MAP Pharmaceuticals, Inc.
Form 10-K
March 05, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2009

OR

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

Commission File Number 001-33719

MAP PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-0507047**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2400 Bayshore Parkway, Suite 200

Mountain View, California	**94043**
(Address of principal executive offices)	**(Zip code)**

(650) 386-3100

(Registrant s telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock per share $0.01 par value	**The NASDAQ Global Market**

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 x

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 x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 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. x

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

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

The aggregate market value of the voting and non-voting common equity stock held by non-affiliates of the registrant was $113,032,495 as of June 30, 2009, the last day of the registrant s second fiscal quarter during its fiscal year ended December 31, 2009, based upon the closing sale

price on The NASDAQ Global Market reported for such date. Shares of Common Stock held by each officer and director and by each person who may be deemed to be an affiliate have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2010, the registrant had outstanding 26,302,226 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 2010 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, 2009.

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PART I

ITEM 1. BUSINESS

Overview

Our goal is to use our proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. We have proprietary product candidates in development that address large market opportunities. Our current focus is to advance our Phase 3 product candidate, LEVADEX orally inhaled migraine therapy, formerly known as MAP0004, a proprietary orally inhaled version of dihydroergotamine mesylate, or DHE, for the potential treatment of migraine.

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. They usually involve pounding or throbbing pain on one side of the head, although pain may occur on both sides. Migraines limit the normal functioning of patients, who often seek dark, quiet surroundings until the episode has passed. Most migraines last between four and 24 hours, but some last as long as three days. According to published studies, the median frequency of attack is 1.5 times per month, although approximately 25% of migraine sufferers experience one or more attacks every week.

Migraine is a major public health problem that affects up to approximately 12% of the population in the United States and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people in the United States suffer from migraine. In 2008, according to market data, approximately 29 million prescriptions were written for the treatment of migraine in the United States. Approximately 12 million of those prescriptions were written for acute migraine specific drugs. The majority of acute migraine specific drug prescriptions written were in the triptan class. In 2009, the triptan market in the United States totaled approximately $2.1 billion in revenues.

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. LEVADEX is an easy to use, at-home therapy in development that patients self-administer using our proprietary hand-held Tempo® inhaler. 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. DHE also is available in an intranasal formulation. We believe LEVADEX has the potential to be suitable as a first-line therapy for some migraine patients.

In May 2009, we announced results of the efficacy portion of our first Phase 3 clinical trial of LEVADEX, or FREEDOM-301, which is being conducted pursuant to a special protocol assessment, or SPA, from the U.S. Food and Drug Administration, or FDA. 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. Additional endpoints showed that LEVADEX provided rapid and sustained pain relief for up to 48 hours after dosing.

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 percent of patients who received LEVADEX compared with 34.5 percent for placebo ($p<0.0001$);

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

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

Nausea free: 67.1 percent of patients who received LEVADEX compared with 58.7 percent 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 anticipated, with 46 percent reporting severe pain and 54 percent 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 six percent, with two percent of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at five percent, compared with two percent for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort (one percent) or chest pain (0 percent), were rare and comparable to placebo. There were no mean 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 14th Congress of the International Headache Society.

In September 2009, we announced that post-hoc analysis of data from this Phase 3 trial shows the potential of LEVADEX to be effective in treating acute 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 and migraine with and without aura.

In October 2009, we announced that we had completed a planned interim safety review of the open-label, long-term safety extension of the FREEDOM 301 clinical trial. At the time of the interim review, more than 400 patients had completed at least six months of treatment and over 7,800 headaches had been treated in the safety extension. No drug-related serious adverse events had been reported.

In January 2010, we announced that the FDA had informed us that a second pivotal efficacy study would not be required for the LEVADEX new drug application, NDA, submission. We had previously anticipated initiating a second pivotal efficacy study in the first quarter of 2010.

The remaining clinical studies for the LEVADEX program include the ongoing 12 month open-label safety extension of the FREEDOM-301 clinical trial, a pharmacokinetics, PK, trial and a pharmacodynamics, PD, trial. We anticipate that patients and subjects in these studies will complete treatment in 2010.

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

Nebulized Budesonide

Unit Dose Budesonide, or UDB, is our proprietary nebulized version of budesonide intended to treat asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide. 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. Our UDB product candidate has been designed to achieve a particle size smaller than previously possible with budesonide. We believe this smaller particle size may allow for faster delivery and efficacy at a lower dose, which together may offer improved safety, compliance and convenience.

In December 2008 we entered into a worldwide collaboration with AstraZeneca AB to develop and commercialize UDB, which became effective on February 2, 2009. 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 when compared to placebo. On July 8, 2009, we received a notice of termination of the collaboration agreement from AstraZeneca. Subsequently, we suspended development of UDB. We are considering options for our pediatric asthma program moving forward, by leveraging our experience with budesonide and our expertise in particle technology, including the development of a next generation therapy with budesonide.

Other Pipeline Products

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

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

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

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

MAP0001: We are demonstrating this stable protein and peptide capability with MAP0001, our proprietary formulation of insulin for the potential treatment of Type 1 and Type 2 diabetes via pulmonary delivery using our proprietary Tempo inhaler. This approach may overcome many of the issues currently associated with the invasive delivery of proteins by injection or infusion in general, and with inhalable insulin therapies in particular.

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

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

Our Product Candidates

LEVADEX for the Acute Treatment of Migraine

LEVADEX, or MAP0004, is our proprietary orally inhaled version of DHE in development intended to treat migraine. In a Phase 3 clinical trial, LEVADEX provided pain relief at 10 minutes after dosing for some patients, and provided statistically significant pain relief at 30 minutes and two hours after dosing. In addition, LEVADEX provided sustained pain relief from two to 24 hours and two to 48 hours. LEVADEX was well tolerated and there were no drug-related serious adverse events reported. Symptoms and sensitivities typically associated with triptans were rare and similar to placebo. Additional analyses indicated the potential of LEVADEX to effectively treat any time during the migraine including four to eight hours after onset of migraine. Based on these results, we believe LEVADEX has the potential to be suitable as a first-line therapy for some migraine patients. 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 hand-held Tempo inhaler. DHE is available as an IV therapy which has been used in clinical settings for over 50 years for the safe and effective treatment of migraine, particularly forms of migraine that are severe or do not respond to triptans or other therapies. We believe DHE s adoption as a first-line therapy has been limited by its invasive mode of administration and high incidence of nausea. In May 2009, we announced results of the efficacy portion of our first Phase 3 clinical trial of LEVADEX, or FREEDOM-301, which is being conducted pursuant to a SPA, from the FDA. 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. Additional endpoints showed that LEVADEX provided rapid and sustained pain relief for up to 48 hours after dosing. In January 2010, we announced that the FDA had informed us that a second pivotal efficacy study would not be required for the LEVADEX NDA submission. We had previously anticipated initiating a second pivotal efficacy study in the first quarter of 2010.

Migraine

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

Migraine is a major public health problem that affects up to approximately 12% of the population in the United States and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people in the United States suffer from migraine. In 2008, according to market data, approximately 29 million prescriptions were written for the treatment of migraine in the United States. Approximately 12 million of those prescriptions were written for acute migraine specific drugs. The majority of acute migraine

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specific drug prescriptions written were in the triptan class. In 2009, the triptan market in the United States totaled approximately $2.1 billion in revenues. There are two general categories of migraine therapies: acute and preventive. Acute therapies dominate the migraine market and are used during infrequent attacks, typically characterized as one to three attacks per month, and are designed to relieve the pain, nausea, phonophobia and photophobia symptoms of migraine. The goals of acute therapy are to stop the attack quickly and consistently, while preventing recurrence, to maintain the patient s ability to function, to use the least amount of medication and to limit adverse side effects. Although triptans are the predominant class of drugs used to specifically target migraine, DHE is another class of acute, migraine-specific therapy.

Limitations of Current Migraine Therapies

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

Triptans have three major limitations:

Slow and variable onset: While triptans have improved the treatment of migraine, the onset of pain relief with these products tend to be relatively slow and variable due to inconsistent systemic absorption via oral and nasal routes of administration.

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

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

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

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

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

Our Potential Solution: LEVADEX

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

Rapid onset: The inhalation of DHE via our Tempo inhaler offered fast onset of pain relief. In our Phase 3 clinical trial, LEVADEX provided significant pain relief at 30 minutes after dosing. In addition, while not statistically significant, 50% more of the patients receiving LEVADEX than the patients receiving placebo reported pain relief at 10 minutes.

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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 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, 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 six percent, with two percent of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at five percent, compared with two percent 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

In May 2009, we announced results of the efficacy portion of our first Phase 3 clinical trial of LEVADEX, or FREEDOM-301, which is being conducted pursuant to an SPA from the FDA. 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. Additional endpoints showed that LEVADEX provided rapid and sustained pain relief for up to 48 hours after dosing.

Phase 3 Clinical Trial Results. 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 trial followed by a 12-month open-label safety assessment. In this trial, patients were randomized to either 0.5 mg LEVADEX or placebo during the efficacy portion of the trial. This clinical trial is being conducted pursuant to an SPA with the FDA.

In May 2009, we announced results of the efficacy portion of our first Phase 3 clinical trial of LEVADEX, or FREEDOM-301. 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. Additional endpoints showed that LEVADEX provided rapid and sustained pain relief for up to 48 hours after dosing.

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 percent of patients who received LEVADEX compared with 34.5 percent for placebo ($p<0.0001$);

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

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

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

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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 percent reporting severe pain and 54 percent 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 six percent, with two percent of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at five percent, compared with two percent for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort (one percent) or chest pain (0 percent), 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 14th Congress of the International Headache Society.

In September 2009, we announced that post-hoc analysis of data from this Phase 3 trial shows the potential of LEVADEX to be effective in treating acute 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 and migraine with and without aura.

In October 2009, we announced that we had completed a planned interim safety review of the open-label, long-term safety extension of the FREEDOM 301 clinical trial. At that point, more than 400 patients had completed at least six months of treatment and over 7,800 headaches had been treated in the safety extension. No drug-related serious adverse events had been reported. The goal of the ongoing long-term safety extension is to evaluate overall safety, including pulmonary and cardiovascular safety, of LEVADEX in at least 300 patients for six months and in at least 150 patients, including migraine sufferers with asthma, for 12 months as part of a potential NDA. The interim review of the data was conducted after a pre-specified number of patients had completed six months of exposure to LEVADEX and was also reviewed by an independent Data Monitoring Committee, DMC. The DMC is an independent group of clinical trial experts, including physicians, formed to critically review and evaluate patient safety data generated in the FREEDOM 301 trial with the objective of ensuring clinical trial patient safety, quality of the data collected and continued scientific validity of the trial design. On an ongoing basis, the DMC reviews data from the safety extension, including results of both pulmonary lung function evaluations using measures such as DLco and FEV_1 and cardiac evaluations using electrocardiograms, echocardiograms and chest X-rays.

In January 2010, we announced that the FDA had informed us that a second pivotal efficacy study would not be required for the LEVADEX NDA submission. We had previously anticipated initiating a second pivotal efficacy study in the first quarter of 2010.

The remaining clinical studies for the LEVADEX program include the ongoing 12 month open-label safety extension of the FREEDOM-301 study, a PK study and a PD study. The PK study will compare the safety, PK

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and metabolic profiles of LEVADEX with IV DHE in smokers and non-smokers. The PD study will evaluate pulmonary artery pressure in healthy volunteers using echocardiograms. We anticipate that patients and subjects in these studies will complete treatment in 2010.

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 conventional 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 lowest 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 second Phase 2 clinical trial was a randomized, double blind, placebo-controlled trial in 19 adult asthmatics. Each patient received three doses, one every week in randomized order over a 15-day period, including two 1.0 mg doses of LEVADEX and one dose of placebo. The clinical trial indicated that LEVADEX was well tolerated by subjects with compromised lung function, and that the pharmacokinetics 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 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 pharmacokinetics and receptor binding research, LEVADEX s administration 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. Pharmacokinetics 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 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 11 to 13 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.

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Because DHE is well characterized and previously approved, we may seek FDA marketing approval of LEVADEX under Section 505(b)(2) of the FFDCA. Section 505(b)(2) of the FFDCA 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

We plan to consider development of LEVADEX for use outside the United States as well as for potential additional indications beyond acute migraine.

We believe there is opportunity to develop LEVADEX for potential use outside of the United States. While acute migraine is a major public health problem affecting approximately 12% of the population in the United States, 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 United States.

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 has the potential to treat additional migraine indications such as cluster headache, menstrual migraine, adolescent migraine, chronic migraine, chronic daily headache and status migrainosus.

Nebulized Budesonide for the Treatment of Asthma in Children

Our proprietary nebulized version of budesonide is for the potential treatment of asthma in children from 12 months to eight years of age. We design our nebulized budesonide to be administered more quickly and to provide efficacy at doses lower than those approved for conventional nebulized budesonide, which is the current leading nebulized treatment for asthma in children. Conventional nebulized budesonide is an inhaled corticosteroid, or ICS, approved by the FDA for treating asthma in children from 18 months up to eight years of age. Conventional nebulized budesonide was first introduced as Pulmicort Respules in Europe in 1990 and in the United States in 2000. We design nebulized budesonide to have a particle size smaller than previously possible. This potentially allows a higher percentage of drug to be delivered into the lung in a shorter period of time. We believe this may reduce the amount of drug deposited in the back of the mouth and throat where it may result in local and systemic side effects.

Unit Dose Budesonide (UDB) Clinical Development Program

UDB is our proprietary nebulized version of budesonide for the potential treatment of asthma in children from 12 months to eight years of age. In a Phase 2 clinical trial, UDB was effective in improving asthma symptoms and was well tolerated when compared to placebo. Nebulization time was three to five minutes. In February 2009, we announced top-line results from our first Phase 3 trial of UDB, indicating that the trial did not meet its co-primary endpoints when compared to placebo. On July 8, 2009, our partner AstraZeneca AB terminated our worldwide collaboration agreement related to the UDB product candidate. Subsequently, we suspended development of UDB. We are considering options for our pediatric asthma program moving forward, by leveraging our experience with budesonide and our expertise in particle technology, including the development of a next generation therapy with budesonide.

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

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In this randomized, double-blind, placebo-controlled trial, 360 steroid naïve children with asthma, 12-months to eight years of age, were randomized to receive 0.25 mg UDB, 0.135 mg UDB or placebo twice a day over a 12-week period. The co-primary endpoints evaluated asthma control as assessed by changes from baseline as compared to placebo in nighttime composite symptom scores, and daytime composite symptom scores, both comprised of cough, wheeze and shortness of breath. Based on our review of these data, both the placebo and active groups experienced improvements in asthma symptoms, but the differences between placebo and active were not statistically significant. We observed a higher than expected response in the placebo groups, starting as early as one week after randomization and continuing throughout the 12-week treatment period, suggesting that patients had milder asthma symptoms than anticipated, which made it difficult to show statistically significant separation between active and placebo groups. Median nebulization times were less than four minutes for both doses in the study. Review of the data has not identified any serious adverse events attributed to the study drug.

Phase 2 Clinical Trial Results. In February 2007, we announced positive results from a Phase 2 clinical trial of UDB as a potential treatment for asthma in children. The clinical trial included 205 asthmatic children aged one to 18 years old across multiple sites in the United States. The objective of the clinical trial was to evaluate the efficacy, tolerability and pharmacokinetics of UDB. The clinical trial compared two different doses of UDB, 0.135 mg and 0.25 mg, administered twice a day, in a randomized, double-blind, placebo-controlled trial. The co-primary endpoints of the clinical trial were the change from baseline in nighttime composite symptom score, which is a composite of the three symptoms of coughing, wheezing and shortness of breath, and the change from baseline in daytime composite symptom score in the same three symptoms. Secondary endpoints included changes from baseline in morning and evening peak expiratory flow, a measure of lung function. In addition, we evaluated trends in Forced Expiratory Volume in one second, or FEV_1, which indirectly measures airway narrowing.

This Phase 2 clinical trial demonstrated that after six weeks of dosing, UDB produced a statistically significant reduction in nighttime and daytime composite symptom scores versus placebo for the 0.135 mg dose of UDB ($p = 0.002$ for the nighttime score and $p = 0.003$ for the daytime score). Positive trends in FEV_1 were seen in those patients old enough to take this test. The higher 0.25 mg twice a day dose was not significantly better than placebo in the co-primary endpoints of nighttime and daytime composite symptom score. However, we observed consistent trends with respect to secondary endpoints and similar magnitude of FEV_1 improvements in both doses compared to placebo, which we believe is sufficient to support future clinical evaluation of the 0.25 mg dose.

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

MAP0005 Combination Particle Technology

We believe MAP0005 serves as a proof of concept for the robust, specific delivery of two therapeutic agents that could benefit from targeted receptor delivery in a fixed ratio within a single particle. We intend to opportunistically evaluate the application of this technology to additional product candidates because we believe our proprietary technologies in this area have potential broad applicability for a number of small molecule combination product candidates in diverse indications via inhalation and other routes of delivery. MAP0005, our proprietary combination of an inhaled corticosteroid and a long-acting beta-agonist, or LABA, for the potential treatment of asthma and chronic obstructive pulmonary disease, or COPD, utilizes our proprietary particle formulation technologies to administer the optimal ratio of multiple drugs in a reproducible and consistent

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manner. We combine two or more drugs together into a single micron sized particle at a pre-defined consistent and reproducible ratio, which may improve the delivery profile and stability of the resultant combination therapy. In April 2008, we announced positive results from a Phase 2a clinical trial evaluating MAP0005 for the potential treatment of asthma and COPD. We believe this approach, as compared to current ICS/LABA combinations, may allow the optimal ratio of each drug to the lung to reach the relevant receptors at the cellular level in the lung in a more reproducible and consistent manner, reducing the amount of drug delivered systemically and potentially improving the side effect profile, while improving therapeutic efficacy.

MAP0001 Stable Protein Particle Technology

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

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

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

Our Technology

Our aerosol delivery and pharmacological profiling technology combines our knowledge of aerosol science and medicine, and enables us to create inhaled drug products with potentially enhanced pharmacological profiles relative to the parent drugs, thereby improving their efficacy and safety. Starting with the bulk drug substance, we develop particles with the physical and chemical characteristics that are well suited for the aerosol delivery of the product candidate. The particle engineering allows more of our drug to reach the areas of the respiratory tract to treat disease and reduces the amount of drug that is deposited in the back of the throat where it can cause local and systemic side effects. We then formulate the drug particles into a delivery medium and package them into the 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 any, already in wide use and regarded as safe, that result in favorable safety characteristics and allow flexibility in delivery format. The resulting drug products can be as consistent and efficient as alternative, often more invasive dosing formats, such as injection, but with the advantages of fast onset, high degree of intake at the target organs, and lower or controlled systemic exposure. The convenience, consistency and efficiency of inhaled administration in combination with the characteristics of our product candidates can offer meaningful therapeutic benefits when compared to existing drugs, increasing the probability of the successful adoption of our product candidates.

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

Delivery of drugs to treat respiratory diseases locally. Diseases such as asthma, COPD and some respiratory tract infections have been treated by pulmonary drug delivery for many years in order to target therapeutic effect to the lung and reduce systemic drug exposure and related side effects. Our technology is designed to improve the therapeutic efficacy and safety of known drugs for these

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applications, by efficiently delivering customized drug particles to those areas in the lung where drug is required and minimizing the drug exposure to other areas of the respiratory tract and body. In addition, our technologies have the potential to broaden the types of respiratory illnesses that can effectively be targeted and treated safely via pulmonary delivery.

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

Aerosol Delivery and Pharmacological Profiling Technology

Our proprietary technologies include particle creation and formulation technologies, which can be applied to small or large molecules, including peptides and proteins. Our technologies also include the development and manufacturing of aerosol delivery devices, including our current Tempo inhaler. Tempo is a proprietary, next generation pressurized metered dose inhaler, or MDI, that dispenses drug automatically when the patient inhales and has high consistency and efficiency compared to other inhalers. Our technologies are covered by over 25 issued U.S. patents and over 30 U.S. patent applications that we own or have licensed, as well as their foreign counterparts.

Particle Creation and Formulation

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

One of our key technologies is the generation of particles by supercritical fluid, or SCF, precipitation. SCF gives us the ability to create very small particles ranging from 100 nanometers to 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.

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.

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Tempo Inhaler Platform

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

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

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

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

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

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

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

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 COPD and MAP0001 for the potential treatment of diabetes.

Our Strategy

Key elements of our strategy include:

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

Advance and expand our product pipeline in our target commercial areas, leveraging our extensive expertise in pulmonary delivery and respiratory science and medicine in a lower risk manner: We intend to focus our pipeline development initially on products with established safety and efficacy

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records, but whose market potential has been limited by safety, relative efficacy and patient compliance. We believe that we can overcome these limitations by leveraging our technologies. These technologies underpin our competitive advantage in developing multiple, high-value products with clearly defined patient benefits.

Build a focused sales force to commercialize LEVADEX: Our goal is to build a focused sales force in the United States to market and sell our products, once approved, to neurologists and headache specialists. We plan to develop or in-license additional product candidates for this sales force and any other sales forces we may develop.

Expand the market opportunity for our most advanced product candidates: In order to expand the commercial opportunity for LEVADEX, we may establish partnerships with pharmaceutical companies to market and sell to primary care physicians. Outside the United States, we may establish commercial partnerships for all of our product candidates in order to accelerate development and regulatory approvals in those countries and further broaden their commercial potential.

Collaborations and License Agreements

AstraZeneca

In December 2008, we entered into an agreement with AstraZeneca, or the 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.

In February 2009, under the terms of this 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 immediately. AstraZeneca elected to terminate the AstraZeneca Agreement pursuant to Section 19.3.1(b) of the AstraZeneca Agreement, which provides that AstraZeneca could terminate the AstraZeneca Agreement in the event that the primary endpoints of the initial Phase 3 clinical trial of UDB were not met. Effective on the date of termination, all rights licensed to AstraZeneca in the agreement reverted back to us. We also announced our plan to suspend development of our UDB product candidate. We were jointly developing UDB with AstraZeneca, and were responsible for executing the development plan.

Elan Pharma International

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

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

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

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

In connection with the execution of the AstraZeneca Agreement, we amended the Elan agreements, so that we and AstraZeneca would have certain rights under the Elan agreements during the term of the AstraZeneca Agreement. Effective on the date of the termination from AstraZeneca, all rights licensed to AstraZeneca in the agreement reverted back to us.

Under the license agreement, we are required to make payments to Elan based upon achievement of certain development and sales milestones. As of December 31, 2009, when and if certain milestones are met we may be obligated to pay Elan up to $16.5 million in total future development and sale milestone payments with respect to our UDB product candidate. In addition, we are also required to make payments to Elan with respect to other product candidates we may develop pursuant to the license agreement. We are also required to pay royalties based on net sales of the product for an initial royalty term, calculated on a country-by-country basis, equal to either the expiration of Elan s patents covering the product in such country, or 15 years after commercial launch in such country, if Elan does not have patents covering the product in such country. After the initial royalty term, we continue to pay royalties on product sales to Elan at reduced rates.

Either party may terminate the agreement upon a material, uncured default of the other party. We may terminate the agreement, with or without cause, at any time upon 90 days written notice.

Nektar Therapeutics

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

Our obligation to pay royalties to Nektar is based on net sales of products, and will continue, on a country-by-country basis, until the longer of expiration of Nektar patents covering the product, ten years after the first commercial sale of the product, or the date that Nektar s know-how becomes known to the general public. In addition, we are required to make future payments based upon achievement of certain product development milestones. As of December 31, 2009, when and if certain milestones are achieved we may be obligated to pay Nektar up to $5.0 million in total future development milestone payments with respect to our LEVADEX product candidate.

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

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

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 are housed within a fully-assembled Tempo inhaler and packaged for clinical and commercial use.

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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 period of five years thereafter we will purchase the fully-assembled Tempo inhalers only from Exemplar, and Exemplar will manufacture and supply from its manufacturing facility all such devices 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 seven issued U.S. patents, and 13 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:

- 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 Collaborations and License Agreements. We rely on such third parties to protect the intellectual property we license, and we do not and have not had any control over the filing or prosecution of patent applications. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Our enforcement of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

Manufacturing

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

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The bulk 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 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. Each has extensive experience with medical-grade clinical and commercial scale product manufacture under cGMP.

Competition

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

If approved for the acute treatment of migraine, we anticipate that LEVADEX would compete against other marketed migraine therapies. In 2008, according to market data, approximately 29 million prescriptions were written for the treatment of migraine in the United States. Approximately 12 million of those prescriptions were written for acute migraine specific drugs. The majority of acute migraine specific drug prescriptions written were in the triptan class. In 2009, the triptan market in the United States totaled approximately $2.1 billion in revenues. The largest selling triptan is sumatriptan with 2009 sales of approximately $800 million in the United States including approximately $600 million from generics and $200 million from branded Imitrex from GlaxoSmithKline. There are six other branded triptan therapies being sold by pharmaceutical companies. Alternative formulations of triptans are available which may have faster onset of action than solid oral dosage forms. Alternative formulations of DHE include Migranal, which is nasally delivered. In April 2008, GlaxoSmithKline s Treximet, a combination oral formulation of sumatriptan and naproxen sodium, was approved by the FDA for the acute treatment of migraine. In July 2009, Zogenix, Inc s Sumavel DosePro needle-free sumatriptan was approved by the FDA for the treatment of acute migraine and cluster headache. In addition to marketed migraine therapies, there are several product candidates under development that could potentially be used to treat migraine and compete with LEVADEX, including products under development by large pharmaceutical companies such as Merck & Co., Inc. and other smaller companies. Merck s MK-097, a calcitonin gene-related peptide antagonist, is in Phase 3 development.

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

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Government Regulation

Federal Food, Drug and Cosmetic Act

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

New Drug Applications

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

- completion of pre-clinical laboratory and animal testing in compliance with the FDA s Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing which must become effective before human clinical trials may begin in the United States;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA s cGMP regulations; and
- submission to and approval by the FDA of an NDA application.

The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of pre-clinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, covering each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the 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 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.

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

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

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

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

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

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. Under the Prescription Drug User Fee Act, or PDUFA, the FDA agrees to specific goals for NDA review time through a two-tiered classification system, Standard Review and Priority Review. Standard Review is applied to a drug that offers at most only minor improvement over existing marketed therapies. Standard Review NDAs have a goal of being completed within a 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 clinical data and/or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and FDA may interpret data differently than we do. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials and surveillance programs, to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these postmarketing programs. Drugs may be marketed only for approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

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Section 505(b)(2) New Drug Applications

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

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product s listed patent or that such patent is invalid is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification, the Section 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) NDA application also will not be accepted or approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product, has expired.

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

DEA Regulation

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

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International Regulation

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

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.

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

Third-Party Payor Coverage and Reimbursement

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

changing Medicare reimbursement methodologies;

fluctuating decisions on which drugs to include in formularies;

revising drug rebate calculations under the Medicaid program; and

reforming drug importation laws.

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

Manufacturing Requirements

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA s cGMP regulations. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to

manufacture our products. We and our third-party manufacturers are also subject to periodic inspections of

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facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Other Regulatory Requirements

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among other things, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FFDCA, 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, 2009, we employed 82 full-time employees. Of the full-time employees, 58 were engaged in product development and clinical activities, and 24 were engaged in sales, general and administrative activities. We plan to continue to expand our product development programs. To support this growth, we will need to expand managerial, operations, development, regulatory, sales, marketing, finance and other functions. None of our employees are represented by a labor union, and we consider our employee relations to be good.

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 or copy any materials we file with the SEC at the SEC s Public Reference Room at 450 Fifth Street, NW, 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.

We incorporated in the state of Delaware, were originally formed as a limited liability company on July 3, 2003 and converted to a corporation on December 11, 2003. We completed our initial public offering in October 2007 and a follow-on public offering in August 2009. Our principal executive offices are located at 2400 Bayshore Parkway, Suite 200, Mountain View, California, 94043. Our telephone number is (650) 386-3100, and our web site address is *www.mappharma.com*. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports are available free of charge on our web site as soon as reasonably practicable after we file these reports with the SEC. Our Code of Ethics can also be found on our website.

Financial Information

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

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ITEM 1A. RISK FACTORS

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

Risks Relating to Our Financial Position and Need for Additional Capital

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

We are not profitable and do not expect to be profitable in the foreseeable future. We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately $40.1 million, $72.9 million and $9.0 million, for the years ended December 31, 2007, 2008 and 2009, respectively. As of December 31, 2009, we had a deficit accumulated during development stage of approximately $184.9 million. We have devoted most of our financial resources to research and development, including our pre-clinical development activities and clinical trials. We have not completed development of, or commercialized, any product candidate and have therefore not generated any product revenues. In that regard, we expect to have substantial expenses as we continue with our Phase 3 clinical program for LEVADEX, our most advanced product candidate, and conduct other clinical trials. In addition, if we are required by the U.S. Food and Drug Administration, or the FDA, to perform studies in addition to those we currently anticipate, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We also expect an increase in our expenses associated with our manufacturing work and with preparing for commercialization. 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. On July 8, 2009, we received a notice of termination of our license agreement with AstraZeneca related to our Unit Dose Budesonide, or UDB, product candidate. Under the AstraZeneca Agreement, AstraZeneca had agreed to fund our remaining development activities for UDB and to reimburse us for costs we incur with respect to future UDB development activities conducted for the U.S. registration, subject to the terms and conditions of the license agreement. Following the termination of the license agreement, we suspended development of UDB. If we are unable to develop and commercialize our other product candidates or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

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

Our operations to date have been primarily limited to organizing and staffing our company, developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, among others:

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our most advanced product candidate, LEVADEX for the potential treatment of migraine;
- potential risks related to any collaborations we may enter into for our product candidates, including LEVADEX;
- delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- the success of clinical trials of our LEVADEX product candidate or future product candidates;
- any delays in regulatory review and approval of product candidates in development;
- the FDA s determination of the special protocol assessment, or SPA, we entered into for LEVADEX;
- our ability to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, to seek FDA marketing approval of our product candidates;
- our ability to rely on Section 505(b)(2) of the FFDCA;
- market acceptance of our product candidates for which we obtain regulatory approval;
- our ability, and our partners ability, to establish an effective sales and marketing infrastructure;
- competition from existing products or new products that may emerge;
- the impact of competition, including generics, in the migraine market on our ability to commercialize LEVADEX;
- the ability of patients to obtain coverage of or sufficient reimbursement for our products outside of the United States;
- the ability to receive regulatory approval or commercialize our products;

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

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

guidelines and recommendations of therapies published by various organizations;

potential product liability claims;

potential liabilities associated with hazardous materials;

our ability to maintain adequate insurance policies;

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

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

our ability, 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;

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our ability to adequately support future growth; 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, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we focus on and proceed with our Phase 3 clinical program and conduct our other clinical trials of LEVADEX, our most advanced product candidate. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies to those that we currently anticipate, in which case the timing of any potential product approval may be delayed. We believe that our existing cash, cash equivalents and short-term investments 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 future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken unprecedented actions intended to address extreme market conditions that include severely restricted credit and declines in real estate values. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may limit our ability to access the capital markets to meet our funding requirements.

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

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

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

the costs and timing of regulatory approval;

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

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the effect of competing technological and market developments;

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

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

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

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

We are largely dependent on the success of 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 UDB and LEVADEX. 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. In July 2009 we announced that we were suspending development of UDB, after our partner AstraZeneca terminated our license agreement. We are now largely dependent on the success of one product candidate, LEVADEX, for which we are conducting a Phase 3 clinical development program. Our ability to generate product revenue, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development, regulatory approval and successful commercialization of this product candidate. We may have inadequate financial or other resources to advance LEVADEX through the clinical trial process, depending on the 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 study is ongoing. 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. We expect to conduct additional clinical trials, including a pharmacokinetics trial in approximately 24 adult smokers comparing them to approximately 24 non-smokers and a pharmacodynamics trial evaluating pulmonary artery pressure in healthy volunteers using echocardiogram before submitting an application to the FDA for regulatory approval. We expect treatment in our remaining LEVADEX clinical trials to be completed in 2010. 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 in our planned clinical trials, 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 product candidate in late stage development. 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 a next generation budesonide therapy for the treatment of asthma in children, should we pursue these activities. 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 a new drug application, or an NDA, from the FDA for each product candidate. We have not submitted an NDA or received marketing approval for any of our product candidates. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. Markets outside of the United States also have requirements for approval of drug candidates which we must comply with prior to marketing.

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

We may enter into collaborations with third parties to develop and commercialize our product candidates, including LEVADEX. Our dependence on 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. increase the cost of developing our product candidates.

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

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

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

obtaining regulatory approval to commence a clinical trial;

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

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

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

maintaining and supplying clinical trial material on a timely basis;

complying with design protocols of any applicable SPAs; and

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

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

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

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

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

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

If we are required to conduct additional clinical trials or other testing of our 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 currently are conducting a Phase 3 clinical program for LEVADEX and will need to complete our long-term safety extension and conduct a pharmacokinetics trial and a pharmacodynamics trial in order to support our new drug application for LEVADEX. 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.

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.

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 four of its co-primary endpoints when LEVADEX was compared to placebo. A long-term safety extension of the study is ongoing. In order to obtain regulatory approval for

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LEVADEX, we need to complete the long-term safety extension and conduct a pharmacokinetics trial and a pharmacodynamics trial. The data collected from our clinical trials may not be adequate to support regulatory approval of LEVADEX or any of our other product candidates. Even if we obtain regulatory approval of a product candidate, the FDA may require continuing 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 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.

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 initial 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.

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

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

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

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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. At this point in time, we have not been requested to perform drug-drug interaction studies, but any such request may delay any potential product approval and will increase our expenses associated with our clinical programs. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

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

While we have negotiated an SPA with the FDA for our first Phase 3 clinical trial of LEVADEX for the potential treatment of migraine, the SPA does not guarantee any particular outcome from regulatory review of the study or the product candidate.

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

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

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

If any of our product candidates for which we 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 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;

ineffective marketing and distribution efforts;

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

lack of cost-effectiveness;

timing of market introduction and perceived effectiveness of competitive products;

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

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

potential product liability claims.

Our and our partners ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our and our partners ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Inhaled versions of certain previously approved drugs have suffered commercial failure, including recently 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.

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

We plan to market or co-promote our products where appropriate and build our own focused sales force in the United States. We currently do not have significant internal sales, distribution and marketing capabilities. For example, in order to commercialize LEVADEX, we intend to develop a focused sales force and marketing capabilities in the United States directed at high prescribers including specialists such as neurologists and headache specialists. The development of a focused sales and marketing infrastructure for our domestic operations will require substantial resources, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay of any product launch. Many of these costs will be incurred in advance of notice to us that any of our product candidates has been approved. In addition, we may not be able to hire a focused sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target, including neurology. If we are unable to establish our focused 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 expect intense competition with respect to our existing and future product candidates.

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

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

- capital resources;
- research and development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights;
- manufacturing and distribution experience; and
- sales and marketing resources and experience.

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

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

If approved for the treatment of acute 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. The majority of marketed prescription products for treatment of migraine are in the triptan class. The largest selling triptan is sumatriptan with 2009 sales of approximately $800 million in the United States including approximately $600 million from generics and $200 million from branded Imitrex from GlaxoSmithKline. 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 treatment of acute migraine and cluster headache. Alternative formulations of dihydroergotamine, or DHE, include Migranal, which is nasally delivered, and which may become generically available prior to commercial introduction, if at all, of LEVADEX. In addition to the marketed migraine therapeutics, there are product candidates under development by large pharmaceutical companies, such as Merck & Co., Inc., and other smaller companies, that could potentially be used to treat acute migraine and compete with LEVADEX. In addition, Allergan, Inc. is developing Botox botulinum toxin for the potential treatment of chronic migraine.

In addition, we may face competition from generic sumatriptan, the active ingredient in Imitrex. The FDA has approved generic versions of sumatriptan. Although we believe generic sumatriptan could not be substituted for 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.

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

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

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

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

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets, 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.

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

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

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

If 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 or change the labeling of the product;
- we may have limitations on how we promote our drugs;
- sales of products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

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

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain

adverse events, pre-approval of promotional materials and restrictions on direct-to-consumer advertising. 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

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drug approval process and the agency s efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for LEVADEX or any other product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications. The FDA historically has required that labeling for products containing DHE include a contraindication for use in women who are, or who may become, pregnant. Although we believe that this contraindication is not applicable to our formulation of DHE, the FDA may disagree and require the LEVADEX labeling to carry this contraindication.

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

- issue warning letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

We or our 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 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

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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.

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

withdrawal of clinical trial participants;

termination of clinical trial sites or entire trial programs;

costs of related litigation;

substantial monetary awards to patients or other claimants;

decreased demand for our product candidates;

impairment of our business reputation;

loss of revenues; and

the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials domestically and in selected foreign countries where we 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.

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

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

Risks Related to Our Dependence on Third Parties

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

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

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 agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

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

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

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

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

On July 8, 2009, we received a notice of termination of our license agreement with AstraZeneca related to our UDB product candidate. Our agreement with AstraZeneca provided that AstraZeneca could terminate the agreement in the event that the primary endpoints of our initial Phase 3 clinical trial of UDB were not met. Following the termination of the license agreement, we suspended development of UDB. In addition, our earlier stage product portfolio includes MAP0005 and MAP0001. We have no current intention to further develop either of these earlier stage product candidates independently. Developing pharmaceutical products, conducting clinical trials, establishing manufacturing capabilities and marketing approved products is expensive. Consequently, we may establish partnerships for further development and commercialization of these two product candidates. We expect to face competition in seeking appropriate partners. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, if any. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may not be successful. If we seek partners to help develop MAP0005 and MAP0001, but are unable to reach agreements with suitable partners, we may fail to commercialize the affected product or program.

Risks Relating to Our Intellectual Property

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

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

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

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the

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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 unforceable, it could impact our ability to commercialize or license our technology.

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

- others may be able to make 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;
- our issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

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

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

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

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party s patent rights and may go to court to stop us from engaging in our normal

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

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents 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 number of license agreements, including with Nektar Therapeutics UK Limited and with Elan Pharma International Limited, pursuant to which we license key intellectual property, including intellectual property relating to our most advanced product candidate. 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

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employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Employee Matters and Managing Growth

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

As of December 31, 2009, we had 82 full-time employees. We may need to expand our managerial, operational, administrative financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. To support this growth, we may hire additional employees within the next 12 months. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our Phase 3 clinical program for LEVADEX and other additional trials effectively, which we anticipate will be conducted with numerous vendors at numerous clinical sites; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

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

Risks Relating to Owning Our Common Stock

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

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock together control over 50% of our outstanding common stock. If these persons were to choose to act together, they

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

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

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

- actual or anticipated fluctuations in our financial condition and operating results;
- status and/or results of our clinical trials;
- results of clinical trials of our competitors products;
- regulatory actions with respect to our products or our competitors products;
- actions and decisions by our collaborators or partners;
- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors operating results or changes in their growth rate;
- competition from existing products, new products or generics that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

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

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

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

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

Persons who were our stockholders prior to the sale of shares in our IPO continue to hold a substantial number of shares of our common stock that they are now able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have also registered 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 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

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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 2. PROPERTIES

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

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

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

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceeding.

ITEM 4. RESERVED

Reserved Pursuant to SEC Release No. 33-9089A.

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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

Year Ended December 31, 2009:	**High**	**Low**
First Quarter	$ 13.08	$ 1.57
Second Quarter	$ 13.85	$ 2.00
Third Quarter	$ 12.52	$ 8.54
Fourth Quarter	$ 10.85	$ 7.86
Year Ended December 31, 2008:		
First Quarter	$ 17.69	$ 10.39
Second Quarter	$ 14.80	$ 9.75
Third Quarter	$ 11.75	$ 6.68
Fourth Quarter	$ 10.44	$ 1.75

Holders of Record

As of February 28, 2010, there were approximately 71 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.

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Performance Graph

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

The following graph shows a comparison from October 5, 2007 (the date our common stock commenced trading on The NASDAQ Global Market) through December 31, 2009 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	03/31/08	06/30/08	09/30/08	12/31/08	03/31/09	06/30/09	09/30/09	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**	**98.18**	**83.98**	**84.74**	**75.71**	**58.03**	**56.24**	**67.54**	**78.20**	**83.82**
NASDAQ Biotechnology	**100.00**	**95.28**	**92.44**	**93.80**	**97.38**	**89.03**	**82.53**	**88.32**	**97.21**	**97.80**

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Recent Sales of Unregistered Securities

None

Use of Proceeds from the Sale of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-143823), or the Registration Statement, that was declared effective by the SEC on October 4, 2007, which registered an aggregate of 5,750,000 shares of our common stock. On October 4, 2007, we sold 5,000,000 shares of common stock at an initial public offering price of $12.00 per share, for aggregate gross proceeds of $60.0 million, managed by Merrill Lynch & Co., Morgan Stanley & Co. and Deutsche Bank Securities. On October 8, 2007, in connection with the exercise of the underwriters over-allotment option, 750,000 additional shares of common stock were sold on our behalf at the initial public offering price of $12.00 per share, for aggregate gross proceeds of $9.0 million. Following the sale of the 5,750,000 shares of common stock, the offering terminated. We paid $4.8 million in underwriting discount and commissions to the underwriters, and we incurred an additional $2.0 million of other expenses related to the offering during the fiscal year ended December 31, 2007. The net offering proceeds to us, after deducting underwriting discounts paid by us and offering costs, were $62.1 million. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning 10% or more of our common stock, or to our affiliates.

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. The offering was made pursuant to a shelf registration statement on Form S-3 that we filed with the Securities and Exchange Commission on February 13, 2009, as amended on April 16, 2009, which became effective on May 5, 2009 (File No. 333-157339).

On November 11, 2009, we entered into a $60 million 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. 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 estimated offering expenses. The shares of common stock sold to Azimuth pursuant to the Purchase Agreement in this offering were registered on our effective Registration Statement on Form S-3 (File No. 333-157339).

We have applied the net proceeds from the public offerings and the Azimuth draw down to our working capital for general corporate purposes. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to capital preservation and liquidity.

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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, 2009, 2008, 2007 and for the period from July 3, 2003 (date of inception) through December 31, 2009, and the consolidated balance sheet data as of December 31, 2009 and 2008, 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, 2006, 2005, and the consolidated balance sheet data as of December 31, 2007, 2006 and 2005, 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,
	2009	2008	2007	2006	2005	2009
	(in thousands, except per share data)					
Consolidated Statement of Operations Data:						
Collaboration revenue	$ 54,166	$	$	$	$	$ 54,166
Operating expenses						
Research and development	47,996	59,277	31,362	22,268	12,285	179,694
Sales, general and administrative	13,139	13,417	9,567	4,128	4,377	47,201
Total operating expenses	61,135	72,694	40,929	26,396	16,662	226,895
Loss from operations	(6,969)	(72,694)	(40,929)	(26,396)	(16,662)	(172,729)
Interest income	119	2,103	2,775	905	348	6,368
Interest expense	(2,118)	(2,056)	(1,343)	(235)		(5,751)
Other income (expense), net	(29)	(281)	(563)	(83)	65	(762)
Net loss	$ (8,997)	$ (72,928)	$ (40,060)	$ (25,809)	$ (16,249)	$ (172,874)
Net loss attributed to common stockholders	$ (8,997)	$ (72,928)	$ (45,635)	$ (30,538)	$ (18,850)	$ (186,799)
Net loss per share attributed to common stockholders basic and diluted(1)	$ (0.41)	$ (3.58)	$ (8.28)	$ (43.11)	$ (28.75)	
Weighted average shares outstanding used in calculating net loss per share attributed to common stockholders basic and diluted(1)	22,195	20,350	5,510	708	656	

	As of Year Ended December 31,				
	2009	2008	2007	2006	2005
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 65,776	$ 44,710	$ 94,990	$ 17,746	$ 7,158
Working capital	44,629	22,091	83,337	13,258	4,115
Total assets	70,996	50,860	100,695	21,625	9,769
Long-term debt, net of current portion	7,337	14,229	6,357	10,061	
Redeemable convertible preferred stock warrant liability				411	
Redeemable convertible preferred stock				64,898	35,069
Deficit accumulated during the development stage	(184,891)	(175,894)	(102,966)	(58,686)	(28,569)
Total stockholders equity (deficit)	41,802	13,147	81,606	(58,676)	(28,566)

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

In 2009, 2008, 2007 and 2006, loss from operations, net loss and basic and diluted net loss per common share attributed to common stockholders include the impact of Accounting Standards Codification, or ASC 718, *Compensation Stock Compensation,* which were not applicable in prior years. Please see Note 2. Summary of Significant Accounting Policies in Part II, Item 8 of this Form 10-K.

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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 use our proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. We have proprietary product candidates in development that address large market opportunities. Our current focus is to advance our Phase 3 product candidate, LEVADEX orally inhaled migraine therapy, formerly known as MAP0004, a proprietary orally inhaled version of dihydroergotamine mesylate, or DHE, for the potential treatment of migraine.

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. They usually involve pounding or throbbing pain on one side of the head, although pain may occur on both sides. Migraines limit the normal functioning of patients, who often seek dark, quiet surroundings until the episode has passed. Most migraines last between four and 24 hours, but some last as long as three days. According to published studies, the median frequency of attack is 1.5 times per month, although approximately 25% of migraine sufferers experience one or more attacks every week.

Migraine is a major public health problem that affects up to approximately 12% of the population in the United States and approximately 15% in Europe. According to the National Headache Foundation, approximately 30 million people in the United States suffer from migraine. In 2008, according to market data, approximately 29 million prescriptions were written for the treatment of migraine in the United States. Approximately 12 million of those prescriptions were written for acute migraine specific drugs. The majority of acute migraine specific drug prescriptions written were in the triptan class. In 2009, the triptan market in the United States totaled approximately $2.1 billion in revenues.

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. LEVADEX is an easy to use, at-home therapy in development that patients self-administer using our proprietary hand-held Tempo® inhaler. 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. DHE also is available in an intranasal formulation. We believe LEVADEX has the potential to be suitable as a first-line therapy for some migraine patients.

In May 2009, we announced results of the efficacy portion of our first Phase 3 clinical trial of LEVADEX, or FREEDOM-301, which is being conducted pursuant to a special protocol assessment, or SPA, from the U.S. Food and Drug Administration, or FDA. 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. Additional endpoints showed that LEVADEX provided rapid and sustained pain relief for up to 48 hours after dosing.

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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 percent of patients who received LEVADEX compared with 34.5 percent for placebo ($p<0.0001$);
- Phonophobia free: 52.9 percent of patients who received LEVADEX compared with 33.8 percent for placebo ($p<0.0001$);
- Photophobia free: 46.6 percent of patients who received LEVADE compared with 27.2 percent for placebo ($p<0.0001$); and
- Nausea free: 67.1 percent of patients who received LEVADEX compared with 58.7 percent 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 anticipated, with 46 percent reporting severe pain and 54 percent 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 six percent, with two percent of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at five percent, compared with two percent for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort (one percent) or chest pain (0 percent), were rare and comparable to placebo. There were no mean 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 14th Congress of the International Headache Society.

In September 2009, we announced that post-hoc analysis of data from this Phase 3 trial shows the potential of LEVADEX to be effective in treating acute 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 and migraine with and without aura.

In October 2009, we announced that we had completed a planned interim safety review of the open-label, long-term safety extension of the FREEDOM 301 clinical trial. At the time of the interim review, more than 400 patients had completed at least six months of treatment and over

7,800 headaches had been treated in the safety extension. No drug-related serious adverse events had been reported.

In January 2010, we announced that the FDA had informed us that a second pivotal efficacy study would not be required for the LEVADEX new drug application, NDA, submission. We had previously anticipated initiating a second pivotal efficacy study in the first quarter of 2010.

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The remaining clinical studies for the LEVADEX program include the ongoing 12 month open-label safety extension of the FREEDOM-301 trial, a pharmacokinetics, PK, trial and a pharmacodynamics, PD, trial. We anticipate that patients and subjects in these trials will complete treatment in 2010.

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

Nebulized Budesonide

Unit Dose Budesonide, or UDB, is our proprietary nebulized version of budesonide intended to treat asthma in children from 12 months to eight years of age. UDB is designed to be administered more quickly and to provide efficacy at lower doses than conventional nebulized budesonide. 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. Our UDB product candidate has been designed to achieve a particle size smaller than previously possible with budesonide. We believe this smaller particle size may allow for faster delivery and efficacy at a lower dose, which together may offer improved safety, compliance and convenience.

In December 2008 we entered into a worldwide collaboration with AstraZeneca AB to develop and commercialize UDB, which became effective on February 2, 2009. 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 when compared to placebo. On July 8, 2009, we received a notice of termination of the collaboration agreement from AstraZeneca. Subsequently, we suspended development of UDB. We are considering options for our pediatric asthma program moving forward, by leveraging our experience with budesonide and our expertise in particle technology, including the development of a next generation therapy with budesonide.

Other Pipeline Products

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

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

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

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

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

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

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

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

We are a development stage company and have not generated any product revenues. Since our inception, we have incurred losses and have an accumulated deficit of $184.9 million as of December 31, 2009. We have financed our operations through equity financing, debt financing, the issuance of convertible notes and collaboration payments. We expect to continue to incur net losses for at least the next several years as we continue to develop our current product candidates, develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates in development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We will need to raise additional capital and expand our commercial organization to launch any products. Significant capital is required to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

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 in accordance with Accounting Standards Codification, or ASC 605, *Revenue Recognition*, which requires that certain criteria must be met before revenue can be recognized: 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. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management s judgments regarding the fixed nature of the fee charged for research performed and milestones met, and the collectability of those fees. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

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Collaboration revenue, which is earned under agreements with third parties for research and development activities, may include nonrefundable license fees, cost reimbursements and contingent milestones and royalties. Our revenue arrangements with multiple elements are evaluated in accordance with ASC 605-*25 Revenue Recognition Multiple-Element Arrangements*, and are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value and whether there is verifiable objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and recognized as collaboration revenue over the research and development period pursuant to the agreement. Such period generally represents the research and development period set forth in the agreement between our third party collaborator and us. The research and development period is estimated at the inception of the arrangement and is periodically reevaluated. Reevaluation of the research and development period may shorten or lengthen the period during which the deferred revenue is recognized. We evaluate the appropriate period based on research progress attained and reevaluate the period when significant changes occur. If the collaboration agreement is terminated, all the remaining unamortized deferred revenue will be recognized as collaboration revenue on the date of termination.

Cost reimbursements are based upon negotiated rates for our full time employee equivalents, or FTE, and actual out-of-pocket costs. They are recognized as collaboration revenue as the related research and development services are performed. The cost reimbursements are generally based on qualified expenses as defined in the collaborative agreement. FTE rates are intended to approximate our anticipated cost.

We recognize milestone payments as revenue upon achievement of the milestone provided the milestone payment is nonrefundable, substantive effort and risk is involved in achieving the milestone and the amount of the milestone is reasonable in relation to the effort expended or risk associated with the achievement of the milestone. If these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract as we complete our performance obligations.

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*, which requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based

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payments including stock options. 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. We selected the Black-Scholes valuation model as the most appropriate valuation method for stock option grants. The fair value of these stock options grants is estimated as of the date of grant using the Black-Scholes valuation model. The risk-free 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 our Employee Stock Purchase Plan. The expected stock price volatility for our common stock was determined by examining the historical volatilities for industry peers and using an average of the historical volatilities of our industry peers as we did not have any significant trading history for our common stock. Industry peers consist of several public companies in the biopharmaceutical industry similar to us in size, stage of life-cycle and financial leverage. The expected term for shares from the Employee Stock Purchase plan is determined based on the historical offering periods for the Employee Stock Purchase Plan. 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 historical stock price volatility and expected term assumptions as more historical data for our common stock becomes available. The expected dividend yield of 0% is based on our history and expectation of dividend payouts. We have not paid and do not anticipate paying any dividends in the near future, other than a certain cumulative dividend on preferred stock pursuant to the terms of our certificate of incorporation, which was paid in connection with our initial public offering, or IPO. As stock-based compensation expense recognized in the condensed consolidated statement of operations for the years ended 2009, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. 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.

Net Operating Loss Carryforwards

At December 31, 2009, we had federal and state net operating loss carryforwards of approximately $162.4 million and $156.5 million, respectively. The net operating loss carryforwards expire between 2014 and 2029, 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 $6.4 million, $31.6 million and $16.4 million during the years ended December 31, 2009, 2008 and 2007, respectively.

As of December 31, 2009, we also had federal and state research and development tax credit carryforwards of approximately $6.6 million and $3.7 million, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2024, and the state credits can be carried forward indefinitely. The Tax Reform Act of 1986 limits the use of net operating loss carryforwards in certain situations where changes occur in the stock ownership of a company. In the event we have a change in ownership, utilization of the carryforwards could be limited.

We adopted ASC 740-10, *Accounting for Uncertainty in Income Taxes*, on January 1, 2007. As of December 31, 2009, we had no unrecognized tax benefits and do not expect any material change during the next year. As of December 31, 2009, we have not recorded any interest or penalties under this pronouncement.

Financial Overview

Collaboration Revenue

We recognize revenues from collaborative research and development activities. Collaboration revenue, which is earned under agreements with third parties for research and development activities, may include nonrefundable upfront payments, cost reimbursements and milestone payments. Total collaboration revenue

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recognized under the AstraZeneca Agreement was $54.2 million for the year ended December 31, 2009 and consists of a $40 million upfront payment and $14.2 million from reimbursement of qualified development expenses. The $40.0 million upfront payment initially was recognized as collaboration revenue on a straight-line basis over the term of our research and development period with respect to UDB. Effective on the date of termination, the remaining unamortized deferred revenue of $33.1 million was recognized as collaboration revenue in the third quarter of fiscal 2009.

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.

Conducting a significant amount of research and development is central to our business model. Through December 31, 2009, we incurred approximately $179.7 million in research and development expenses since our inception in 2003. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of clinical trials. We plan to incur substantial research and development expenses for the foreseeable future in order to complete development of our most advanced product candidate, LEVADEX, and to conduct earlier-stage research and development projects. Pursuant to the AstraZeneca Agreement, AstraZeneca reimbursed our development costs related to the UDB program beginning on the effective date of February 2, 2009. The AstraZeneca Agreement was terminated on July 8, 2009.

The following table summarizes the percentages of our research and development expenses related to our two most advanced product candidates and other earlier stage projects for the three years ended December 31, 2009, 2008 and 2007, 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 is allocated based on management estimates.

	Year Ended December 31,			Period from July 3, 2003 (Date of Inception) through December 31, 2009
	2009	2008	2007	
Our product candidates:				
LEVADEX	62%	44%	51%	51%
UDB (suspended)	25%	50%	39%	40%
Other projects	13%	6%	10%	9%
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

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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. However, we will need substantial additional capital in the future in order to complete the development and potential commercialization of LEVADEX and other product candidates.

Sales, General and Administrative Expenses

Sales, general and administrative expenses consist primarily of compensation for executive, finance, marketing, legal and administrative personnel, including 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. Through December 31, 2009, we incurred approximately $47.2 million in sales, general and administrative expenses since our inception in 2003.

Results of Operations

Comparison of Years Ended December 31, 2009 and 2008

	Year Ended December 31,		Increase/	% Increase/
	2009	2008	(Decrease)	(Decrease)
	(in thousands, except percentages)			
Collaboration revenue	$ 54,166	$	$ 54,166	N/A

Collaboration Revenue. 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 $40.0 million upfront payment initially was recognized as collaboration revenue on a straight-line basis over the term of our research and development period with respect to UDB. Effective on the date of termination, the remaining unamortized deferred revenue of $33.1 million was recognized as collaboration revenue in the third quarter of fiscal 2009.

	Year Ended December 31,		Increase/	% Increase/
	2009	2008	(Decrease)	(Decrease)
	(in thousands, except percentages)			
Research and development expenses	$ 47,996	$ 59,277	$ (11,281)	(19)%
Sales, general and administrative expenses	13,139	13,417	(278)	