,336 and 30,189,650 shares issued and outstanding at December 31, 2011 and 2010, respectively	300	296
Additional paid-in capital	311,755	301,924
Deficit accumulated during the development stage	(272,503)	(239,564)
Total stockholders' equity	39,552	62,656
Total liabilities and stockholders' equity	\$ 107,338	\$ 82,794

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 per share amounts)**

	Years Ended December 31,			Cumulative Period from July 3, 2003 (Date of Inception) to December 31, 2011
	2011	2010	2009	
Collaboration revenue	\$ 23,069	\$	\$ 54,166	\$ 77,235
Operating expenses:				
Research and development	33,663	37,775	47,996	251,132
Sales, general and administrative	22,060	15,713	13,139	84,974
Total operating expenses	55,723	53,488	61,135	336,106
Loss from operations	(32,654)	(53,488)	(6,969)	(258,871)
Interest income	63	37	119	6,468
Interest expense	(316)	(1,242)	(2,118)	(7,309)
Other income (expense), net	(32)	20	(29)	(774)
Net loss	(32,939)	(54,673)	(8,997)	(260,486)
Cumulative stock dividend attributed to preferred stockholders				(13,925)
Net loss attributed to common stockholders	\$ (32,939)	\$ (54,673)	\$ (8,997)	\$ (274,411)
Net loss per share attributed to common stockholders -				
Basic and diluted	\$ (1.08)	\$ (2.01)	\$ (0.41)	
Weighted average shares outstanding used in calculating net loss per share attributed to common stockholders -				
Basic and diluted	30,377	27,261	22,195	

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 amounts)

	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 stock-based compensation expense recognized under ASC 718			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
			6		(6)	

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

Elimination of fractional shares resulting from reverse stock split						
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 stock-based compensation expense recognized under ASC 718				1,711		1,711
Stock-based compensation for non-employee services				249		249
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>	<b>20,228,362</b>	<b>197</b>	<b>184,194</b>	<b>181</b>	<b>(102,966)</b>	<b>81,606</b>

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

(a development stage enterprise)

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

(In thousands, except share and per share amounts)

	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 in conjunction with exercise of stock options and purchase under employee stock purchase plan	318,088	3	719			722
Employee stock-based compensation expense recognized under ASC 718			3,359			3,359
Stock-based compensation for non-employee services			534			534
Adjustment to issuance cost related to IPO			(9)			(9)
Components of other comprehensive loss:						
Change in unrealized loss on marketable securities				(137)		(137)
Net loss					(72,928)	(72,928)
Total comprehensive loss						(73,065)
<b>Balances at December 31, 2008</b>	20,546,450	200	188,797	44	(175,894)	13,147
Issuance of common stock in conjunction with exercise of stock options and purchase under employee stock purchase plan	644,399	6	1,156			1,162
Employee stock-based compensation expense recognized under ASC 718			4,835			4,835
Stock-based compensation for non-employee services			80			80
Issuance of common stock from follow-on public offering, net of issuance costs	3,500,000	35	31,584			31,619
Issuance of common stock from warrant exercise	5,817					
Components of other comprehensive loss:						
Change in unrealized loss on marketable securities				(44)		(44)
Net loss					(8,997)	(8,997)
Total comprehensive loss						(9,041)
<b>Balances at December 31, 2009</b>	24,696,666	241	226,452		(184,891)	41,802
Issuance of common stock in conjunction with exercise of stock options and purchase under employee stock purchase plan	502,994	5	2,268			2,273
Employee stock-based compensation expense recognized under ASC 718			6,572			6,572
Issuance of common stock from equity offering, net of issuance costs	3,450,000	35	46,994			47,029
Issuance of common stock from drawing down of Azimuth equity line of credit, net of issuance costs	1,527,695	15	19,638			19,653
Issuance of common stock from warrant exercise	12,295					
Components of other comprehensive loss:						
Net loss					(54,673)	(54,673)

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

Total comprehensive loss						(54,673)
<b>Balances at December 31, 2010</b>	30,189,650	296	301,924		(239,564)	62,656
Issuance of common stock in conjunction with exercise of stock options, vesting of restricted stock units, net of taxes and purchase under employee stock purchase plan	396,686	4	2,485			2,489
Employee stock-based compensation expense recognized under ASC 718			7,344			7,344
Adjustment to issuance costs from equity offering			2			2
Components of other comprehensive loss:						
Net loss					(32,939)	(32,939)
Total comprehensive loss						(32,939)
<b>Balances at December 31, 2011</b>	30,586,336	\$ 300	\$ 311,755	\$	\$ (272,503)	\$ 39,552

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, 2011
	2011	2010	2009	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (32,939)	\$ (54,673)	\$ (8,997)	\$ (260,486)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation and amortization	1,450	1,222	1,476	7,328
Accretion of investment discounts, net			(1)	(1,595)
Accretion of debt payment premium	64	244	391	999
Stock-based compensation	7,344	6,572	4,915	25,185
Loss on disposal and other non-cash items	26	309	683	2,284
Changes in operating assets and liabilities:				
Accounts receivable	(636)			(636)
Prepaid expenses and other current assets	(119)	(24)	185	(988)
Other assets	3	96	(51)	113
Accounts payable	157	(1,008)	1,285	2,036
Accrued liabilities	(2,509)	(2,128)	(3,924)	6,853
Deferred revenue	56,930			56,930
Other liabilities	(54)	27	30	63
<b>Net cash provided by (used in) operating activities</b>	<b>29,717</b>	<b>(49,363)</b>	<b>(4,008)</b>	<b>(161,914)</b>
<b>Cash flows from investing activities:</b>				
Purchase of intangible assets and in-process research and development				(412)
Purchase of property and equipment	(1,754)	(2,080)	(1,316)	(13,275)
Purchase of short-term investments				(169,497)
Sales and maturities of short-term investments			12,740	171,411
Purchase of restricted investment				(310)
<b>Net cash provided by (used in) investing activities</b>	<b>(1,754)</b>	<b>(2,080)</b>	<b>11,424</b>	<b>(12,083)</b>
<b>Cash flows from financing activities:</b>				
Proceeds from issuance of convertible notes payable				4,300
Proceeds from issuance of debt				31,006
Net proceeds from issuance of common stock through equity plans	2,489	2,273	1,162	6,711
Repayment of debt	(7,645)	(7,283)	(6,348)	(32,105)
Proceeds from issuance of common stock resulting from drawdown of equity line of credit, net of issuance costs		19,653		19,653
Proceeds from issuance of common stock in equity offering, net of issuance costs(1)	2	47,031	31,619	140,820
Proceeds from issuance of convertible preferred stock, net of issuance costs				102,428
<b>Net cash provided by (used in) financing activities</b>	<b>(5,154)</b>	<b>61,674</b>	<b>26,433</b>	<b>272,813</b>
Net increase in cash and cash equivalents	22,809	10,231	33,849	98,816
Cash and cash equivalents at beginning of period	76,007	65,776	31,927	

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

Cash and cash equivalents at end of period	\$ 98,816	\$ 76,007	\$ 65,776	\$ 98,816
--	-----------	-----------	-----------	-----------

### Supplemental disclosures of cash flow information

Cash paid for interest	\$ 1,252	\$ 998	\$ 1,727	\$ 6,999
------------------------	----------	--------	----------	----------

### Supplemental disclosure of non-cash investing and financing activities

Purchase of property and equipment through accounts payable	\$ 705	\$ 1,090	\$	\$ 705
Conversion of notes payable to convertible preferred stock	\$	\$	\$	\$ 4,300
Issuance of convertible preferred stock warrants	\$	\$	\$	\$ 327
Accretion of cumulative dividends on redeemable convertible preferred stock	\$	\$	\$	\$ 13,925
Conversion of redeemable convertible preferred stock to common stock upon IPO	\$	\$	\$	\$ 106,727
Reclassification of preferred warrants to common warrants	\$	\$	\$	\$ 948
Issuance of common stock to preferred stockholders as cumulative dividend	\$	\$	\$	\$ 13,925

(1) The difference between \$47,031,000 and \$47,029,000 in Consolidated Statements of Stockholders' Equity is \$2,000 in offering costs accrued and not yet paid at December 31, 2010.

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**

***Nature of Operation***

MAP Pharmaceuticals, Inc., incorporated in the state of Delaware, originally was formed as a limited liability company on July 3, 2003 and converted to a corporation on December 11, 2003. Our goal is to enhance the therapeutic benefits and commercial attractiveness of proven drugs in the field of neurology, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history, by applying our proprietary formulation and inhalation technologies. Our current focus is to advance the development of our product candidate, LEVADEX<sup>®</sup>, formerly known as MAP0004, 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.

We have incurred losses and negative cash flow since our inception in July 2003. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we may continue to incur net losses for the next several years. We will need substantial additional capital in the future in connection with the development and potential commercialization of LEVADEX and to fund the development and potential commercialization of any future product candidates. Prior to achieving profitable operations, we intend to continue to fund operations through public or private financings, strategic partnerships or other arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

**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 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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Principles of Consolidation***

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

***Revenue Recognition***

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Collaboration revenue, which is earned under license agreements with third parties, may include nonrefundable license fees, cost reimbursements and contingent milestones.

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

Before January 1, 2011, we evaluated license arrangements with multiple elements in accordance with Accounting Standards Codification, or ASC, 605-25 *Revenue Recognition - Multiple-Element Arrangements*. In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2009-13 *Revenue Arrangements with Multiple Deliverables*, or ASU 2009-13, which amended the accounting standards for certain multiple element revenue arrangements to:

provide updated guidance on whether multiple elements exist, how the elements in an arrangement should be separated, and how the arrangement consideration should be allocated to the separate elements;

require an entity to allocate arrangement consideration to each element based on a selling price hierarchy, also called the relative selling price method, where the selling price for an element is based on vendor-specific objective evidence ( VSOE ), if available; third-party evidence ( TPE ), if available and VSOE is not available; or the best estimate of selling price ( ESP ), if neither VSOE nor TPE is available; and

eliminate the use of the residual method and require an entity to allocate arrangement consideration using the selling price hierarchy. The revenue allocated to each element is then recognized when the basic revenue recognition criteria are met for that element.

On January 1, 2011, we adopted ASU 2009-13 on a prospective basis. The new accounting standard for revenue recognition, if applied in the same manner to the year ended December 31, 2010, would not have any impact to total revenue and deferred revenue for that fiscal year as we did not have any collaboration revenue in fiscal 2010 or any deferred revenue as of December 31, 2010. The new accounting guidance for revenue recognition is not expected to have a significant effect on total net revenue in periods after initial adoption, although the impact on the timing of revenue will vary depending on the evaluation of the elements of any new arrangements.

VSOE is based on the price charged when the element is sold separately and is the price actually charged for that deliverable. We typically are not able to establish VSOE for the elements of a license arrangement because each arrangement is unique, an arrangement typically consists of multiple elements and we have limited history of entering into license arrangements.

When VSOE cannot be established, we attempt to establish the selling price of the elements of a license arrangement based on TPE. TPE is determined based on a competitor's price for similar deliverables when sold separately. We typically are not able to determine TPE for license arrangements, as they contain a significant level of differentiation such that the comparable pricing of a competitor's license arrangement with similar functionality cannot be obtained, and we are therefore unable to reliably determine what a similar competitor's license arrangement's selling price would be on a standalone basis.

When we are unable to establish the selling price of an element using VSOE or TPE, we use the ESP in our allocation of the upfront payment. The objective of the ESP is to determine the price at which we would transact a sale if the element of the license arrangement were sold on a standalone basis.

Our process for determining ESPs involves management's judgment. Our process considers multiple factors such as discounted cash flows, estimated direct expenses and other costs and available data, which may vary over time, depending upon the circumstances, and relate to each deliverable. If the estimated obligation period of one or more deliverables should change, the future amortization of the revenue would also change. We regularly review ESP and maintain internal controls over the establishment and updates of the estimates.



---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

The Allergan Agreements entered into in February 2011 contain multiple elements, including a license to commercialize our product candidate, regulatory approval and manufacturing for our product candidate, and various committee participations. We received an upfront cash payment of \$60.0 million from Allergan upon execution of the Allergan Agreements. In accordance with ASU 2009-13, we evaluated whether there is standalone value for each of the various deliverables. As we have determined that the license and other non-contingent deliverables do not have standalone value, they must be combined with all the remaining deliverables to Allergan because the License could not be deemed to be fully delivered for its intended purpose unless we continue to perform our other obligations under the Collaboration Agreement. Accordingly, they do not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront cash payment is deferred and will be recognized on a straight-line basis over the term of the Allergan Agreements through 2028, which represents the estimated obligation period.

We recognize a contingent milestone payment as revenue in its entirety upon our achievement of the milestone. A milestone is substantive if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

***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, or CROs, in connection with pre-clinical studies;

fees paid to CROs and investigative sites in connection with clinical trials; and

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

Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain number of patients, site initiation and completion of clinical trial milestones. In accruing services fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and status meetings with CROs and review of contractual terms. Our estimates are dependent on the timeliness and accuracy of data provided by our CROs and other vendors.

***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



**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

agencies and subject to certain concentration limits by corporations. We also strive to limit risk by specifying a minimum credit quality for corporate debt securities of A1/P1 for commercial paper and AAA for other securities. The maximum maturity for these securities does not exceed 12 months. We believe our established guidelines for investment of our excess cash maintains safety and liquidity through our policies on diversification and investment maturity. Our cash and cash equivalent balances can be in excess of federally insured amounts.

At December 31, 2011, Allergan accounted for 100% of our accounts receivable. For the year ended December 31, 2011, Allergan accounted for 100% of our collaboration revenue. For the year ended December 31, 2009, AstraZeneca accounted for 100% of our collaboration revenue.

We do not own or operate manufacturing facilities for clinical or commercial manufacture of our product candidates, which includes drug substance and drug packaging, including the components of the TEMPO inhaler, the device used to administer certain of our drug candidates, including LEVADEX. 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.

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.

***Property and Equipment, Net***

Property and equipment are stated at cost, subject to adjustments for impairment, less accumulated depreciation and amortization. Depreciation and amortization are provided on a straight-line basis over the following estimated useful lives:

Laboratory equipment	3-5 years
Manufacturing equipment	3-5 years
Office furniture and fixtures	7 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of useful life or remaining lease term

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.

***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: (i) expenses incurred under agreements with contract research organizations and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) milestone payments paid to our collaborative partners who work on our processing



---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

and supply of clinical trial material; (iii) the cost of manufacturing and supplying clinical trial materials; (iv) payments to contract service organizations, as well as consultants; (v) employee-related expenses, which include salaries and benefits; (vi) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies; and (vii) stock-based compensation expense. All research and development expenses are expensed as incurred.

***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.

***Stock-Based Compensation***

Effective January 1, 2006, we adopted ASC 718 *Compensation – Stock Compensation*, or ASC 718, using the prospective transition method, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. ASC 718 requires companies to estimate the fair value of the stock-based payment awards on the date of grant using an option-pricing model. Our financial statements reflect the impact of ASC 718. 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.

For RSUs with time-based vesting, the fair value is based on the closing price of our common stock on the date of grant. We measure compensation expense for these RSUs at fair value on the date of grant and recognize the expense over the expected vesting period, after considering the estimated forfeitures.

For RSUs with performance-based vesting, the fair value is based on the closing price of our common stock on the date of grant. A probability assessment that performance goals will be achieved is made quarterly. The compensation expense is recognized over the vesting period, and is adjusted periodically for forfeiture rate and any changes to our probability assessment of the number of performance-based RSUs expected to vest as a result of our achievement of the performance goals.

We account for equity instruments issued to non-employees in accordance with ASC 505-50 *Equity – Equity-Based Payments to Non-Employees*. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

***Comprehensive Loss***

We report comprehensive loss in accordance with ASC 220 *Reporting Comprehensive Income*. Components of other comprehensive loss, including unrealized loss on our available-for-sale securities, are included in total comprehensive loss.

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

The following table presents the components of comprehensive loss for the three years ended December 31, 2011, 2010 and 2009 (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Net loss	\$ (32,939)	\$ (54,673)	\$ (8,997)
Other comprehensive loss:			
Change in unrealized loss on marketable securities			(44)
Total other comprehensive loss			(44)
Total comprehensive loss	\$ (32,939)	\$ (54,673)	\$ (9,041)

Accumulated other comprehensive loss is entirely comprised of unrealized gains or losses on marketable securities.

***Net Loss per Share***

Basic net loss per share is computed by dividing net loss attributed to common stockholders by the weighted average number of common shares outstanding during the period. Our potential dilutive shares, which include common stock options, warrants to purchase common stock, common stock issuable pursuant to the Employee Stock Purchase Plan, or ESPP, RSUs with time-based vesting and RSUs with performance-based vesting 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.

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

	Year Ended December 31,		
	2011	2010	2009
<b>Numerator</b>			
Net loss attributed to common stockholders	\$ (32,939)	\$ (54,673)	\$ (8,997)
<b>Denominator</b>			
Weighted average common shares outstanding	30,377,418	27,260,955	22,194,686
Basic and diluted net loss per share	\$ (1.08)	\$ (2.01)	\$ (0.41)

The following outstanding common stock options, warrants to purchase common stock, common stock issuable pursuant to our ESPP and RSUs with time-based vesting 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. The RSUs with performance-based vesting were also excluded from the computation of diluted net loss per share because they were contingently issuable shares.

Year Ended December 31,		
2011	2010	2009

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

Options to purchase common stock	4,378,053	4,071,903	3,628,845
Warrants to purchase common stock	26,903	26,903	51,571
Common stock issuable pursuant to the ESPP	11,906	8,886	10,545
RSUs with time-based vesting	162,893		
RSUs with performance-based vesting	39,250	98,000	

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

***Operating Leases***

We lease office and laboratory facilities under operating leases. Lease agreements may include rent escalation clauses and tenant improvement allowances. We recognize scheduled rent increases on a straight-line basis over the lease term beginning with the date we take possession of the leased space. Differences between rental expense and actual rental payments are recorded as deferred rent liabilities included in Other liabilities on the consolidated balance sheets.

***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 May 2011 the FASB and IASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04. ASU 2011-04 created a uniform framework for applying fair value measurement principles for companies around the world and clarified existing guidance in US GAAP. ASU 2011-04 is effective for the first reporting annual period beginning after December 15, 2011 and shall be applied prospectively. We will adopt ASU 2011-04 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-04 will have a material impact on our consolidated financial statements.

In June 2011 the FASB issued ASU No. 2011-05, *Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income*, or ASU 2011-05, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders' equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. However, the FASB agreed to an indefinite deferral of the reclassification requirement. We will adopt ASU 2011-05 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-05 will have a material impact on our consolidated financial statements.

**NOTE 3. FAIR VALUE MEASUREMENTS**

We adopted ASC 820, *Fair Value Measurements*, or ASC 820, as it relates to financial assets and financial liabilities. ASC 820 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements.

ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. This standard is now the single source in GAAP for the definition of fair value, except for the fair value of leased property as defined in ASC 840 *Accounting for Leases*, which establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

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





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

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

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

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

The following is a summary of our cash, cash equivalents and restricted investment as of December 31, 2011 and 2010, respectively (in thousands):

		<b>As of December 31, 2011</b>	
	<b>Amortized Cost</b>	<b>Unrealized Gain (Loss)</b>	<b>Estimated Fair Value</b>
Cash	\$ 3,569	\$	\$ 3,569
Certificates of deposit	310		310
Money market funds	95,247		95,247
	\$ 99,126	\$	\$ 99,126
<b>Reported as:</b>			
Cash and cash equivalents			\$ 98,816
Restricted investment			310
			\$ 99,126

		<b>As of December 31, 2010</b>	
	<b>Amortized Cost</b>	<b>Unrealized Gain (Loss)</b>	<b>Estimated Fair Value</b>
Cash	\$ 2,327	\$	\$ 2,327
Certificates of deposit	310		310
Money market funds	73,680		73,680
	\$ 76,317	\$	\$ 76,317
<b>Reported as:</b>			
Cash and cash equivalents			\$ 76,007
Restricted investment			310

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

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

As of December 31, 2011 and December 31, 2010, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above were as follows, respectively (in thousands):

<b>As of December 31, 2011</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Certificates of deposit	\$	\$ 310	\$	\$ 310
Money market funds	95,247			95,247
<b>Total</b>	<b>\$ 95,247</b>	<b>\$ 310</b>	<b>\$</b>	<b>\$ 95,557</b>

<b>As of December 31, 2010</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Certificates of deposit	\$	\$ 310	\$	\$ 310
Money market funds	73,680			73,680
<b>Total</b>	<b>\$ 73,680</b>	<b>\$ 310</b>	<b>\$</b>	<b>\$ 73,990</b>

Our investments in money market funds are measured at fair value on a recurring basis. Our money market funds comply with Rule 2a-7 of the Investment Company Act of 1940 and are required to be priced and have a fair value of \$1.00 net asset value per share. These money market funds are actively traded and reported daily through a variety of sources. Due to the structure and valuation required by the Investment Company Act of 1940 regarding Rule 2a-7 funds, the fair value of the money market fund investments is classified as Level 1.

The fair value of the certificates of deposit is classified as Level 2 due to the nature of a contractual restriction in our lease agreement which limits our ability to liquidate the investment.

**NOTE 4. BALANCE SHEET COMPONENTS****Accounts receivable**

Accounts receivable consists of the following (in thousands):

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Accounts receivable	\$ 636	\$
	\$ 636	\$

The accounts receivable balance as of December 31, 2011 was due to the amount reimbursable to us from Allergan under cost-sharing provisions in the Allergan Agreements.

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

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

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Laboratory equipment	\$ 4,947	\$ 4,770
Manufacturing equipment	3,759	
Office furniture and fixtures	480	609
Computer equipment and software	1,060	1,086
Leasehold improvements	751	637
Construction-in-progress	1,792	3,503
	12,789	10,605
Less: Accumulated depreciation and amortization	(6,003)	(4,802)
	<b>\$ 6,786</b>	<b>\$ 5,803</b>

Depreciation and amortization expense was approximately \$1.5 million, \$1.2 million and \$1.5 million, and \$7.3 million for the years ended December 31, 2011, 2010, 2009, and for the cumulative period from July 3, 2003 (date of inception) to December 31, 2011, respectively.

***Accrued Liabilities***

Accrued liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Research and development	\$ 1,367	\$ 4,735
Payroll and related expenses	4,888	3,993
Professional services	596	626
Other	82	88
	<b>\$ 6,933</b>	<b>\$ 9,442</b>

***Debt***

As of December 31, 2011, we had no debt outstanding.

In May 2008, we entered into the 2008 Working Capital Loan, for \$20.0 million, in order to repay an earlier working capital loan and to support general corporate purposes. The 2008 Working Capital Loan bore interest at an annual rate of 9.95%, with an effective rate of approximately 12% after factoring in a \$1.0 million payment due at the termination of this agreement. The 2008 Working Capital Loan had interest-only payments up to and including January 2009, matured in October 2011, and included customary loan covenants. The 2008 Working Capital Loan amounts were collateralized by all of our assets, excluding intellectual property. We repaid in full the 2008 Working Capital Loan in October 2011.

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

In September 2006, we entered into a \$3.0 million loan facility agreement for the purpose of financing equipment purchases, or the Equipment Loan, and borrowed \$1.0 million under this facility. The Equipment Loan bore interest at an annual interest rate of 9.5% and was repaid in full as of September 30, 2009.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 5. COMMITMENTS AND CONTINGENCIES*****Operating Leases***

In June 2004, we entered into a lease agreement for laboratory and office facilities in Mountain View, California, or the Lease. The Lease was subsequently amended in August 2006, March 2008, and September 2008. In November 2011, we further amended the Lease, providing for additional square footage in a separate building and certain renewal options. The amended lease will expire in June 2013. Under the Lease, we pay operating costs, including property taxes, insurance and maintenance, in addition to monthly rent. Rent is subject to an annual increase for the duration of the Lease, which we recognize on a straight-line basis.

Rent expense was approximately \$1.3 million, \$1.3 million, \$1.1 million, and \$7.1 million for the years ended December 31, 2011, 2010, 2009 and for the cumulative period from July 3, 2003, (date of inception) to December 31, 2011, respectively.

As of December 31, 2011, future minimum lease payments are as follows (in thousands):

<b>Year ending December 31,</b>	<b>Amount</b>
2012	\$ 1,672
2013	863
<b>Total future minimum lease payments</b>	<b>\$ 2,535</b>

In accordance with the terms of the Lease, we are obligated to maintain an irrevocable letter of credit from a bank as a security deposit. As collateral for the letter of credit, we are required to maintain a bank deposit account of \$0.3 million, which is shown as a restricted investment on our consolidated balance sheets at December 31, 2011 and 2010.

***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 indemnification. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our certificate of incorporation and bylaws, we have indemnification obligations to our officers and directors for certain events or occurrences, subject to certain limits, while they are serving at our request in their respective capacities. 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.

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

**NOTE 6. LICENSE AND SUPPLY AGREEMENTS**

***Agreement with Allergan***

On January 28, 2011, we entered into a Collaboration Agreement (the Collaboration Agreement ) and a Co-Promotion Agreement (the Co-Promotion Agreement, and together with the Collaboration Agreement, the Allergan Agreements ) with Allergan, Inc., Allergan USA, Inc. and Allergan Sales, LLC (collectively, Allergan ). Pursuant to the terms of the Allergan Agreements, we have granted Allergan a co-exclusive license (the Allergan License ) to market and co-promote LEVADEX<sup>®</sup>our proprietary novel migraine therapy for delivery by inhalation, to neurologists and pain specialists in the United States in collaboration with us.

In July 2011, Allergan exercised its option to expand the Collaboration Agreement to include Canada for neurologists and pain specialists. Under the Allergan Agreements, we retain the right to market and co-promote LEVADEX to other physicians within the United States and Canada and also retain all rights to LEVADEX in all other countries. We and Allergan will each provide sales representatives and other sales support for such marketing and promotional efforts. The Allergan Agreements specify minimum annual sales detail requirements to be provided by each party, and establish maximum annual amounts of detailing costs that each party will be obligated to incur pursuant to a commercialization plan.

The parties will collaborate in the development of LEVADEX for the treatment of pediatric migraine and for at least one other indication. We may develop LEVADEX for certain other indications independently of the collaboration if Allergan does not agree to develop LEVADEX for such indications pursuant to the Allergan Agreements. We are responsible for manufacturing and distributing LEVADEX, and anticipate booking product revenues from sales of LEVADEX resulting from the parties' collaboration.

The parties share profits and losses resulting from the collaboration equally. We are solely responsible for payment of all remaining costs of obtaining regulatory approval of LEVADEX for the acute treatment of migraine in adults, except that if the U.S. Food and Drug Administration, or FDA, notifies us that additional development or manufacturing activities costing in excess of a certain threshold amount will be required for such regulatory approval, the parties will share any such excess costs. The parties generally share equally all other costs of developing LEVADEX under the Allergan Agreements, except that neither party shall be obligated for more than a certain threshold amount in a given year, or for more than a certain threshold amount in the aggregate, for development or manufacturing costs or expenses incurred by us for such activities.

The Collaboration Agreement may be terminated (i) by Allergan, at will, after first commercial sale of LEVADEX in the United States, upon 180 days' prior written notice, (ii) by Allergan, upon written notice to us, if we receive a complete response letter or equivalent communication from the FDA, that Allergan determines will extend potential approval beyond a certain date or requires a certain minimum level of additional investment, (iii) by us, upon written notice to Allergan, if Allergan commercializes a competing product in the United States or Canada and (iv) by us, upon written notice to Allergan, if Allergan challenges or opposes patent rights licensed to Allergan pursuant to the Collaboration Agreement. Additionally, either party may terminate the Collaboration Agreement in the event of an uncured material breach. The Co-Promotion Agreement will terminate upon termination of the Collaboration Agreement.

In February 2011, Allergan paid us an upfront payment of \$60.0 million, out of which we recognized \$3.1 million as collaboration revenue for the year ended December 31, 2011 and deferred the remaining \$56.9 million, which will be amortized as collaboration revenue through the end date of the deliverable under the Collaboration Agreement with the longest term. Our participation in joint committees with Allergan has the longest obligation period, requiring our participation throughout the term of the Collaboration Agreement. The term of the Collaboration Agreement is the later of (a) December 31, 2025, and (b) the date that our last patent right covering



---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

LEVADEX in the United States expires. The date that our last patent right covering LEVADEX in the United States expires is 2028. As a result, we will amortize the remaining \$56.9 million of the initial \$60.0 million through 2028.

During the third quarter ended September 30, 2011, the FDA accepted for filing our LEVADEX NDA. As a result, pursuant to the terms of the Allergan Agreements, Allergan paid us a milestone payment of \$20.0 million. We have determined that the achievement of this milestone was substantive and we recorded the \$20.0 million as collaboration revenue on our consolidated statements of operations for the year ended December 31, 2011.

In addition to the \$20.0 million milestone described above, under the terms of the Collaboration Agreement, we may also receive up to an additional \$77.0 million in milestone payments, including \$50.0 million for the first commercial sale of LEVADEX associated with the initial indication (the acute treatment of migraine), up to \$25.0 million for the achievement of certain FDA-approved product labeling in the United States and \$2.0 million for regulatory approval of the initial indication for LEVADEX in Canada.

Sales, general and administrative expenses for the year ended December 31, 2011, as well as for the cumulative period from July 3, 2003 (date of inception) to December 31, 2011, were net of \$1.4 million of costs reimbursed or reimbursable by Allergan under cost-sharing provisions in the Allergan Agreements.

***Agreement with Nektar***

Under our June 2004 agreement, as amended, with Nektar Therapeutics UK Limited, or the Nektar Agreement, we were granted a worldwide, exclusive license, with a right to sublicense, under Nektar patents and know-how, to develop and commercialize any formulation of a form of dihydroergotamine for administration by inhalation using a device. We also agreed to pay royalties at specified rates based on net sales.

For the year ended December 31, 2011, we paid Nektar a milestone payment of \$1.0 million as a result of entering into the Allergan Agreements, and recorded it as research and development expenses on our consolidated statements of operations for the year ended December 31, 2011. We paid \$0 for both the year ended December 31, 2010 and 2009. We have paid \$3.6 million for the cumulative period from July 3, 2003 (date of inception) to December 31, 2011. Either party may terminate the Nektar Agreement upon a material, uncured default of the other party. We may terminate the Nektar Agreement, with or without cause, at any time upon six months' prior written notice.

***Agreement with AstraZeneca***

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

In February 2009, under the terms of the AstraZeneca Agreement, AstraZeneca paid us a nonrefundable upfront cash payment of \$40.0 million. On February 23, 2009, we announced top-line results of our initial Phase 3 clinical trial of UDB for the potential treatment of children with asthma. We announced that the clinical trial did not meet its co-primary endpoints, asthma control as assessed by changes from baseline in nighttime and daytime composite symptom scores, in either of the doses evaluated when compared with placebo.

On July 8, 2009, we received notice from AstraZeneca of the termination of the AstraZeneca Agreement. Effective on the date of termination, all rights licensed to AstraZeneca in the AstraZeneca Agreement reverted

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

back to us. We were jointly developing UDB with AstraZeneca, and were responsible for executing the development plan. In the third quarter of 2009 we suspended development of our UDB product candidate.

Total collaboration revenue recognized under the AstraZeneca Agreement was \$54.2 million for the year ended December 31, 2009 and consists of a \$40.0 million upfront payment and \$14.2 million from reimbursement of qualified development expenses. We received \$54.2 million in cash for the agreement period.

**NOTE 7. STOCKHOLDERS EQUITY**

***Reverse Stock Split***

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

***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 5,000,000 shares of \$0.01 par value preferred stock. As of December 31, 2011 and 2010, there were no shares of preferred stock issued or outstanding.

***Common Stock***

In October 2007, we completed our 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.

In August 2009, we completed a follow-on public offering in which we sold and issued 3,500,000 shares of our common stock at a per share price of \$9.70. We raised a total of \$34.0 million in gross proceeds, or approximately \$31.6 million in net proceeds after deducting expenses and underwriters' discounts and commissions.

On November 11, 2009, we entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Azimuth Opportunity Ltd., or Azimuth, which provides us with what is sometimes termed an equity line of credit arrangement. Upon the terms and subject to the conditions set forth in the Purchase Agreement, Azimuth committed to purchase up to \$60.0 million worth of shares of our common stock over the 24-month term of the Purchase Agreement; provided, however, in no event may we sell under the Purchase Agreement more than such number of shares of common stock which is equal to one share less than 20% of our outstanding shares of common stock on the effective date of the Purchase Agreement. From time to time over the term of the Purchase Agreement, and at our sole discretion, we may present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the price per share over ten consecutive trading days or such other period mutually agreed upon by Azimuth and us, with each draw down subject to limitations based on the price of our common stock and a maximum limit of 2.5% of our market capitalization at the time of such draw down, or such other limit as mutually agreed upon by Azimuth and us. In January 2010 we accessed our equity line of credit and sold 1,527,695 shares of common stock at a price of approximately \$13.70 per share less a discount of approximately 4.5% per share for a net price of approximately \$13.09 per share. The total purchase price for all these shares was \$20.0 million or approximately \$19.7 million.

---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

after deducting the offering expenses. On November 29, 2011, we amended the Purchase Agreement to extend the term by up to 24 months past the original expiration date of December 1, 2011. As of December 31, 2011, the remaining aggregate dollar value of shares available for sale under the Purchase Agreement was \$40.0 million.

In October 2010, we completed an equity offering in which we sold a total of 3,450,000 shares of common stock at an offering price of \$14.50 per share. We raised a total of \$50.0 million in gross proceeds, or approximately \$47.0 million in net proceeds after deducting underwriting discounts, commissions and offering expenses.

***Warrants***

We issued warrants to purchase 73,989 shares of common stock to selected lenders in connection with an earlier working capital loan which was fully paid in May 2008 and the Equipment Loan which was fully paid in September 2009. The warrants are exercisable at a price of \$7.43 per share and expire in September 2013. In October 2009 and March 2010, warrants to purchase 22,418 shares and 24,668 shares were exercised, respectively, resulting in a net issuance of 5,817 shares and 12,295 shares, respectively. As of December 31, 2011, warrants to purchase the remaining 26,903 shares of common stock were outstanding.

***Equity Plans***

***2005 Equity Incentive Plan***

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

***2007 Equity Award Plan***

In September 2007, we adopted the 2007 Equity Award Plan, or 2007 Plan, which became effective upon the completion of the IPO. The remaining common stock available for issuance under the 2005 Plan was made available for future grant under the 2007 Plan. Outstanding options under the 2005 Plan that expire or are canceled without having been exercised in full or are repurchased or forfeited will be available for future issuance under the 2007 Plan. Under the 2007 plan, with the approval of the Compensation Committee of the Board of Directors, we may grant restricted stock, RSU, stock appreciation rights and new shares of common stock upon exercise of stock options.

**Restricted Stock Units**

In February 2010, the Compensation Committee of the Board of Directors approved awards of RSUs with performance-based vesting from the 2007 Plan to certain of our employees. Each RSU represents one equivalent share of our common stock to be awarded upon vesting at the end of the performance periods, if specific performance goals set by the Compensation Committee are achieved. No RSUs with performance-based vesting will vest if the performance goals are not met. The fair value of these RSUs is based on the closing price of our

Table of Contents

## MAP PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

common stock on the date of grant. We measure compensation expense for these RSUs over the expected vesting period and we adjust it periodically for any changes to our probability assessment of the number of RSUs expected to vest as a result of our achievement of the performance goals. We make a quarterly probability assessment as to whether the performance goals will be achieved. The RSUs do not entitle participants to the rights of holders of common stock, such as voting rights, until the shares are issued.

Beginning in 2011, the Compensation Committee of the Board of Directors has approved awards of RSUs with time-based vesting from the 2007 Plan to certain of our employees. Each RSU represents one equivalent share of our common stock to be awarded after the vesting period. These RSUs vest over four years at a rate of 25% annually. The fair value for these RSUs is based on the closing price of our common stock on the date of grant. We measure compensation expense for these RSUs at fair value on the date of grant and recognize the expense over the expected vesting period on a straight-line basis. The RSUs do not entitle participants to the rights of holders of common stock, such as voting rights, until the shares are issued.

For RSUs that vest, we withhold a number of shares of common stock equal in value to the amount of the minimum statutory tax withholding obligations that arise due to such vesting, and issue shares of common stock for the remainder of the vested amount. The settlement of vested RSUs on a net share basis results in fewer shares issued by us.

For the year ended December 31, 2011, activity for RSUs under the 2007 Plan was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
<b>RSUs Outstanding at December 31, 2010</b>	98,000	\$ 16.19
RSUs granted	176,993	\$ 15.81
RSUs vested	(40,500)	\$ 16.19
RSUs forfeited	(32,350)	\$ 16.10
<b>Unvested RSUs outstanding at December 31, 2011</b>	202,143	\$ 15.88

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.

Option activity for fiscal year 2011 was as follows:

	Number of Shares	Outstanding Options Weighted Average Exercise Price	Aggregate Intrinsic Value (In thousands)
<b>Balances, at December 31, 2010</b>	4,071,903	\$ 9.64	
Options granted	797,725	\$ 15.95	
Options exercised	(299,537)	\$ 6.09	\$ 2,809(1)

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

Options forfeited	(152,491)	\$ 13.97	
Options expired	(39,547)	\$ 12.41	
<b>Balances, at December 31, 2011</b>	4,378,053	\$ 10.86	\$ 14,634(2)

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

- (1) Amounts represent the difference between the exercise price and market price of MAP Pharmaceuticals stock at the time of exercise.
- (2) Amount represents the difference between the exercise price and \$13.17, the closing price of MAP Pharmaceuticals stock on December 30, 2011, as reported on the NASDAQ Global Market, for all in-the-money options outstanding.
- The following table summarizes options outstanding that have vested and are expected to vest based on options outstanding as of December 31, 2011:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value(1) (In thousands)	Weighted Average Remaining Contractual Life (In years)
Vested	2,859,052	\$ 8.84	\$ 13,558	6.1
Vested and expected to vest(2)	4,297,681	\$ 10.76	\$ 14,633	6.9

- (1) Amounts represent the difference between the exercise price and \$13.17, the closing price of MAP Pharmaceuticals stock on December 30, 2011, as reported on the NASDAQ Global Market, for all in-the-money options outstanding.
- (2) Options outstanding that have vested and expected to vest are net of estimated future option forfeitures in accordance with the provisions of ASC 718.
- The weighted average grant date fair value of options granted was \$9.34 in 2011, \$8.59 in 2010 and \$5.02 in 2009.

The total fair value of options granted to employees that vested during the years ended December 31, 2011, 2010 and 2009 was approximately \$5.1 million, \$3.9 million and \$2.7 million, respectively.

As of December 31, 2011, 2,109,189 shares of common stock were available for future grant under the 2007 Plan. In December 2011, the Board of Directors authorized increasing the number of shares under the 2007 Equity Award Plan by one million shares, effective January 1, 2012.

*Employee Stock Purchase Plan*

Upon the effectiveness of the IPO in October 2007, we adopted the Employee Stock Purchase Plan, or Purchase Plan. We initially reserved a total of 500,000, subsequently increased the reserve by an additional 635,000, shares of common stock for issuance under the Purchase Plan. 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 or end of a purchase period.

As of December 31, 2011, 636,163 shares of common stock were available for future grant and 498,837 shares of common stock have been issued under the employee stock purchase plan. In December 2011, the Board of Directors authorized increasing the number of shares under the Employee Stock Purchase Plan by 215,000 shares, effective January 1, 2012.



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

*Issuance of shares:* Upon exercise of stock options, vesting of RSUs and purchases of shares under the ESPP, we will issue common stock.

We received net proceeds of approximately \$2.5 million, \$2.3 million and \$1.2 million in cash from sales of shares through our equity plans for the years ended December 31, 2011, 2010 and 2009, respectively, and \$6.7 million for the cumulative period from July 3, 2003 (date of inception) through December 31, 2011.

*Stock-Based Compensation for Employees*

The following table summarizes the stock-based compensation expense for stock options, RSUs and shares from the ESPP that we recorded in the statements of operations in accordance with ASC 718 for the years ended December 31, 2011, 2010 and 2009, respectively (in thousands):

	Years Ended December 31,		
	2011	2010	2009
Research and development	\$ 3,246	\$ 2,975	\$ 1,955
Sales, general and administrative	4,098	3,597	2,880
	\$ 7,344	\$ 6,572	\$ 4,835

We used the following assumptions to estimate the fair value of options granted under our stock option plans for the years ended December 31, 2011, 2010 and 2009, respectively:

	Years Ended December 31,		
	2011	2010	2009
Risk-free interest rate	0.91%-2.21%	1.08%-2.45%	1.62%-2.52%
Expected volatility	69%-71%	62%-75%	62%-65%
Expected term (in years)	5	5	5
Expected dividend yield			

We used the following assumptions to estimate the fair value of shares purchased under our ESPP for the years ended December 31, 2011, 2010 and 2009, respectively:

	Years Ended December 31,		
	2011	2010	2009
Risk-free interest rate	0.05%-0.2%	0.14%-0.24%	0.14%-0.30%
Expected volatility	30%-52%	38%-76%	76%-99%
Expected term (in years)	0.5	0.5	0.5
Expected dividend yield			

We selected the Black-Scholes valuation model as the most appropriate valuation method for stock option grants and shares from the ESPP. The fair value of the stock option grants and shares from the ESPP is estimated as of the date of grant using the Black-Scholes valuation model.

*Risk-Free Interest Rate:* The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of our stock options or shares from the ESPP.





---

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

*Expected Volatility:* The expected stock price volatility of stock options 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 sufficient trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar to us in size, stage of life-cycle and financial leverage. We will continue to analyze the expected stock price volatility of stock options as more historical data for our common stock becomes available. Effective on January 1, 2010, the expected stock price volatility for shares from the ESPP is determined based on our own historical volatilities.

*Expected Term:* The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the historical experience that we have had with stock option grants as well as the expected term of 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 the full term of our stock options. We will continue to analyze the expected term of stock options as more historical data for our common stock becomes available. The expected term for shares from the ESPP is determined based on the length of offering periods for the ESPP.

*Expected Dividend Yield:* The expected dividend yield of 0% is based on our history and expectation of dividend payouts. We do not anticipate paying any dividends in the near future. We have not paid any dividends, other than a cumulative dividend on our preferred stock paid in connection with our IPO in 2007, pursuant to the terms of our certificate of incorporation.

*Forfeitures:* Forfeitures are determined based on when awards are ultimately expected to vest. ASC 718 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.

As of December 31, 2011, there were unrecognized compensation costs of approximately \$5.4 million related to non-vested stock option awards granted after January 1, 2006 that will be recognized on a straight-line basis over the weighted average remaining period of 2.0 years.

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

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. Management believes that the fair value of the stock options is more reliably measurable than the fair value of the service received. The fair value of stock options granted to non-employees is calculated at each grant date and remeasured at each reporting date. The stock-based compensation expense will fluctuate as the price of our common stock fluctuates. We recorded stock-based compensation expense for non-employees of \$0, \$0 and \$0.1 million for the years ended December 31, 2011, 2010 and 2009, respectively and \$0.9 million for the cumulative period from July 3, 2003 (date of inception) through December 31, 2011.

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

In March 2004, our Board of Directors adopted the 2004 Long-Term Incentive Plan, or Incentive Plan, which provides cash-based and equity-based incentives to eligible persons, including employees, non-employee directors, and consultants, advisors or independent contractors designated by the Compensation Committee of the Board of Directors. Cash and equity-based awards are generally based upon the attainment of performance goals over a particular period. The Board of Directors may specify a vesting period for cash and equity awards that may be longer than the performance period. The expense related to the cash and equity awards will be recognized over the performance period or the vesting period, whichever is longer, on a straight line basis. The Incentive Plan shall terminate on February 1, 2014, unless sooner terminated by the Board of Directors. As of December 31, 2011, no incentives under this plan remained available for grant.

**Table of Contents****MAP PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****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 company contributions to this plan.

**NOTE 10. INCOME TAXES**

We have not recorded any income tax expense for the periods ended December 31, 2011, 2010 and 2009.

The reconciliation of income tax expenses (benefit) at the statutory federal income tax rate of 34% to net income tax expenses (benefit) for the years ended December 31, 2011, 2010 and 2009 is as follows (in thousands):

	Years Ended December 31,		
	2011	2010	2009
U.S. federal taxes (benefit) at statutory rate	\$ (11,199)	\$ (18,682)	\$ (3,058)
Stock compensation expense	239	(567)	(96)
Others	28	23	19
Change in valuation allowance	10,932	19,226	3,135
	\$	\$	\$

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

	December 31,	
	2011	2010
<b>Deferred tax assets</b>		
Net operating loss carryforwards	\$ 95,883	\$ 84,875
Tax credit carryforwards	10,013	10,207
Capitalized intangibles	119	93
Accruals and reserves	6,045	4,243
Total deferred tax assets	112,060	99,418
Less: Valuation allowance	(112,060)	(99,418)
Net deferred tax assets	\$	\$

The valuation allowance increased by \$12.6 million, increased by \$23.3 million, and increased by \$6.4 million during the years ended December 31, 2011, 2010 and 2009, respectively.

At December 31, 2011, we had net operating loss carry forwards of approximately \$242.4 million and \$231.0 million available to reduce future taxable income, if any, for Federal and California state income tax purposes, respectively. The net operating loss carry forwards expire between 2014 and 2030.

We also had federal and state research and development credit carry forwards of approximately \$7.4 million and \$3.9 million, respectively, at December 31, 2011. The federal credits will expire starting in 2024 if not utilized. The California credits have no expiration date.



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

Pursuant to ASC 718, the benefit of stock options will only be recorded to equity when they reduce cash taxes payable. As of December 31, 2010, the portion of the federal and state net operating loss related to stock options is approximately \$7.9 million.

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

We adopted ASC 740-10 on January 1, 2007. As of December 31, 2011, we had no unrecognized tax benefits. As of December 31, 2011, we have not recorded any interest or penalties under this pronouncement.

We file U.S. and state income tax returns with varying statutes of limitations. The tax years 2004 and forward remain open to examination due to the carryover of unused net operating losses or tax credits.

**NOTE 11. UNAUDITED SELECTED QUARTERLY FINANCIAL DATA (in thousands, except per share amounts)**

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

	<b>Fiscal 2011 Quarter Ended</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30<sup>(2)</sup></b>	<b>December 31</b>
Collaboration revenue <sup>(1)</sup>	\$ 558	\$ 837	\$ 20,837	\$ 837
Income (loss) from operations	\$ (15,853)	\$ (11,218)	\$ 8,222	\$ (13,805)
Net income (loss) attributable to common stockholders	\$ (16,000)	\$ (11,302)	\$ 8,183	\$ (13,820)
Net income (loss) per common share:				
Basic	\$ (0.53)	\$ (0.37)	\$ 0.27	\$ (0.45)
Diluted	\$ (0.53)	\$ (0.37)	\$ 0.26	\$ (0.45)
Weighted average common shares used in computing net income (loss) per common share:				
Basic	30,211	30,333	30,440	30,522
Diluted	30,211	30,333	31,611	30,522

	<b>Fiscal 2010 Quarter Ended</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Loss from operations	\$ (13,667)	\$ (12,152)	\$ (13,930)	\$ (13,739)
Net loss attributable to common stockholders	\$ (14,058)	\$ (12,489)	\$ (14,178)	\$ (13,948)
Basic and diluted net loss per common share	\$ (0.54)	\$ (0.47)	\$ (0.53)	\$ (0.46)
Weighted average common shares used in computing basic and diluted net loss per common share	25,852	26,480	26,629	30,043 <sup>(3)</sup>

- (1) In February 2011, Allergan paid us an upfront payment of \$60.0 million, which we are deferring and recognizing on a straight-line basis over the term of the Allergan Agreements. See Note 6, with respect to the accounting treatment for this upfront payment.

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

- (2) In August 2011, we received \$20.0 million milestone payment from Allergan upon the FDA's acceptance for filing of our LEVADEX NDA and recorded it as collaboration revenue in the third quarter of 2011.
  
- (3) Weighted average common shares used in computing basic and diluted net loss per common share for the fourth quarter of 2010 includes the effect of the equity offering completed in October 2010, in which we sold a total of 3,450,000 shares of common stock at an offering price of \$14.50 per share.

**Table of Contents**

**MAP PHARMACEUTICALS, INC.**

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

**NOTE 12. SUBSEQUENT EVENT**

On March 26, 2012, we received a Complete Response letter, in which the FDA described the reasons it was unable to approve our NDA and identified issues that the Company needs to address in order to obtain FDA approval of LEVADEX. Specifically, the FDA requested that the Company address issues relating to the chemistry, manufacturing and controls, or CMC, of LEVADEX. FDA also stated that manufacturing deficiencies identified during a recent facility inspection of one of our third party manufacturers need to be resolved to FDA's satisfaction. The FDA also indicated that it had not been able to complete its review of inhaler usability information requested late in the review cycle by the FDA. We currently are working to address the issues identified in the Complete Response letter.

**Table of Contents**

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of disclosure controls and procedures.* As of the end of the period covered by this report, an evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13(a)-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that evaluation, our principal executive officer and principal financial officer, concluded that as a result of the material weakness described below, our disclosure controls and procedures were not effective as of December 31, 2011 to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

*Management's annual report on internal control over financial reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or Rule 15d-(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making its assessment, management used the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. A material weakness in internal control over financial reporting is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on its assessment, management determined that they had not maintained effective controls over complex multiple element revenue arrangements. Specifically, effective controls were not designed and in place with regard to the evaluation of, and accounting for, complex multiple element revenue arrangements. This control deficiency resulted in a restatement of revenues and deferred revenues, related to an upfront payment received from Allergan, for the first three quarterly periods during the year ended December 31, 2011. Additionally, this control



**Table of Contents**

deficiency could result in a misstatement of the aforementioned account balances or disclosures that would result in further misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, the Company's management has determined the control deficiency constitutes a material weakness. Because of this material weakness, management has concluded that our internal control over financial reporting was not effective as of December 31, 2011.

The effectiveness of our internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report on page 73 of this Form 10-K.

*Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Plan of Remediation of Material Weakness.* Subsequent to the identification of the material weakness related to the evaluation of, and accounting for, complex multiple element revenue arrangements, we are re-evaluating our accounting and financial reporting controls for complex multiple element revenue arrangements, including the application of the provisions of Accounting Standard Codification Topic 605-25 Revenue Recognition Multiple-Element Arrangements to any future agreements that include complex multiple elements.

**ITEM 9B. OTHER INFORMATION**

None

**Table of Contents**

**PART III**

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

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2011.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to MAP Pharmaceuticals, Inc. Proxy Statement for its 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2011.

**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 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2011.

**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 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2011.

**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 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2011.

**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>	73
Financial Statements	
<u>Consolidated Balance Sheets</u>	74
<u>Consolidated Statements of Operations</u>	75
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	76
<u>Consolidated Statements of Cash Flows</u>	78
<u>Notes to Consolidated Financial Statements</u>	79

(2) *Financial Statement Schedules*

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

(3) *Exhibits.*

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

(b) Exhibits:

See Item 15(a)(3) above.

(c) Financial Schedules:

See Item 15(a)(2) above.

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

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on March 30, 2012.

**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>
<i>/s/</i> TIMOTHY S. NELSON <b>Timothy S. Nelson</b>	President and Chief Executive Officer, Director (Principal Executive Officer)	March 30, 2012
<i>/s/</i> CHRISTOPHER Y. CHAI <b>Christopher Y. Chai</b>	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2012
<i>/s/</i> SCOTT R. WARD <b>Scott R. Ward</b>	Chairman of the Board of Directors	March 30, 2012
<i>/s/</i> THOMAS A. ARMER, PH. D. <b>Thomas A. Armer, Ph. D.</b>	Chief Scientific Officer, Director	March 30, 2012
<i>/s/</i> GERRI A. HENWOOD <b>Gerri A. Henwood</b>	Director	March 30, 2012
<i>/s/</i> BERNARD J. KELLEY <b>Bernard J. Kelley</b>	Director	March 30, 2012
<i>/s/</i> MATTHEW V. MCPHERRON <b>Matthew V. McPherron</b>	Director	March 30, 2012



**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> W. JAMES O SHEA <b>W. James O Shea</b>	Director	March 30, 2012
<i>/s/</i> H. WARD WOLFF <b>H. Ward Wolff</b>	Director	March 30, 2012

106

**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 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).
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 March 20, 2005, between Timothy S. Nelson and the Registrant (filed as Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.7#	Amendment to Employment Agreement dated July 22, 2005, between Timothy S. Nelson and the Registrant (filed as Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.8#	Employment Agreement dated April 14, 2008, between Thomas A. Armer and the Registrant (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33719), filed on May 14, 2008, and incorporated herein by reference).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.9#	Restricted Stock Agreement dated August 12, 2004, between Thomas A. Armer and the Registrant (filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.10#	Offer Letter dated September 14, 2006, between Christopher Y. Chai and the Registrant (filed as Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.11#	Amended and Restated Offer Letter dated September 11, 2007, between Anastasios Gianakakos and the Registrant (filed as Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-143823), filed on June 18, 2007, and incorporated herein by reference).
10.12#	Form of Change in Control Agreement between the 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	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).
10.17	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).
10.18	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).
10.19*	Amendment to Restated and Amended License Agreement between Nektar Therapeutics UK Limited and the Registrant dated October 8, 2007 (filed as Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 and incorporated herein by reference).
10.20	Third Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated November 30, 2007 (filed as Exhibit 10.27 to the Registrant's Annual Report on Form 10-K filed on March 20, 2008, and incorporated herein by reference).
10.21	Loan and Security Agreement by and among the Registrant, Oxford Finance Corporation and Silicon Valley Bank dated May 2, 2007 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 7, 2008, and incorporated herein by reference).



**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.22	Fourth Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated March 26, 2008 (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 14, 2008, and incorporated herein by reference).
10.23	Transfer and Assignment Agreement dated June 19, 2008 between Telesso Technologies Limited and the Registrant (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 13, 2008, and incorporated herein by reference).
10.24	Amended and Restated Fourth Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated July 15, 2008 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 13, 2008, and incorporated herein by reference).
10.25#	Severance Agreement dated March 19, 2009, between Timothy S. Nelson and the Registrant (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 8, 2009, and incorporated herein by reference).
10.26	Common Stock Purchase Agreement dated November 11, 2009, between Azimuth Opportunity Ltd and the Registrant (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 12, 2009, and incorporated herein by reference).
10.27#	Form of RSU grant agreement relating to MAP Pharmaceuticals, Inc. 2007 Equity Award Plan (filed as Exhibit 10.39 to the Registrant's Annual Report on Form 10-K filed on March 5, 2010, and incorporated herein by reference).
10.28#	Offer Letter dated July 5, 2007, between Charlene Friedman and the Registrant (filed as Exhibit 10.37 to the Registrant's Annual Report on Form 10-K filed on March 12, 2009, and incorporated herein by reference).
10.29#	Offer Letter dated June 18, 2008, between Donald Kellerman and the Registrant (filed as Exhibit 10.29 to the Registrant's Annual Report on Form 10-K filed on March 4, 2011, and incorporated herein by reference).
10.30	Collaboration Agreement by and among MAP Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. dated January 28, 2011 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A filed on February 16, 2011, and incorporated herein by reference).
10.31	Co-Promotion Agreement by and between MAP Pharmaceuticals, Inc., Allergan USA, Inc., dated January 28, 2011 (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A filed on February 16, 2011, and incorporated herein by reference).
10.32	First Amendment to Loan and Security Agreement among Silicon Valley Bank, Oxford Finance Corporation and the Registrant dated October 28, 2008 (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on May 6, 2011, and incorporated herein by reference).
10.33	Second Amendment to Loan and Security Agreement among Silicon Valley Bank, Oxford Finance Corporation and the Registrant dated April 15, 2011 (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on May 6, 2011, and incorporated herein by reference).
10.34	First Amendment to Collaboration Agreement by and among MAP Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. dated January 28, 2011 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011, and incorporated herein by reference).

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.35	Fifth Amendment to Lease Agreement between the Registrant and ARE-2425/2400/2450 Garcia Bayshore, LLC dated November 1, 2011 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2011, and incorporated herein by reference).
10.36#	Offer Letter dated June 12, 2006, between Scott Borland and the Registrant.
10.37	Amendment No. 1 to Common Stock Purchase Agreement between Azimuth Opportunity Ltd and the Registrant, dated November 29, 2011.
10.38#	First Amendment to Change in Control Agreement dated February 1, 2012, between Timothy S. Nelson and the Registrant.
10.39#	First Amendment to Change in Control Agreement dated February 6, 2012, between Thomas A. Armer and the Registrant.
10.40#	First Amendment to Severance Agreement dated February 1, 2012, between Timothy S. Nelson and the Registrant.
10.41#	First Amendment to Employment Agreement dated February 6, 2012, between Thomas A. Armer and the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Principal Executive Officer Required Under Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required Under Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101.INS^	XBRL Instance Document
101.SCH^	XBRL Taxonomy Extension Schema Document
101.CAL^	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF^	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB^	XBRL Taxonomy Extension Label Linkbase Document
101.PRE^	XBRL Taxonomy Extension Presentation Linkbase Document

# 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.

^ XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and is not otherwise subject to liability under those sections.