MEDICINOVA INC
Form 10-K
March 28, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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, 2012

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: 001-33185

MEDICINOVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**33-0927979**
(State or Other Jurisdiction of Incorporation	**(I.R.S. Employer Identification No.)**
or Organization)	
4275 Executive Square, Suite 650, La Jolla, CA	**92037**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 373-1500

(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, par value $0.001 per share	The NASDAQ Stock Market LLC

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

Series A Participating Preferred Stock Purchase Rights

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 15(d) of the 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). [X] Yes [ ] No

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes [ ] No [X]

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $22,014,000 based on the closing price of the registrant s common stock on the Nasdaq Global Market of $1.63 per share on June 29, 2012. Shares of common stock held by each executive officer and director and each person who beneficially owns 10% or more of the outstanding common stock have been excluded from this calculation. This determination of affiliate status may not be conclusive for other purposes.

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of March 27, 2013 was 18,244,502.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant s 2013 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K.

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MEDICINOVA, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2012

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements that involve a number of risks and uncertainties, many of which are beyond our control. Our actual results may differ from those anticipated or expressed in these forward-looking statements as a result of various factors, including those set forth below under the caption Item 1A. Risk Factors, and the differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include discussions regarding our operating strategy, growth strategy, licensing and acquisition strategy, cost savings initiatives, industry and economic conditions, market factors, financial condition, liquidity and capital resources, results of operations, expected progress of the development of our product candidates, potential licensing, collaboration and partnering plans, anticipated trends and challenges in our business and the markets in which we operate, competitive position, intellectual property protection, critical accounting policies and the impact of recent accounting pronouncements. In this report, for example, we make forward-looking statements regarding the potential for our product candidates to receive regulatory approval for one or more indications on a timely basis or at all; the progress and results of pending clinical trials for certain of our product candidates, including any delays in commencing or completing enrollment for our ongoing or planned clinical trials; plans for future clinical trials and regulatory submissions; unexpected adverse side effects or inadequate therapeutic efficacy of certain of our product candidates that could delay or prevent regulatory approval or commercialization or that could result in product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of and obtaining regulatory approval for our product candidates; the scope and validity of patent protection for our product candidates; the market potential for our target markets and our ability to compete; the potential to attract and maintain relationships with one or more strategic partners and terms of any related transactions; intense competition if any of our product candidates are ever commercialized; our ability to realize the anticipated strategic and financial benefits of our acquisition of Avigen, Inc., or Avigen; the potential impact of uncertainties in the credit and capital markets or a future deterioration of these markets on our investment portfolio; and our ability to raise sufficient capital or debt financing when needed, or at all. Such forward-looking statements include statements preceded by, followed by or that otherwise include the words may, might, will, intend, should, could, can, would, expect, believe, estimate, anticipate, predict, potential, plan or similar words. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Item 1. Business

Overview

We are a development stage biopharmaceutical company focused on developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs with a commercial focus on the U.S. market. We are currently focusing our development activities on MN-166, an ibudilast-based drug candidate for the treatment of neurological disorders, and obtaining additional funding to advance clinical trial development of MN-221, a novel, highly selective $ß_2$ -adrenergic receptor agonist being developed for the treatment of acute exacerbations of asthma and chronic obstructive pulmonary disease, or COPD.

We completed a Phase 2 clinical trial of MN-166 for the treatment of multiple sclerosis (MS) in 2008. Positive safety and neuroprotective efficacy indicators were observed in that trial and we are seeking collaborations to resume a clinical development program for the treatment of progressive multiple sclerosis. In the area of drug dependence, in 2010, investigators at Columbia University and the New York State Psychiatric Institute completed a double blinded, placebo controlled, Phase 1b/2a opioid withdrawal clinical trial that was

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funded by the National Institute on Drug Abuse, or NIDA. Investigators at Columbia and the New York State Psychiatric Institute recently commenced a NIDA funded, double blinded, placebo controlled, Phase 2a clinical trial to determine the effect of MN-166 for the withdrawal treatment of patients addicted to prescription opioids or heroin. This trial is expected to proceed through mid-2014 and, assuming a positive outcome, is expected to be followed by a Phase 2 trial for opioid dependence. Investigators at UCLA recently completed enrollment of a Phase 1b NIDA funded clinical trial of MN-166 in methamphetamine-dependent volunteers. We expect results from the trial to be announced in the second quarter of 2013. In September 2012 we announced approval and funding by NIDA of a Phase 2 clinical trial studying the use of MN-166 for the treatment of methamphetamine addiction. In collaboration with UCLA, this clinical trial will build on the UCLA Phase 1b trial. A Phase 2 investigator sponsored clinical trial of MN-166 in the treatment of chronic medication overuse headache (MOH) pain has been initiated by a headache and pain specialist in Australia and is expected to be completed by mid-2013. We have provided supplies of MN-166 and safety and regulatory support for the drug dependence trials and MOH trial. We intend to complement additional grant supported clinical development with targeted MediciNova support.

We completed a Phase 2 clinical trial of MN-221 for the treatment of acute exacerbations of asthma treated in the emergency room in 2012 and conducted an End-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, in October 2012. We plan to conduct the MN-221 program according to the feedback received from the FDA following the End-of-Phase 2 meeting. In that meeting, the FDA identified the risk/benefit profile of MN-221 as a focal point for further development and advised that a clinical outcome, such as a reduction in hospitalizations, would need to be a pivotal trial primary endpoint. Previously completed Phase 2 studies have evaluated the potential for MN-221 to reduce hospitalizations due to acute exacerbations of asthma. We believe the appropriate clinical development for MN-221 will involve conducting dose regimen and acute exacerbations of asthma trial design optimization studies prior to commencing pivotal trials. Currently, we are working to address the manufacturing requirements before further clinical development is commenced. In the area of COPD exacerbations, we have completed two Phase 1b clinical trials of MN-221. We have determined that any future MN-221 clinical trial development will be partner-dependent from a funding perspective.

Including MN-166 and MN-221 and our other product development programs, we have acquired licenses to eight compounds for the development of ten product candidates which include clinical development for the treatment of acute exacerbations of asthma, MS and other central nervous system (CNS) disorders, bronchial asthma, interstitial cystitis (IC), solid tumor cancers, generalized anxiety disorders/insomnia, preterm labor and urinary incontinence.

Our Strategy

Our goal is to build a sustainable biopharmaceutical business through the successful development of differentiated products for the treatment of serious diseases with unmet medical needs in high-value therapeutic areas. Our focus is on the U.S. market. Key elements of our strategy are as follows:

Pursue the development of MN166 for multiple potential indications primarily through non-dilutive financings. We intend to advance our diverse MN-166 (ibudilast) program through a combination of investigator sponsored trials and trials funded through government grants or private and public grants. In addition to providing drug supply and safety regulatory support, we may fund portions of the investigator or consortium sponsored trials. For example, we intend to increase our financial participation in the Phase 2 clinical trial of MN-166 for the treatment of methamphetamine addiction that investigators at UCLA will conduct primarily with funding from NIDA. We intend to enter into additional strategic alliances to support further clinical development of MN-166.

Strategically partner with one or more leading pharmaceutical companies to complete late stage product development and successfully commercialize our products. We develop and maintain relationships with pharmaceutical therapeutic area leaders. Upon completion of proof-of-concept Phase

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2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical companies who seek late stage product candidates, such as MN-221, to support further clinical development and product commercialization.

Product Development Programs

Our product development programs address diseases that we believe are not well served by currently available therapies and represent significant commercial opportunities. We believe that we have product candidates that offer innovative therapeutic approaches that may provide significant advantages relative to current therapies.

Our product acquisitions have focused primarily on product candidates with significant preclinical and early clinical testing data that have been developed by the licensors outside of the U.S. We utilize the existing data in preparing Investigational New Drug Applications, or INDs, or their foreign equivalents, and in designing and implementing additional preclinical or clinical trials to advance the regulatory approval process in the U.S. or abroad.

Following are the details of our product development programs:

MN-166 (Ibudilast)

MN-166 is a novel, first-in-class, non-opioid drug for the treatment of several indications with potentially large addressable patient populations including drug addiction, progressive MS and pain. MN-166 is a relatively potent and selective inhibitor of macrophage migration inhibitory factor (MIF) and phosphodiesterases (PDEs) -4 and -10. It is a first-in-class, orally bioavailable small molecule, glial attenuator that suppresses pro-inflammatory cytokines IL-1ß, TNF-a, and IL-6, and may increase the release of the anti-inflammatory cytokine IL-10 and neuroprotective growth factors (e.g. GDNF). It has additionally been shown to be a toll-like receptor 4 (TLR4) functional antagonist, which property may contribute to its attenuation of neuroinflammation. While considered a New Molecular Entity, or NME, in the U.S. and Europe, ibudilast was first approved in Japan more than 20 years ago for the treatment of cerebrovascular disorders and bronchial asthma. Ibudilast has been prescribed to over three million patients and has an established post-marketing safety profile as reported in nearly 15,000 patients studied at the prescribed doses in Japan.

Based on our research, we have filed patent applications for multiple uses of MN-166 (ibudilast) for the treatment of neurological conditions, as well as patents on analogs which we believe have the potential to be effective second generation molecules. Some of the patent estate has received allowance in the U.S. and foreign countries.

Opioid withdrawal: According to the Substance Abuse and Mental Health Services Administration s (SAMHSA) 2011 National Survey on Drug Use and Health, there are approximately 1.4 million people with nonmedical pain reliever dependence and approximately 369,000 people with heroin dependence in the U.S. The economic costs of nonmedical use of prescription opioids in the U.S. was estimated at $53.4 billion in 2006, according to a study published in The Clinical Journal of Pain. Most of the medications currently approved by the FDA for the treatment of opioid dependence are opioid agonists which carry the risk of secondary dependence or abuse and have opioid-related safety risks. Accordingly, there is an unmet need for a safe, effective, non-addictive therapy for the treatment of opioid withdrawal and dependence. In 2010, investigators at Columbia University and New York State Psychiatric Institute completed a Phase 1b/2a double blinded placebo-controlled clinical trial of MN-166 for the treatment of opioid withdrawal and analgesia, or OWA, in which 30 patients were enrolled. The trial was funded by NIDA. Investigators at Columbia University and New York State Psychiatric Institute recently commenced an investigator led double-blinded,

placebo-controlled, Phase 2a clinical trial of MN-166 for the treatment of addictions to prescription opioids or heroin in which 24 patients were enrolled. This trial is expected to proceed through mid 2014 and, assuming a positive outcome, is expected

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to be followed by a Phase 2 trial for opioid dependence. MN-166 and analogs have been shown in preclinical models of opioid (morphine or oxycodone) withdrawal to reduce significantly patient withdrawal symptoms. MN-166 and analogs are differentiated from other drug candidates in clinical trials that may demonstrate similar effects, in that MN-166 and analogs are not narcotics and do not, themselves, provide reward or reinforcement in behavioral models of dependence. Thus, while current therapies involve substitution of one opioid for another (e.g. methadone for heroin), MN-166 represents a novel non-opioid approach for the treatment of opioid withdrawal and dependence. Results from the recently-completed OWA trial indicated dose-related attenuation of the opioid withdrawal syndrome relative to the placebo control for the 80mg dose of MN-166, measured using the Subjective Opioid Withdrawal Scale (SOWS). SOWS is a rating scale for measuring the signs and symptoms of opiate withdrawal. SOWS contains 16 symptoms that patients rate for intensity on a scale of 0 (not at all) to 4 (extremely). The trial also observed an enhanced opioid analgesia relative to the placebo control for the 80mg dose of MN-166, measured using the McGill Pain Questionnaire. Other measures of withdrawal (Clinicians Opioid Withdrawal Scale) or analgesia (quantitative time endpoints for cold pressor test) did not demonstrate a dose-related response.

Methamphetamine addiction: Methamphetamine is a highly addictive stimulant that is closely related to amphetamine. It is long lasting and toxic to dopamine nerve terminals in the central nervous system. It is a white, odorless, bitter-tasting powder taken orally or by snorting or injecting, or a rock crystal that is heated and smoked. Methamphetamine increases wakefulness and physical activity, produces rapid heart rate, irregular heartbeat and increased blood pressure and body temperature. Long-term use can lead to memory loss, aggression, psychotic behavior, heart damage, malnutrition and severe dental problems. All users, but particularly those who inject the drug, risk infectious diseases such as HIV/AIDS and hepatitis. According to the Substance Abuse and Mental Health Services Administration s (SAMHSA) 2011 National Survey on Drug Use and Health, there are approximately 439,000 methamphetamine abusers in the U.S. An independent study conducted by the Rand Corporation estimated the economic burden of methamphetamine use in the U.S. at $23.4 billion in 2005. There are no medications currently approved by the FDA for the treatment of methamphetamine dependence. We, in collaboration with NIDA, have demonstrated MN-166 (ibudilast) s utility in methamphetamine relapse in animals. As a result of the animal studies, NIDA funded an exploratory Phase 1b methamphetamine interaction clinical trial of MN-166 led by investigators at UCLA. This trial has now completed enrollment with results expected to be publicly released in the second quarter of 2013. In September 2012 we announced approval and funding by NIDA of a Phase 2 clinical trial studying the use of MN-166 for the treatment of methamphetamine addiction. Investigators at UCLA will lead the planned Phase 2 trial with our participation.

We recently received Fast Track designation from the FDA for MN-166 (ibudilast) for the treatment of methamphetamine dependence. Fast Track is a process designed to facilitate the development and expedite the review of drugs that are intended to treat serious diseases and have the potential to fill an unmet medical need. An important feature of the FDA s Fast Track program is that it emphasizes early and frequent communication between the FDA and the sponsor throughout the entire drug development and review process to improve the efficiency of product development. Accordingly, Fast Track status can potentially lead to a shortened timeline to ultimate drug approval.

Progressive Multiple Sclerosis (MS): MS is an inflammatory disease of the CNS in which the body s immune system attacks the protective sheath surrounding nerve fibers. According to the National Multiple Sclerosis Society, MS affects approximately 400,000 people in the U.S. and approximately 2.5 million people worldwide. The most obvious effect of MS is its destruction of nerve fibers leading to the loss of muscle control. However, MS also affects multiple CNS functions. Currently, there is no known cure for the disease. According to the National Multiple Sclerosis Society, relapsing-remitting MS, or RRMS, is the most common type of the disease, and 85 percent of people with MS are initially diagnosed with RRMS. A majority of RRMS patients progress to secondary progressive MS (SPMS). The most severe type of MS, primary progressive MS (PPMS), represents about 10% of all MS. According to sales data included in most recent annual reports of leading MS drug companies, including Biogen Idec Inc., Merck Serono S.A., Reva Pharmaceutical Industries Ltd., Bayer AG, Novartis AG and Sanofi, worldwide sales of drugs to treat MS exceeded $13.9 billion in 2012.

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Based on its anti-inflammatory activity and safety profile, MN-166 was evaluated for potential activity in MS in two pilot clinical trials sponsored by academic investigators in Japan. In the first pilot trial, the average relapse rate was reduced, there was no significant change in the mean Expanded Disability Status Score, or EDSS, a measure of MS drug efficacy and disease progression, and no side effects of MN-166 were reported. In a second pilot trial, MN-166 tended to normalize the levels of several chemical mediators of inflammation, including TNF-a and interferon gamma.

We completed a two-year Phase 2 multi-center, randomized, double-blind, placebo-controlled clinical trial of MN-166 for the treatment of patients with relapsing MS in April 2008. This clinical trial involved 297 patients with relapsing MS in several countries in Eastern Europe. Patients received either 30 mg of MN-166 per day, 60 mg of MN-166 per day or a placebo. In the second year of the study, all patients received active drugs. Patients who received 30 or 60 mg of MN-166 per day during the first year of the study remained on the assigned dose for the second 12 months of the study; patients who received placebo during the first 12 months of the study were randomized to receive either 30 or 60 mg of MN-166 per day (double-blind maintained) during the second 12 months of the study. Clinical and radiological outcomes were evaluated. MN-166 treatment resulted in positive findings on three independent measures indicative of a potential disease-progression modifying effect. First, sustained disability progression was significantly less likely (by approximately 50 percent) in those patients receiving MN-166 at either 30 or 60 mg per day for 24 months than in those patients receiving the drug for 12 months (p=0.026). Sustained disability progression was measured as a greater than or equal to 1.0 point increase from baseline in the EDSS score for four consecutive months. Second, the significant reduction in brain volume loss (p=0.035), as measured by cranial MRI scans, observed after 12 months in patients treated with 60 mg per day of MN-166 compared to placebo was again demonstrated in year two of the study. Brain volume loss was significantly less (p=0.030) in patients receiving 60 mg per day of MN-166 for 24 months compared to the other treatment groups. Third, MN-166 treatment at 60 mg per day significantly reduced the relative risk for conversion of new inflammatory lesions identified at month two to PBHs eight months later at month ten by 37 percent (p=0.011); such lesions that remain unchanged for eight months are considered PBHs as compared to transient inflammatory lesions that are more closely associated with relapses. MN-166 treatment at 30 mg per day resulted in a trend toward reducing evolution to PBH (p=0.074). MN-166 was well tolerated at all doses over the two years of this clinical trial, with the most common adverse events possibly related to MN-166 involving mild, transient gastrointestinal disturbances and depression. Of the 297 patients enrolled in this clinical trial, 245 patients completed the full two years of treatment. In September 2008, data from this completed two-year clinical trial was presented at the World Congress for Treatment and Research in MS.

Based on some of our prior Phase 2 trial outcomes and opinions provided by multiple sclerosis experts and advisors, MN-166 may be well positioned as a therapy for progressive MS. It is our intent to advance MN-166 into a Phase 2 proof-of-concept trial for the treatment of progressive MS and to fund that development via strategic collaborations or other means of raising additional capital. There can be no assurance that we will be able to successfully secure such strategic collaborations or fundraising activities.

Neuropathic pain: Neuropathic pain is a complex chronic pain in which the nerve fibers are damaged or dysfunctional. Although precise estimates of the prevalence of neuropathic pain are not available, there are approximately 3 million people with painful diabetic neuropathy in the U.S., according to a study published in the Clinical Journal of Pain. Effective treatment of chronic neuropathic pain remains an unmet and serious need. Until recently, conceptualization of neuropathic pain had been neuronically-based with most drugs approved or in development being related to neuronal targets. This approach has been revised significantly in light of recognition of the profound role glial activation has in creating and sustaining enhanced pain states. Accordingly, a pharmacotherapy that is orally administered daily and directed at attenuating glial activation may offer pain relief as a stand-alone medication or as an additive to existing drug therapies and would have significant utility. MN0166 (ibudilast) is a chronic pain drug candidate that may meet all of these criteria. Microphage migration inhibitory factor (MIF) activity and glial activation in the brain and spinal cord contribute to the establishment and amplification of the chronic pain state. MN-166 (Ibudilast) has demonstrated activity in preclinical models of neuropathic pain and may be effective in a wide range of neuropathic pain syndromes including neuropathy,

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post-herpetic neuralgia, HIV neuropathy, radiculopathy, spinal cord injury and chemotherapy-induced neuropathy. While ibudilast was initially developed as a non-selective phosphodiesterase (PDE) inhibitor for the treatment of bronchial asthma, its efficacy in some neuropathic pain models appears to be independent of this activity and yet still linked to glial attenuation. Ibudilast has advanced through multiple Phase 1 and 2a clinical trials in both healthy volunteers and patients for neuropathic pain, inclusive of a Phase 1b/2a clinical trial in diabetic neuropathic pain. The program, under current FDA standards, is able to enter Phase 2 development for neuropathic pain in the U.S. based on our completed preclinical and clinical development. A Phase 2 investigator sponsored, double-blind, placebo-controlled clinical trial of MN-166 in the treatment of chronic medication overuse headache (MOH) pain in which 40 patients are enrolled has been initiated by a headache and pain specialist in Australia and is expected to be completed by mid-2013.

MN-221 (bedoradrine)

MN-221 is a novel, highly selective ß$_2$ -adrenergic receptor agonist being developed for the treatment of acute exacerbations of asthma and COPD. We licensed MN-221 from Kissei Pharmaceutical Co., Ltd., or Kissei, in February 2004. Preclinical studies conducted *in vitro* and *in vivo* showed MN-221 to be highly selective for the ß$_2$ -adrenergic receptor. In these studies, the ß$_1$ -adrenergic receptor stimulating activity of MN-221 was less than that of other ß$_2$-adrenergic receptor agonists in isolated rat atrium and *in vivo* cardiac function tests in rats, dogs and sheep, thereby suggesting that the stimulating action of older, less selective ß$_2$ -adrenergic receptor agonists on the heart via ß$_1$ -adrenergic receptors may be reduced with MN-221. *Some in vitro* studies also suggested that MN-221 may act as only a partial ß$_1$ -adrenergic receptor agonist in cardiac tissue, while acting as a full ß$_2$ -adrenergic receptor in lung tissue. In addition, a preclinical drug interaction study in dogs completed during 2008 demonstrated that, while each of albuterol and MN-221 induced an increase in heart rate independently, the addition of MN-221 by intravenous administration in combination with inhaled albuterol did not add to the heart rate increase associated with inhaled albuterol alone. We believe that this improved receptor binding and functional selectivity provides good pharmacological specificity and may result in fewer cardiovascular side effects than are commonly observed with other ß$_2$ -adrenergic receptor agonists used to treat this condition. We have developed and studied an intravenous formulation of MN-221 appropriate for hospital use.

Acute Exacerbations of Asthma:

An acute exacerbation of asthma is an acute asthma symptom episode such as shortness of breath, wheezing and chest tightness due to constricted airways. Severe acute exacerbation of asthma is an emergency situation that can lead to emergency department treatment and, in some cases, hospital admission or, more rarely, death. Inhaled short acting beta-agonist agents are the mainstays of acute treatment for these types of asthma attacks and are included in the recommended standard of care according to the National Asthma Education and Prevention Program guidelines from the U.S. Department of Health and Human Services, or DHSS, for patients suffering from acute exacerbations of asthma.

Data from the National Center for Health Statistics show that in the U.S., annual visits to emergency departments for asthma are approximately 1.75 million, and there were approximately 456,000 hospitalizations and approximately 3,447 deaths due to asthma in 2007. According to the National Heart, Lung and Blood Institute, the direct costs associated with hospital care due to asthma were estimated at $5.5 billion in the U.S. in 2010. Despite significant improvement in the long-term control treatment for asthma, we believe that the number of patients presenting to emergency departments with asthma exacerbations who do not respond to initial standard of care for asthma exacerbations and who may be admitted to the hospital for further care are very similar to these prior figures. Accordingly, we believe that there remains an unmet medical need for a safe and effective treatment for acute exacerbations of asthma that could prevent some of these hospitalizations.

In March 2012 we completed enrollment of a randomized, double-blind, placebo-controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of MN-221 in patients with acute exacerbations of asthma treated in the emergency room, which involved 176 patients. The trial

was designed to compare standardized care

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to standardized care plus MN-221 at a dose of 1,200 micrograms administered intravenously over one hour. Once a patient received the initial standardized care treatment regimen, the patient was assessed for response to that treatment. If the patient s FEV1 (Forced Expiratory Volume in One Second) was less than or equal to 50 percent of predicted and the patient met all other study entry criteria, the patient was randomized to receive either MN-221 or placebo. MN-221 did not statistically meet the primary endpoint in the trial, which was improvement in FEV1 (compared to placebo). MN-221, however, showed a significant benefit over placebo for FEV1 (liters), Area Under the Curve (AUC Hour 0-1, 0-2, 0-3) of change from baseline (p=0.043, p=0.050, p=0.066 respectively). The trial also demonstrated a reduction in hospital admissions with MN-221 added to standard drug treatments. There was also significant improvement in clinical symptoms with MN-221 treated patients and the safety profile of MN-221 continues to be positive as no safety/tolerability issues of clinical significance were observed. Patients enrolled in the clinical trial continued to receive standardized care as needed. In October 2012 we met with the FDA to review future development of this product candidate. The FDA identified the risk/benefit profile of MN-221 as a focal point for further development and advised that a clinical outcome, such as a reduction in hospitalizations, would need to be a pivotal trial primary endpoint. We have decided that future MN-221 development will be designed based on the feedback received from the FDA. In the area of COPD exacerbations, we have completed two Phase 1b clinical trials. We have determined that any future MN-221 clinical trial development will be partner-dependent from a funding perspective.

We completed a randomized, double-blind, placebo-controlled, dose escalation, multi-center Phase 2 clinical trial of MN-221 in 23 stable mild-to-moderate asthmatics in August 2007. At each dose level in the escalation, patients were randomized to receive either a 15-minute intravenous infusion of MN-221 or placebo. This clinical trial achieved statistical significance in its primary endpoint of mean change in FEV1 from baseline to measurement at 15 minutes (the end of the infusion) at doses of 10, 16, 30 and 60 micrograms per minute of MN-221 (p-value less than or equal to 0.0006) compared to placebo. MN-221 produced a significant linear, dose-related increase in mean change in post-infusion FEV1 from baseline (p-value less than or equal to 0.0001) following a 15-minute intravenous infusion of MN-221. Significant improvements in mean change in post-infusion (15 minute) FEV1 from baseline were observed at doses of 10, 16, 30 and 60 micrograms per minute (p-value less than or equal to 0.0006) and at the dose of 3.5 micrograms per minute (p-value=0.0106) compared to placebo. In the protocol correct population for this clinical trial, which consisted of 21 patients, the dose-related increases in FEV1 were maintained for four hours (p-value = 0.0393) and at eight hours (p-value = 0.0424) following the 15-minute infusion of MN-221. MN-221 was well tolerated in this Phase 2 clinical trial, with only the expected $ß_2$ -adrenergic receptor pharmacology noted in some patients (*e.g.*, fall in serum potassium, elevation in plasma glucose, mild headache and mild tremors). There were no clinically significant cardiovascular, electrocardiogram, or ECG, or vital sign changes observed at any dose tested. In addition, no serious adverse effects were observed in this clinical trial.

We completed a randomized, open-label, placebo-controlled Phase 2a clinical trial to evaluate the safety and efficacy of MN-221 in patients with moderate to severe, but stable asthma, which involved 17 patients in two dose cohorts, in September 2008. In one dosing cohort, each patient received MN-221 at a dose of 1,125 micrograms or placebo over one hour by a continuous intravenous infusion. In the other dosing cohort, each patient received MN-221 at a dose of 1,080 micrograms or placebo over two hours by a continuous intravenous infusion. Both infusion rates of MN-221 produced a marked and clinically significant improvement in FEV1. FEV1 results were expressed as percent predicted based on standard reference equations accounting for an individual s race, gender, age and height. At the end of the one-hour infusion, FEV1 increased by 17.5 percent predicted for MN-221 compared to an increase of three percent predicted for placebo. At the end of the two-hour infusion, FEV1 increased by an average of 12.1 percent predicted for MN-221 compared to an increase of 1.4 percent predicted for placebo. In accordance with the study protocol, no inferential statistical testing was performed. MN-221 was well tolerated by the patients who received either infusion rate of MN-221. There were no clinically significant safety concerns noted among adverse events, ECG data, vital sign data or laboratory assessments collected throughout this clinical trial.

We completed a randomized, modified single-blind, placebo-controlled, dose escalation Phase 2 clinical trial to evaluate MN-221 in patients with severe, acute exacerbations of asthma in emergency departments, which

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included 29 patients (13 treated with standard care only and 16 treated with MN-221 plus standard care) at planned escalating doses of 240 to 1,080 micrograms, in April 2009. All patients received standardized care consisting of inhaled albuterol, ipratropium and oral steroid treatment. No safety concerns with adding MN-221 to standardized care were identified following review of ECG laboratory and adverse experience data. The hospitalization rate among patients treated with standardized care only was 46 percent (six of 13), which was the anticipated rate, compared to a hospitalization rate of 25 percent (four of 16) among patients receiving MN-221 plus standardized care. Improvement in FEV1 values generally appeared to be greater for patients receiving MN-221 in addition to standardized treatment. As specified in the protocol for this clinical trial, no inferential statistics (*e.g.*, p-values) were calculated for this study.

We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. The joint venture agreement provides for the joint venture company, Zhejiang Sunmy Bio-Medical Co., Ltd. (Zhejiang Sunmy), to develop and commercialize MN-221 in China. A sublicense will be required under which Zhejiang Sunmy will license MN-221 from us. We have not entered into the sublicense of MN-221 with Zhejiang Sunmy as of the date of this report. There is no assurance the sublicense will be executed and there is no assurance that Zhejiang Sunmy will be able to proceed with the development of MN-221 in China.

Chronic Obstructive Pulmonary Disease Exacerbations:

A COPD exacerbation is a sustained worsening of the patient s condition that is acute in onset and necessitates a change in regular medication in a patient with underlying COPD. Exacerbations are associated with a significant increase in mortality, hospitalization and healthcare utilization. The number of deaths due to COPD in the U.S. has more than doubled since 1980 to more than 124,000, according to a 2011 report on COPD from the American Lung Association, which used data from the Centers for Disease Control and Prevention. In 2010, according to the American Lung Association, the direct health care costs for COPD were $29.5 billion and indirect costs were $20.4 billion in the U.S. We believe there remains an unmet medical need for a safe and effective treatment for COPD exacerbations that could relieve bronchospasm and prevent some of these hospitalizations.

In July 2009 we announced our plan to evaluate MN-221 for the treatment of COPD exacerbations. Inhaled ß2-adrenergic receptor agonists, which are the current standard of care, are often inadequate to control the symptoms of COPD exacerbations. We believe that MN-221 may offer an immediate intravenous delivery for this life-threatening condition for patients who cannot get the full benefit from treatment with inhaled ß2-adrenergic receptor agonists due to severe bronchoconstriction. In addition, we believe that MN-221 may offer the potential for fewer cardiovascular side effects than older ß2-adrenergic receptor agonists due to its greater selectivity for the ß2-adrenergic receptor. This could be very significant due to the relative older age population seen in COPD patients who tend to have more underlying heart disease. On October 13, 2011, we entered into an agreement with Kissei to expand research and development services pertaining to the use of MN-221, including MN-221 for the treatment of COPD exacerbations.

We completed a randomized, double-blind, placebo-controlled Phase 1b study involving 48 moderate-to-severe COPD patients who received a one hour intravenous infusion of MN-221 at three different escalating dose levels (300 micrograms, 600 micrograms, or 1200 micrograms) or placebo in the first quarter of 2010. In March 2010, based on preliminary findings, we announced that all doses of MN-221 produced a clinically significant improvement in FEV1 (L) as compared to the baseline and placebo. At the end of the one hour infusion, FEV1(L) increased as compared to baseline by an average of 21.5 percent (p=0.0025) for the 1200 micrograms dose, 16.2 percent (p=0.020) for the 600 micrograms dose, and 9.2 percent (p=NS) for the 300 micrograms dose compared to a decrease of 4.0 percent for the placebo. MN-221 at doses of 600 micrograms and 1200 micrograms appeared to have an effect for at least six hours as compared to placebo. MN-221 was well tolerated by all patients who received infusions of MN-221.

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In August 2012 we completed a Phase 1b/2a clinical trial of MN-221 for the treatment of moderate to severe COPD patients. A total of 25 subjects were randomized to placebo (5 subjects) or MN-221 (20 subjects) treatment groups; with similar enrollment at each of two clinical research units. The patient group included those who had concomitant illnesses and were using other medications that are typical in this disease population. In addition, we tested the safety, tolerability, pharmacokinetics, and preliminary efficacy of repeat-administration placebo or MN-221 (1,200 micrograms) over a few days of residence in a clinical trial unit, and we assessed the correlation and potential future clinical trial utility of certain respiratory function test devices. Efficacy results indicated moderately improved pulmonary function (FEV1) in the MN-221 recipients but not the placebo recipients. Moreover, the improvement of FEV1 on subsequent MN-221 dosing days was as good as or better than treatment on day one. Our comparison of the simple hand-held FEV1 monitor with the spirometer machine used in our other clinical trials of MN-221 indicated good correlation and pharmacokinetic analyses indicated no significant accumulation of plasma MN-221 over the multiple dosing intervals.

Our other product development programs consist of the following:

- MN-001 for the treatment of bronchial asthma, for which we initiated a Phase 3 clinical program in the fourth quarter of 2006 that we subsequently terminated in the second quarter of 2007, and for which we developed prototypes of once-per-day oral dosing formulations;

- MN-001 for the treatment of interstitial cystitis, for which we completed a Phase 2 clinical trial in the first quarter of 2007;

- MN-029 for the treatment of solid tumors, for which we completed one Phase 1 clinical trial in the second quarter of 2006 and one Phase 1 clinical trial in the fourth quarter of 2007;

- MN-305 for which we completed a Phase 2 clinical trial for the treatment of generalized anxiety disorder in the second quarter of 2006 and a Phase 2 clinical trial for the treatment of insomnia in the fourth quarter of 2007;

- MN-221 for the treatment of preterm labor, for which we completed a Phase 1 clinical trial to investigate the pharmacokinetic profile of MN-221 in healthy pregnant women not in labor in the second quarter of 2007;

- MN-246 for the treatment of urinary incontinence, for which we completed a Phase 1 clinical trial in the fourth quarter of 2006 and a Phase 1 food effects study in the first quarter of 2007;

- MN-447 for the treatment of thrombotic disorders, which remains in preclinical development; and

- MN-462 for the treatment of thrombotic disorders, which remains in preclinical development.

Sales and Marketing

We currently have no marketing and sales capabilities and we expect to rely on a strategic partner to complete late stage product development and commercialize our products.

Manufacturing

We rely on third parties to manufacture bulk active pharmaceutical ingredients, or API, and finished investigational products for research, development, preclinical and clinical trials. We expect to continue to rely on third-party manufacturers for the manufacture of the API and finished products for our clinical and any future commercial production requirements. We believe that there are several manufacturing sources available at commercially reasonable terms to meet our clinical requirements and any future commercial production requirements for the API of our products and the finished drug products.

For the MN-166 (ibudilast) development program, we have sourced and imported delayed-release ibudilast capsules, marketed in Japan as Pinatos®, from Taisho-Teva Pharmaceuticals (Taisho). We are currently working with Taisho on further formulation development to address our future clinical trial needs.

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Pursuant to the terms of our license agreement with Kissei for MN-221, Kissei has the exclusive right to manufacture the commercial supply of the API for MN-221. If we enter into a supply agreement with Kissei, we will purchase from Kissei all API that we require for the commercial supply of MN-221, if such product candidate is approved for commercial sale by the FDA or other regulatory authorities. In September 2011, we entered into a letter agreement with Kissei pursuant to which, among other provisions, we agreed upon a new price for clinical supplies of API.

In March 2009, we entered into an agreement with Hospira Worldwide, Inc., or Hospira, for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of finished product for MN-221 utilizing Hospira s proprietary ADD-Vantage drug delivery system, if such product candidate is approved for commercial sale by the FDA or other regulatory authorities. Pursuant to the terms of the agreement with Hospira, Hospira will receive development fees from us upon completion of specified development activities, which we will expense as the costs are incurred. We are also obligated under the agreement to purchase a minimum number of units each year following regulatory approval, which number will be based on our forecasts submitted to Hospira on a rolling basis. In addition to the agreement with Hospira, we anticipate entering into a commercial supply agreement with a contract manufacturer for finished product of MN-221 in standard vials. However, at present, we do not have an established agreement regarding the commercial supply of MN-221 in standard vials or for the API or finished product of any of our product candidates.

Intellectual Property and License Agreements

Since our inception in September 2000, we have entered into eight license agreements with pharmaceutical companies which cover our current product candidates. We have also entered into license agreements with universities, including the University of Colorado and the University of Adelaide, which cover additional intellectual property related to our product candidates. In general, we seek to procure patent protection for our anticipated products, or obtain such protection from the relevant patents owned by our licensors. To date, we have obtained licensed rights under 14 issued U.S. patents. We also have obtained licensed rights to 93 issued and pending foreign patents and applications corresponding to these U.S. patents and patent applications. In addition to these licensed rights, we hold 15 issued U.S. patents and have filed 17 additional U.S. patent applications. We also hold 151 issued and pending foreign patents and applications corresponding to these U.S. patents and patent applications. We are not aware of any third-party infringement of the patents owned or licensed by us and are not party to any material claims by third parties of infringement by us of such third parties intellectual property rights. The following is a description of our existing license agreements and intellectual property rights for each of our product candidates.

MN-166

On October 22, 2004, we entered into an exclusive license agreement with Kyorin Pharmaceutical for the development and commercialization of MN-166. Kyorin Pharmaceutical is a fully integrated Japanese pharmaceutical company and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan), sub-licensable license to the patent rights and know-how related to MN-166 for the treatment of MS, except for ophthalmic solution formulations. MN-166 is not covered by a composition of matter patent. The U.S. method of use patent for MN-166 in MS underlying the license is set to expire on August 10, 2018. Corresponding method of use patents in certain foreign countries are set to expire on August 10, 2018. Under the terms of the agreement, we granted to Kyorin Pharmaceutical an exclusive, royalty-free, sub-licensable license to use the preclinical, clinical and regulatory databases to develop ophthalmic products incorporating the MN-166 compound anywhere in the world and non-ophthalmic products incorporating the MN-166 compound outside of our territory.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party. We may terminate the agreement for any reason with 90 days written notice to Kyorin Pharmaceutical or, in the event that a third party claims that MN-166 infringes upon such third party s intellectual property rights, with 30 days written notice.

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The term of this agreement is determined on a country-by-country basis and extends until the later of the expiration of the obligation to make payments under the agreement or the last date on which the manufacture, use or sale of the product would infringe a valid patent claim held by Kyorin Pharmaceutical but for the license granted by the agreement or the last date of the applicable market exclusivity period. In the absence of a valid patent claim and generic competition in a particular country, the agreement will expire on the earlier of five years from the date of the first commercial sale of the product by us or the end of the second consecutive calendar quarter in which generic competition exists in such country.

Under the license agreement, we have paid Kyorin Pharmaceutical $700,000 to date, and we are obligated to make payments of up to $5.0 million based on the achievement of certain clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products.

We own, co-own or hold licenses to seven issued U.S. patents and ten pending U.S. patent applications as well as corresponding pending foreign patent applications covering MN-166 (ibudilast) and its analogs. These patents and patent applications are primarily related to our development portfolio of small molecule-based products and are currently directed to methods of treating various indications using ibudilast and its analogs.

We have been granted a U.S. patent which covers the use of MN-166 (ibudilast) for the treatment of progressive forms of MS. The patent, which was granted in March 2012, will expire no earlier than November 2029, which does not include a potential extension under patent term restoration rules, and covers a method of treating primary progressive multiple sclerosis (PPMS) or secondary progressive MS (SPMS) by administering ibudilast either alone or in combination with other drugs. Counterparts of this patent application have been granted in certain foreign jurisdictions. We have been granted a patent which covers the use of MN-166 (ibudilast) for the treatment of neuropathic pain in the U.S. and it expires no earlier than December 2025. Counterparts of this patent application have been granted in certain foreign jurisdictions. We have been granted a patent which covers the use of MN-166 (ibudilast) for the treatment of drug addiction or drug dependence or withdrawal syndrome in the U.S. and it expires no earlier than January 2030. We received a Notice of Allowance for a pending patent application, based on this U.S. patent in drug addiction, from the European Patent Office (EPO) and a patent maturing from this application is expected to expire no earlier than September 2026. We received a Notice of Allowance for a pending patent application that covers the use of MN-166 (ibudilast) to enhance opioid analgesia in acute pain settings from the European Patent Office (EPO) and a patent maturing from this application is expected to expire no earlier than January 2028. A similar patent application to this allowed European patent is pending in the U.S.

MN-221

On February 25, 2004, we entered into an exclusive license agreement with Kissei for the development and commercialization of MN-221. Kissei is a fully integrated Japanese pharmaceutical company and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan), sub-licensable license to various patent rights and know-how related to MN-221 and other compounds disclosed or included in, or covered by, these patent rights, for all indications This license includes an exclusive license under one U.S. patent and certain corresponding patents and patent applications in foreign countries and is sub-licensable upon receipt of the written consent of Kissei. The U.S. patent for MN-221 has composition of matter and method of use claims. The U.S. composition of matter patent underlying the license issued on October 17, 2000 and is set to expire no earlier than February 18, 2017. Corresponding composition of matter patents in various other countries are set to expire no earlier than February 18, 2017.

In addition to the licensed patents, we have filed patent applications in the U.S. and certain foreign countries regarding additional uses and formulations of MN-221. We have received a Notice of Allowance from the U.S. Patent and Trademark Office for a pending patent application, which covers the use of MN-221 for the treatment of acute exacerbations of asthma. The MN-221 patent maturing from this allowed patent application is expected to expire no earlier than November 2030 and includes claims covering the use of MN-221 (bedoradrine) in

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combination with a standard of care (SOC) treatment regimen. The allowed claims include specific coverage for different routes of administration, including intravenous, oral and inhalation. Counterparts of this patent application are pending in certain foreign jurisdictions.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party, and we may terminate the agreement for scientific or commercial reasons upon 100 days prior written notice to Kissei during the development phase and 180 days prior written notice to Kissei during the commercialization phase.

The term of the agreement is determined on a country-by-country basis and extends until the expiration of the last Kissei patent (or equivalent) under license to expire or in the event that a valid claim does not exist or, if a valid claim expired more than ten years from the date of first commercial sale, ten years from the date of first commercial sale. In either case, the term of the agreement would not extend for any particular country past the date on which generic competition exists in such country.

Under the license agreement, we have paid Kissei $1.0 million to date, and are obligated to make payments of up to $17.0 million based on the achievement of certain clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products. Under the terms of the letter agreement we entered into with Kissei in September 2011, we agree to renegotiate in good faith with Kissei the existing levels of the milestone payment amounts and royalty rates.

MN-001

On March 14, 2002, we entered into an exclusive license agreement with Kyorin Pharmaceutical for the development and commercialization of MN-001. We obtained an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan) sub-licensable license to the patent rights and know-how related to MN-001 and its active metabolite, MN-002, disclosed and included in, or covered by, these patents, in all indications, except for ophthalmic solution formulations. This license includes an exclusive, sub-licensable license under two U.S. patent and certain corresponding patents in foreign countries. The U.S. composition of matter patent for MN-001 underlying the license expired on February 23, 2009, and the U.S. composition of matter patent for MN-002 underlying the license expired on December 30, 2011. Foreign composition of matter patents for MN-001 and MN-002 have also expired. We intend to rely upon the applicable period of post-approval exclusivity, in addition to any patents that may issue from our own patent applications. Under the terms of the agreement, we granted to Kyorin Pharmaceutical an exclusive, royalty-free, sub-licensable license to use the preclinical, clinical and regulatory databases to develop ophthalmic products incorporating the MN-001 compound anywhere in the world and non-ophthalmic products incorporating the MN-001 compound outside of our territory.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party, and we may terminate the agreement for any reason with 90 days written notice to Kyorin Pharmaceutical or, in the event that a third party claims that the licensed patent rights or know-how infringe upon such third party s intellectual property rights, with 30 days written notice.

The term of this agreement is determined on a country-by-country basis and extends until the later of the expiration of the obligation to make payments under the agreement or the last date on which the manufacture, use or sale of the product would infringe a valid patent claim held by Kyorin Pharmaceutical but for the license granted by the agreement or the last date of the applicable market exclusivity period. In the absence of a valid patent claim and generic competition in a particular country, the agreement will expire on the earlier of five years from the date of the first commercial sale of the product by us or the end of the second consecutive calendar quarter in which generic competition exists in such country.

Under the license agreement, we have paid Kyorin Pharmaceutical $4.0 million to date, and we are obligated to make payments of up to $5.0 million based on the achievement of certain clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products.

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We filed and the U.S. Patent and Trademark Office issued eight U.S. patents covering certain compositions, uses and manufacturing processes associated with MN-001 and its metabolite, MN-002. Patent applications corresponding to these U.S. patents were filed in certain foreign countries and some of the foreign patents have issued.

MN-029

On June 19, 2002, we entered into an exclusive license agreement with Angiogene Pharmaceuticals for the development and commercialization of the ANG-600 series of compounds. Angiogene Pharmaceuticals is a privately held, British drug discovery company. We obtained an exclusive, worldwide, sub-licensable license to the patent rights and know-how related to the ANG-600 series of compounds disclosed in and included or covered by these patents for all indications. MN-029 is one of the ANG-600 series compounds covered by this license. This license includes an exclusive, sub-licensable license under -four U.S. patents and certain corresponding patents and patent applications in foreign countries. The U.S. composition of matter patent for MN-029, which issued on November 11, 2003, is set to expire on January 14, 2020. Patent applications corresponding to this U.S. patent were filed in certain foreign countries and some of those foreign patents have been issued. The U.S. patent covering methods of treating solid cancer tumors by administering MN-029, which issued on July 25, 2006, is set to expire in July, 2020.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party, and we may terminate the agreement at any time by giving 30 days advance written notice to Angiogene Pharmaceuticals.

The term of this agreement is determined on a country-by-country basis and extends until the earlier of the expiration of the last Angiogene Pharmaceuticals patent (or equivalent) under license which has a valid claim to expire or 15 years from the date of first commercial sale.

Under the license agreement, we have paid Angiogene Pharmaceuticals $1.4 million to date and are obligated to make payments of up to $16.5 million based on the achievement of certain clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products.

MN-305

On April 27, 2004, we entered into an exclusive license agreement with Mitsubishi Pharma Corporation, the predecessor to Mitsubishi Tanabe Pharma Corporation, for the development and commercialization of MN-305. Mitsubishi Tanabe Pharma Corporation is a fully integrated Japanese pharmaceutical company and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan), sub-licensable license to the patent rights and know-how related to MN-305 and its active metabolite disclosed and included or covered by these patents for all indications. The license is sub-licensable upon receipt of the written consent of Mitsubishi Tanabe Pharma Corporation. This license includes an exclusive, sub-licensable license under five U.S. patents and certain corresponding patents and patent applications in foreign countries. The U.S. composition of matter patent for MN-305, which issued on December 1, 1992, expired on March 14, 2011. Patent applications corresponding to this U.S. patent were filed in certain foreign countries, and these foreign counterparts expired on or before March 14, 2011. The U.S. patent covering the use of MN-305 to treat anxiety, which issued on August 10, 1993, expired on March 14, 2011.

Under the terms of the agreement, we granted to Mitsubishi Tanabe Pharma Corporation a license to use our know-how and patents relating to MN-305 to develop products incorporating the MN-305 compound outside of our territory. Mitsubishi Tanabe Pharma Corporation also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties.

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The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party. We may terminate the agreement if, in our reasonable opinion, the safety, patient tolerability, efficacy, profile or commercial viability of MN-305 does not justify continued development with 90 days written notice to Mitsubishi Tanabe Pharma Corporation or, in the event that a third party claims that the licensed intellectual property related to MN-305 infringes such third party s intellectual property rights, with 30 days written notice.

The term of this agreement is determined on a country-by-country basis and extends until the later of ten years from the date of first commercial sale in a specific country or the expiration of a valid patent claim in such country. In the event that we enter into a sublicense with a third party, the term of the agreement will extend for as long as we receive royalty payments from such third party.

Under the license agreement, we have paid Mitsubishi Tanabe Pharma Corporation $1.0 million to date, and we are obligated to make payments of up to $18.8 million based on the achievement of certain clinical, regulatory and sales milestones. We are also obligated to pay a royalty on net sales of the licensed products.

MN-246

On December 8, 2004, we entered into an exclusive license agreement with Mitsubishi Pharma Corporation, the predecessor to Mitsubishi Tanabe Pharma Corporation, for the development and commercialization of MN-246. We obtained an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan), sub-licensable license to the intellectual property surrounding MN-246, its derivatives and any other compounds disclosed or claimed in the licensed Mitsubishi Tanabe Pharma Corporation patent assets. The license is sub-licensable upon receipt of the written consent of Mitsubishi Tanabe Pharma Corporation and includes an exclusive license under one U.S. patent and certain corresponding patents in foreign countries. The U.S. patent covering MN-246 and methods of making and using MN-246, which issued on May 30, 2000, is set to expire on October 24, 2016. Patent applications corresponding to this U.S. patent were filed in certain foreign countries, and these foreign counterparts are set to expire no earlier than October 24, 2016.

The issued U.S. patent covers generic phenylethanolamines encompassed by a given chemical formula, including MN-246, processes for the production of such phenylethanolamines, a pharmaceutical composition of such phenylethanolamines and methods of use for such phenylethanolamines for the treatment of a variety of human or animal ailments, including accelerated or spasmodic gastrointestinal motility, dysuria, pollakisuria, urinary incontinence, obesity and diabetes. Under the terms of the agreement, we granted to Mitsubishi Tanabe Pharma Corporation a license to use our know-how and patents relating to MN-246 to develop products incorporating the MN-246 compound outside of our territory. Mitsubishi Tanabe Pharma Corporation also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party. We may terminate the agreement if, in our reasonable opinion, the safety, patient tolerability, efficacy, profile or commercial viability of MN-246 does not justify continued development with 90 days written notice to Mitsubishi Tanabe Pharma Corporation or in the event that a third party claims that the licensed intellectual property related to MN-246 infringes such third party s intellectual property rights with 30 days written notice.

The term of this agreement is determined on a country-by-country basis and extends until the later of ten years from the date of first commercial sale in a specific country or the expiration of a valid patent claim in such country. In the event that we enter into a sublicense with a third party,

the term of the agreement will extend for as long as we receive royalty payments from such third party.

Under the license agreement, we have paid Mitsubishi Tanabe Pharma Corporation $750,000 to date, and we are obligated to make payments of up to $14.5 million based on the achievement of certain clinical, regulatory and sales milestones. We are also obligated to pay a royalty on net sales of the licensed products.

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MN-447

On November 1, 2006, we entered into an exclusive license agreement with Meiji Seika Kaisha for the development and commercialization of MN-447. Meiji Seika Kaisha is a fully integrated Japanese pharmaceutical company and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People s Republic of China, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sub-licensable license from Meiji Seika Kaisha for MN-447 (and any other compound claimed or covered by U.S. patent 6,420,558) for any human use. This license includes an exclusive sub-licensable license under one U.S. patent and certain corresponding patents in foreign countries. The U.S. patent covering MN-447 and methods of treating an integrin avß3-mediated disease, platelet thrombosis, aggregation and related disorders, which issued on July 16, 2002, is set to expire on April 9, 2019. Patent applications corresponding to this U.S. patent were granted in certain foreign countries. Under the terms of the license, we granted a license to Meiji Seika Kaisha to use our know-how and patents relating to MN-447 to develop products incorporating the MN-447 compound outside of our territory.

This license agreement may be terminated by either party following an uncured breach of any material provision of the agreement by the other party upon 90 days written notice or the inability or delay in performing under the agreement due to a force majeure event which lasts longer than 12 months. We also have the right to terminate the agreement in the event of third party intellectual property claims which are not timely remedied by us and Meiji Seika Kaisha or if, in our reasonable opinion, the safety, patient tolerability, efficacy, profile or commercial viability of MN-447 does not justify continued development. Meiji Seika Kaisha also has the right to terminate the agreement in the event that we cease development of MN-447 for a period of one year or longer.

The term of the agreement is determined on a country-by-country basis. The agreement expires on the expiration of the royalty term in each country. The royalty term starts on the first date of the first commercial sale and expires on the later of (1) the expiration of market exclusivity, or (2) 15 years after the date of the first commercial sale.

Under the license agreement, we have paid Meiji Seika Kaisha $400,000 to date, and we are obligated to make payments of up to $8.7 million based on the achievement of certain clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products.

MN-462

On November 1, 2006, we entered into an exclusive license agreement with Meiji Seika Kaisha for the development and commercialization of MN-462. We obtained an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People s Republic of China, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sub-licensable license from Meiji Seika Kaisha for MN-462 (and any other compound claimed or covered by U.S. patent 6,576,627) for any human use. This license includes an exclusive sub-licensable license under certain corresponding patents in foreign countries. The U.S. patent covering MN-462 medicament compositions containing MN-462, and methods of therapeutic treatment or preventive treatment of thrombotic disease, which issued on June 10, 2003, is set to expire on September 13, 2020. Patent applications corresponding to this U.S. patent were granted in certain foreign countries. Under the terms of the license, we granted a license to Meiji Seika Kaisha to use our know-how and patents relating to MN-462 to develop products incorporating the MN-462 compound outside of our territory.

This license agreement may be terminated by either party following an uncured breach of any material provision of the agreement by the other party upon 90 days written notice or the inability or delay in performing under the agreement due to a force majeure event which lasts longer

than 12 months. We also have the right to terminate the agreement in the event of third party intellectual property claims which are not timely remedied by us and Meiji Seika Kaisha or if, in our reasonable opinion, the safety, patient tolerability, efficacy, profile or

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commercial viability of MN-462 does not justify continued development. Meiji Seika Kaisha also has the right to terminate the agreement in the event that we cease development of MN-462 for a period of one year or longer.

The term of the agreement is determined on a country-by-country basis. The agreement expires on the expiration of the royalty term in each country. The royalty term starts on the first date of the first commercial sale and expires on the later of (1) the expiration of market exclusivity, or (2) 15 years after the date of the first commercial sale.

Under this license agreement, we have paid Meiji Seika Kaisha $400,000 to date, and we are obligated to make payments of up to $8.7 million based on the achievement of certain clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products.

General

Our proposed commercial activities may conflict with patents which have been or may be granted to competitors, universities and/or others. Third parties could bring legal action against us, our licensors or our sub-licensees claiming patent infringement and could seek damages or enjoin manufacturing and marketing of the affected product or its use or the use of a process for the manufacturing of such products. If any such actions were to be successful, in addition to any potential liability for indemnification, damages and attorneys fees in certain cases, we could be required to obtain a license, which may not be available on commercially reasonable terms or at all, in order to continue to manufacture, use or market the affected product. We also rely upon unpatented proprietary technology because, in some cases, our interests would be better served by reliance on trade secrets or confidentiality agreements than by patents. However, others may independently develop substantially equivalent proprietary information and techniques or gain access to or disclose such proprietary technology. We may not be able to meaningfully protect our rights in such unpatented proprietary technology. We may also conduct research on other pharmaceutical compounds or technologies, the rights to which may be held by, or be subject to patent rights of, third parties. Accordingly, if products based on such research are commercialized, such commercial activities may infringe patents or other rights, which may require us to obtain a license to such patents or other rights. We are not aware of any third-party infringements of patents we hold or licenses and have not received any material claims by third parties of infringement by us of such parties intellectual property rights.

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being issued or that, if issued, any of such patents will afford protection against competitors with similar technology or products or could not be circumvented or challenged. For example, we have U.S. patents covering the method of using MN-166 to treat MS, the method of using MN-166 to treat addiction and the method of using MN-166 to treat neuropathic pain, but we do not have any composition of matter patent claims for MN-166 because it has expired. As a result, unrelated third parties may develop products with the same API as MN-166 so long as such parties do not infringe our method of use patents, other patents we have exclusive rights to through our licensor or any patents we may obtain for MN-166.

In addition, if we develop certain products that are not covered by any patents, we will be dependent on obtaining market exclusivity under the new five-year chemical entity exclusivity provisions of Hatch-Waxman Act for such products in the U.S. and/or 10-year data exclusivity provisions in Europe. If we are unable to obtain strong proprietary protection for our products after obtaining regulatory approval, competitors may be able to market competing generic products by taking advantage of an abbreviated procedure for obtaining regulatory clearance, including the ability to demonstrate bioequivalency to our product(s) without being required to conduct lengthy clinical trials. Certain of our license agreements provide for reduced royalties or, in some cases, foregone royalties in the event of generic competition.

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Competition

The development and commercialization of new drugs is extremely competitive and characterized by extensive research efforts and rapid technological progress. Competition in our industry occurs on a variety of fronts, including developing and bringing new products to market before others, developing new products to provide the same benefits as existing products at lower cost and developing new products to provide benefits superior to those of existing products. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies in the U.S. and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs. Many of our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer and more affordable or more easily administered than ours or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any products that we are able to obtain approval for, if at all.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, research and development resources (including personnel and technology), clinical trial experience, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies.

MN-166 for Drug Addiction

Our MN-166 product candidate has been in development for treatment of opioid withdrawal and methamphetamine addiction. Current treatments for opioid withdrawal symptoms include narcotics such as generic methadone and Reckitt Benckiser Pharmaceuticals, Inc. s Subutex® (buprenorphine) and Suboxone® (buprenorphine + the opioid antagonist naloxone) and Alkermes Vivitrol® (naltrexone monthly injection). We are aware of additional compounds in development for the treatment of opioid dependence at companies including Titan Pharmaceuticals, Orexo, and BioDelivery Sciences. Limited non-narcotic drug candidates for opioid withdrawal symptoms exist. Britannia Pharmaceuticals Limited s BritLofex® (Lofexidine), licensed for development in U.S. clinical trials to US WorldMeds LLC, is an alpha adrenoceptor agonist like clonidine which may have somewhat less orthostatic hypotension limitations. There are no pharmaceuticals currently approved for the treatment of methamphetamine addiction.

MN-166 for Multiple Sclerosis

Our MN-166 product candidate is pending development for the treatment of progressive MS. Only one drug, mitoxantrone, is approved for treating this disease.

MN-166 for Neuropathic Pain

Our MN-166 product candidate has been in development for treatment of neuropathic pain. Current treatments for neuropathic pain include anti-epileptics such as Pfizer Inc. s Neurontin® (gabapentin) and Lyrica® (pregabalin), and antidepressants, including Eli Lilly & Co. s Cymbalta® (duloxetine). We are aware of additional compounds for chronic neuropathic pain that are currently in development at numerous companies

including GlaxoSmithKline plc, Pfizer Inc., Cognetix, Inc., GW Pharmaceuticals plc, Endo Pharmaceuticals Holdings Inc., Avanir Pharmaceuticals, Pain Therapeutics, Inc., and XenoPort, Inc.

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MN-221 for Acute Exacerbations of Asthma

Our MN-221 product candidate is being developed for the treatment of acute exacerbations of asthma in the emergency room setting. The current standard of care for acute exacerbations of asthma is inhaled albuterol (a $ß_2$ -adrenergic receptor agonist), inhaled ipratropium (an anticholinergic) and oral or injected corticosteroids. In addition, subcutaneously administered terbutaline (a $ß_2$ -adrenergic receptor agonist) is sometimes used to treat this condition, particularly in pediatric patients.

MN-221 for Chronic Obstructive Pulmonary Disease Exacerbations

Our MN-221 product candidate is also being developed for the treatment of COPD exacerbations. The standard of care for COPD exacerbations is similar to that of acute exacerbations of asthma in that inhaled bronchodilators and anticholinergics are administered; however, antibiotics are also administered and parenteral terbutaline is excluded because of the exclusively adult patient population. A greater percentage of patients diagnosed with COPD exacerbations are hospitalized than patients diagnosed with asthma exacerbations, and such patients continue the same treatment paradigm as in the emergency department.

Government Regulation

Government authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing and import and export of pharmaceutical products and biologics such as those we are developing. In the U.S., the FDA, under the Federal Food, Drug and Cosmetic Act, as amended, and other federal statutes and regulations, subjects pharmaceutical products to extensive and rigorous review. Any failure to comply with applicable requirements, both before and after approval, may subject us, our third-party manufacturers, contractors, suppliers and partners to administrative and judicial sanctions, such as a delay in approving or refusal to approve pending applications, fines, warning letters, product recalls, product seizures, total or partial suspension of manufacturing or marketing, injunctions and/or criminal prosecution.

U.S. Regulatory Approval

Overview. In the U.S., drugs and drug testing are regulated by the FDA under the Federal Food, Drug and Cosmetic Act, as well as state and local government authorities. All of our product candidates in development will require regulatory approval by government agencies prior to commercialization. To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy, as well as detailed information on the manufacture and composition of the product and proposed labeling. Our product candidates are in the early stages of testing and none has been approved. The steps required before a drug can be approved generally involve the following:

- completion of preclinical laboratory and animal tests;
- submission of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin in the U.S.;

completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each indication for which approval is sought;

submission to the FDA of a New Drug Application, or NDA, accompanied by a substantial user fee;

development of manufacturing processes which conform to FDA-mandated commercial good manufacturing practices, or cGMPs, and satisfactory completion of FDA inspections to assess cGMP compliance and clinical investigator compliance with good clinical practices; and

FDA review and approval of an NDA, which process may involve input from advisory committees to the FDA and may include post-approval commitments for further clinical studies and distribution restrictions intended to mitigate drug risks.

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The testing, collection of data, preparation of necessary applications and approval process requires substantial time, effort and financial resources. Additionally, statutes, rules, regulations and policies may change and new regulations may be issued that could delay such approvals. The FDA may not act quickly or favorably in reviewing our applications, and we may encounter significant difficulties and costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

Preclinical Tests. Preclinical tests include laboratory evaluation of the product candidate, its chemistry, toxicity, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. The results of the preclinical tests, together with manufacturing information, analytical data and other available information about the product candidate, are submitted to the FDA as part of an IND. Preclinical tests and studies can take several years to complete and, despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

The Investigational New Drug Application, or IND Process. An IND must be effective to administer an investigational drug to humans. The IND will automatically become effective 30 days after its receipt by the FDA unless the FDA, before that time, places the IND on clinical hold. At any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold if the FDA deems it appropriate. In such case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue. The IND application process may become extremely costly and substantially delay development of our products. Moreover, positive results in preclinical tests or prior human studies do not necessarily predict positive results in subsequent clinical trials.

Clinical Trials. Human clinical trials are typically conducted in three sequential phases that may overlap:

Phase 1: The drug is initially introduced into a small number of human subjects or patients and tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism.

Phase 2: The drug is introduced into a limited patient population to assess the efficacy of the drug in specific, targeted indications, assess dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks.

Phase 3: The drug is introduced into an expanded patient population at geographically dispersed clinical trial sites to further evaluate clinical efficacy and safety.

Prior to initiation of each clinical trial, an independent Institutional Review Board, or IRB, for each medical site proposing to conduct the clinical trials must review and approve the study protocol and study subjects must provide informed consent for participation in the study.

We cannot be certain that we will successfully complete Phase 1, 2 or 3 testing of our drug candidates within any specific time period, if at all. Clinical trials must be conducted in accordance with the FDA s good clinical practices requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

The NDA Process. If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of an NDA. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical product for marketing and sale in the U.S. The NDA must contain a description of the manufacturing process and quality control methods, as well as

results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the submission of the NDA, unless an exemption applies.

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Upon submission of the NDA, the FDA makes a threshold determination as to whether the application is sufficiently complete to permit review and, if not, will issue a refuse to file letter. If the submission is accepted for filing, the FDA begins an in-depth review of the NDA and will attempt to review and take action on the application in accordance with performance goals established in connection with the user fee laws. Among the conditions for NDA approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures conform on an ongoing basis with cGMPs.

If the FDA s evaluations of the NDA and the clinical and manufacturing procedures and facilities cGMPs are favorable, the FDA may issue either an approval letter or a complete response letter containing guidance on the conditions that must be met in order to secure approval of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. The FDA may also grant approval with requirements to complete post-marketing studies, referred to as Phase 4 clinical trials, or restrictive product labeling, or may impose other restrictions on marketing or distribution, such as the adoption of a Risk Evaluation and Mitigation Strategy, or REMS. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug.

The Hatch-Waxman Act. Under the Hatch-Waxman Act, certain newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Pediatric exclusivity of six months may also be available if agreement is reached with the FDA and qualifying studies of product candidates in pediatric populations are conducted.

Manufacturing and Other Regulatory Requirements. Both before and after approval, we and our third-party manufacturers must comply with a number of regulatory requirements. For example, if we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, manufacturing changes or additional labeling claims, we will need FDA review and approval. Advertising and other promotional materials must comply with FDA requirements and established requirements applicable to drug samples. In addition, we may not label or promote the product for an indication that has not been approved by the FDA. Securing FDA approval for new indications or product enhancements and, in some cases, for new labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical trials under the FDA s IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products.

The NDA holders and manufacturers of approved products will be subject to continual review and periodic inspections by the FDA and other authorities, where applicable, and must comply with ongoing requirements, including the FDA s cGMP requirements. Manufacturers must provide certain safety and efficacy information and make certain other required reports. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, record-keeping and other requirements. The FDA periodically inspects drug manufacturing facilities to evaluate compliance with cGMP requirements. 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. Because we intend to contract with third parties for manufacturing of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

In addition to FDA restrictions on marketing of pharmaceutical products, several other state and federal laws have been applied to restrict certain sales and marketing practices in the pharmaceutical industry. These

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laws include licensing requirements, compliance program requirements, annual certificates and disclosures, anti-kickback statutes and false claims statutes. The federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal health care programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly promoting their products for off-label uses, which in turn led to claims being submitted to and paid by the Medicare and Medicaid programs. The majority of states also have statutes or regulations similar to the Anti-Kickback Statue and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

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.

Foreign Regulatory Approval

We will have to complete approval processes, similar or related to the U.S. approval processes, in virtually every foreign market for our products in order to conduct clinical or preclinical research and to commercialize our drug candidates in those countries. The approval procedures and the time required for approvals vary from country to country and may involve additional testing. In addition, regulatory approval of prices is required in most countries other than the U.S. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

Similar to the U.S. regulatory framework, the various phases of preclinical and clinical research are subject to significant regulatory controls within the European Union. Variations among national regimes exist. However, most jurisdictions require regulatory and ethics committees approval of interventional clinical trials. Most European regulators also require the submission of adverse event reports during a study and a copy of the final study report.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other innovative medicinal products with novel characteristics. It provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit applications in other European Union member states, requesting them to mutually recognize the marketing authorization already granted. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize the existing approval.

Where possible, we will strive to choose the European regulatory filing route that will most rapidly enable us to obtain the needed regulatory approvals. However, the chosen regulatory strategy may not secure regulatory approvals or approvals of the chosen product indications. In addition, these approvals, if obtained, may take longer than anticipated.

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Employees

We have assembled an experienced and cohesive management and support team, with core competencies in general management, clinical development, regulatory affairs and corporate development. We have 12 full-time employees as of the date of this report. We believe that our relations with our employees are good, and we have no history of work stoppages.

Company Information

We were originally incorporated in the State of Delaware in September 2000. Our principal executive offices are located at 4275 Executive Square, Suite 650, La Jolla, CA 92037. Our telephone number is 858-373 1500. Our website is www.medicinova.com, which includes links to reports we have filed with the Securities and Exchange Commission, or SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

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Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. 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 Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

Risks Related to Our Business and Industry

We have incurred significant operating losses since our inception and expect that we will incur continued losses for the foreseeable future.

We have incurred significant net losses since our inception. For the year ended December 31, 2012, we had a net loss of $11.0 million. At December 31, 2012, from inception, our accumulated deficit was $296.2 million, including $50.4 million of non-cash stock-based compensation charges. We expect to incur substantial net losses for the next several years as we continue to develop certain of our existing product development programs, and over the long-term if we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own. As of December 31, 2012, we had available cash and cash equivalents of $4.0 million and working capital of $3.4 million. We expect to have approximately $3 million in available cash as of March 31, 2013, and, assuming we raise additional capital, we expect to spend approximately $6 million from April 1, 2013 through December 31, 2013 to execute our strategic plan and fund operations. As of the date of this report, we have working capital sufficient to fund operations through June 30, 2013. These factors raise substantial doubt about our ability to continue as a going concern. Between August 21, 2012 and the date of this report we have generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire Capital Fund LLC (Aspire) including proceeds of $1.5 million on the sale 800,000 shares of our common stock subsequent to December 31, 2012. We have the right, subject to the terms of the Common Stock Purchase Agreement, to cause Aspire to acquire up to 3,231,096 shares for total gross proceeds not to exceed $20 million (including the 2,019,696 shares issued or sold to Aspire to date for $3.0 million)) subject to daily dollar limitations and subject to the maximum dollar amount we can sell from time to time under our registration statement on Form S-3. We expect to sell additional shares under this agreement during 2013. We are also pursuing other opportunities to raise capital through the sale of our common stock or through other strategic initiatives. There can be no assurances that there will be adequate financing available to us on acceptable terms, or at all. If the Company is unable to obtain additional financing, we may have to sell one or more of our programs or cease operations.

Our future cash requirements will also depend on many factors, including:

- progress in, and the costs of future planned clinical trials and other research and development activities;
- the scope, prioritization and number of our product development programs;
- our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;

the time and costs involved in obtaining regulatory approvals;

the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;

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- the costs associated with any expansion of our management, personnel, systems and facilities;
- the costs associated with any litigation;
- the costs associated with the operations or wind-down of any business we may acquire;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obtain regulatory approval to market our product candidates.

We expect our research and development expenses to decline in 2013 relative to 2012 as we completed our Phase 2 clinical trial of MN-221 for the treatment of acute exacerbations of asthma in 2012. Our estimate of cash requirements for future operating expenses assumes that we do not incur significant clinical development expenditures unless we are raise additional capital and/or enter into one or more strategic alliances. We do expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing drug products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

If we have taxable income in the future, utilization of the net operating losses, or NOL, and tax credit carry-forwards will be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred. These ownership changes will limit the amount of NOL and tax credit carry-forwards that can be utilized to offset future taxable income and tax, respectively.

If we fail to obtain the capital necessary to fund our operations, we will be unable to develop and commercialize our product candidates.

We have consumed substantial amounts of capital since our inception. From our inception to December 31, 2012, we had an accumulated deficit of $296.2 million. Our cash and cash equivalents were $4.0 million at December 31, 2012.

Our business will continue to require us to incur substantial research and development expenses, such as the costs of advancing our MN-166 development program. We believe that without raising additional capital from accessible sources of financing, we will not otherwise have adequate funding to continue our operations and to complete the development of our existing product candidates or the commercialization of any products we successfully develop. There is no guarantee that adequate funds will be available when needed from debt or equity financings, arrangements with partners, or from other sources, on terms attractive to us. The inability to obtain sufficient additional funds when needed to fund our operations would require us to significantly delay, scale back, or eliminate some or all of our clinical or regulatory activities and reduce general and administrative expenses.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

To date, we have funded our operations primarily from sales of our securities and, to a lesser extent, debt financing. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue if we can enter into collaborations, strategic alliances or other agreements that would provide us with such revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve and maintain profitability.

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We are largely dependent on the success of our MN-166 product candidate and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. The research, testing, manufacturing, labeling, approval, sales, marketing and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market any of our product candidates in the U.S. until we submit and receive approval of a New Drug Application, or NDA, for a product candidate from the FDA or its foreign equivalent from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. The success of our business currently depends on the successful development and commercialization of our MN-166 product candidate, for the treatment of neurological disorders including opioid withdrawal, methamphetamine addiction, chronic MOH pain and MS. This product candidate has not completed the clinical development process, and therefore we have not submitted an NDA or foreign equivalent or received marketing approval. We plan to focus our resources on accelerating and optimizing MN-166 development in collaboration with the investigators conducting multiple grant-funded, proof-of-concept clinical trials.

The clinical development program for MN-166 may not lead to commercial products for a number of reasons, including our clinical trials failure to demonstrate to the FDA s satisfaction that this product candidate is safe and effective, or our failure to obtain necessary approvals from the FDA or similar foreign regulatory authorities for any reason. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process or are unable to secure a strategic collaboration or partnership with a third party. Any failure or delay in completing clinical trials or obtaining regulatory approval for MN-166 in a timely manner would have a material and adverse impact on our business and our stock price.

Because the results of early clinical trials are not necessarily predictive of future results, MN-166 or any other product candidate we advance into clinical trials in any indication may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Our product candidates are subject to the risks of failure inherent in drug development. We will be required to demonstrate through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population for its target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing, even at statistically significant levels.

Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. Any of our planned clinical trials for MN-166 or our other product candidates may not be successful for a variety of reasons, including the clinical trial designs, the failure to enroll a sufficient number of patients, undesirable side effects and other safety concerns and the inability to demonstrate sufficient efficacy. If a product candidate fails to demonstrate sufficient safety or efficacy, we would experience potentially significant delays in, or be required to abandon, development of such product candidate.

If we are unable to secure a collaboration for MN-221, we may be unable to complete its clinical development.

Following our May 2012 announcement of the preliminary results of the Phase 2 MN-221-CL-007 clinical trial, we met with the FDA to review future development of this product candidate. The FDA identified the risk/benefit profile of MN-221 as a focal point for further development and advised that a clinical outcome, such as a reduction in hospitalizations, would need to be a pivotal trial primary endpoint. We have decided that future MN-221 development will be designed based on the feedback received from the FDA. We have also determined that future MN-221

clinical trial development will be partner-dependent from a funding perspective.

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We will rely on the joint venture company formed in China in 2011 to develop and commercialize MN-221 in China and there is no assurance that the joint venture will be able to successful in doing so.

We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. We have invested $680,000 for 30% interest in the joint venture company, Zhejiang Sunmy. A sublicense agreement under which Zhejiang Sunmy will license MN-221 from us will be required. We have no assurances that Zhejiang Sunmy will be successful in its efforts to conduct clinical trials necessary to gain regulatory approval in China, will be able to successfully manufacture drug candidates for the Chinese market or will receive the future funding it will require to conduct operations. We have not entered into the sublicense of MN-221 with Zhejiang Sunmy as of the date of this report. There is no assurance the sublicense will be executed and there is no assurance that Zhejiang Sunmy will be able to proceed with the development of MN-221 in China or that we will someday recover our investment in Zhejiang Sunmy.

In order to commercialize a therapeutic drug successfully, a product candidate must receive regulatory approval after the successful completion of clinical trials, which are long, complex and costly, have a high risk of failure and can be delayed or terminated at any time.

Our product candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. The process of obtaining FDA and other regulatory approvals is costly, time-consuming, uncertain and subject to unanticipated delays. To receive regulatory approval for the commercial sale of any of our product candidates, we must conduct, at our own expense, adequate and well-controlled clinical trials in human patients to demonstrate the efficacy and safety of the product candidate. Clinical testing is expensive, takes many years and has an uncertain outcome. To date, we have obtained regulatory authorization to conduct clinical trials for eight of our product development programs. Investigational New Drug Applications, or INDs, were approved by the FDA and are active for seven of our product candidates. We also obtained Clinical Trial Authorizations, or CTAs, for the MN-221-CL-007 Phase 2 clinical trial for MN-221 in Canada, Australia and New Zealand. Through the acquisition of Avigen, we have assumed responsibility for clinical trials including one active IND for neuropathic pain and cross-reference and drug product support of the NIDA-funded opioid withdrawal investigator-initiated IND with Columbia University drug addiction clinical researchers. In the third quarter of 2010, the FDA approved a NIDA-funded investigator-initiated IND with University of California Los Angeles (UCLA) to proceed with an initial trial of our neurological drug candidate, MN-166 (ibudilast), as a potential new pharmacotherapy for methamphetamine addiction. In the third quarter of 2012 UCLA and MediciNova announced approval and funding by NIDA of a Phase 2 clinical trial studying the use of MN-166 for the treatment of methamphetamine addiction.

It may take years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell any of our product candidates that are ultimately approved by the FDA or foreign regulatory authorities. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, in May 2012, we announced the preliminary results from our Phase 2b clinical trial of MN-221 for patients with acute exacerbations of asthma failed to statistically meet its primary endpoint. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after obtaining promising results in earlier clinical trials. In addition, any delays in completing clinical trials or the rejection of data from a clinical trial by a regulatory authority will result in increased development costs and could have a material adverse effect on the development of the impacted product candidate.

In connection with the conduct of clinical trials for each of our product candidates, we face many risks, including the risks that:

the product candidate may not prove to be effective in treating the targeted indication;

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clinical trial participants and/or patients may experience serious adverse events or other undesirable drug-related side effects;

the results may not confirm the positive results of earlier trials;

the FDA or other regulatory authorities may not agree with our proposed development plans or accept the results of completed clinical trials; and

our planned clinical trials and the data collected from such clinical trials may be deemed by the FDA or other regulatory authorities not to be sufficient, which would require additional development for the product candidate before it can be evaluated in late stage clinical trials or before the FDA will consider an application for marketing approval.

If we do not complete clinical development of our product candidates successfully, we will be unable to obtain regulatory approval to market products and generate revenues from such product candidates. We may also fail to obtain the necessary regulatory approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. In addition, even if we believe that the preclinical and clinical data are sufficient to support regulatory approval for a product candidate, the FDA and foreign regulatory authorities may not ultimately approve such product candidate for commercial sale in any jurisdiction, which would limit our ability to generate revenues and adversely affect our business. In addition, even if our product candidates receive regulatory approval, they remain subject to ongoing FDA regulations, including obligations to conduct additional clinical trials, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

We are subject to stringent regulation of our product candidates, which could delay the development and commercialization of our product candidates.

We, our third-party manufacturers, service providers, suppliers and partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. None of our product candidates can be marketed in the U.S. until it has been approved by the FDA. None of our product candidates has been approved by the FDA to date, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval for a product takes many years of clinical development and requires substantial resources. Additionally, changes in regulatory requirements and guidance may occur or new information regarding the product candidate or the target indication may emerge, and we may need to perform additional, unanticipated non-clinical or clinical testing of our product candidates or amend clinical trial protocols to reflect these changes. Any additional unanticipated testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce or negate our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners and our product candidates are subject to numerous FDA requirements, including requirements related to testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA s requirements may change and additional government regulations may be promulgated that could affect us, our partners and our product candidates. 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, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad.

In order to market any of our products outside of the U.S., we and our strategic partners and licensees 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 product testing and additional

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administrative review periods beyond the requirements of the FDA and 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 U.S. Regulatory approval in one country, including FDA approval in the U.S, does not ensure regulatory approval in another. In addition, a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. A product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales, and any approval that we receive may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the U.S. or other countries, we may be subject to regulatory and other consequences, including fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

Even if our product candidates receive regulatory approval, they 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, including additional research and development and clinical trials. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for MN-166, our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the terms of its use, or it may not include one or more of our intended indications.

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

- issue warning letters or untitled 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.

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MN-166 or any other product candidate that we advance into clinical trials may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization or limit its commercial potential.

Undesirable side effects caused MN-166 or any other product candidate that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

In addition, if MN-166 or any other product candidate we may develop receives marketing approval and we or others later identify undesirable side effects caused by the product, a number of significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or place restrictions on the way it is prescribed; and
- regulatory authorities may require a larger clinical benefit for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements that could diminish the usage of the product or otherwise limit the commercial success of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product or implement a risk evaluation and mitigation strategy;
- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients;
- we may not be able to enter into collaboration agreements on acceptable terms and execute our business model; and
- our reputation may suffer.

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

If we experience delays in the commencement or completion of our clinical trials, we could incur significantly higher product development costs and our ability to obtain regulatory approvals for our product candidates could be delayed or limited. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of study sites and enroll a sufficient number of patients at such sites. We do not know whether enrollment in our future clinical trials for our product candidates will be completed on time, or whether our additional planned and ongoing clinical trials for our product candidates will be completed on schedule, if at all.

The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays in:

obtaining regulatory approval to commence or amend a clinical trial;

reaching agreements on acceptable terms with prospective clinical 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;

recruiting and enrolling patients to participate in clinical trials;

retaining patients who have initiated a clinical trial but who 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;

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manufacturing sufficient quantities of a product candidate; and

IRB approval or approval from foreign counterparts to conduct or amend a clinical trial at a prospective site.

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

ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results, which may result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;

inspections of our own clinical trial operations, the operations of our CROs or our clinical trial sites by the FDA or other regulatory authorities, which may result in the imposition of a clinical hold or potentially prevent us from using some of the data generated from our clinical trials to support requests for regulatory approval of our product candidates;

our failure or inability, or the failure or inability of our CROs, clinical trial site staff or other third party service providers involved in the clinical trial, to conduct clinical trials in accordance with regulatory requirements or our clinical protocols;

lower than anticipated enrollment or retention rates of patients in clinical trials;

new information suggesting unacceptable risk to subjects or unforeseen safety issues or any determination that a trial presents unacceptable health risks;

insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials; and

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

If we experience delays in the completion of our clinical trials for a product candidate, the commercial prospects for such product candidate may be harmed, we may incur increased costs for development of such product candidate and our ability to obtain regulatory approval for such product candidate could be delayed or limited. Many of the factors that cause or lead to delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for a product candidate. In addition, any amendment to a clinical trial protocol may require us to resubmit our clinical trial protocols to IRBs or their foreign counterparts for reexamination, which may delay or otherwise impact the costs, timing or successful completion of a clinical trial.

The loss of any rights to develop and market any of our product candidates could significantly harm our business.

We license the rights to certain compounds to develop and market our product candidates. Currently, we have licensed rights relating to eight compounds for the development of ten product candidates.

We are obligated to develop and commercialize certain product candidates in accordance with mutually agreed upon terms and conditions. Our ability to satisfy some or all of the terms and conditions of our license agreements is dependent on numerous factors, including some factors that are outside of our control. Any of our license agreements may be terminated if we breach our obligations under the agreement materially and fail to cure any such breach within a specified period of time.

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If any of our license agreements is terminated, we would have no further rights to develop and commercialize the product candidate that is the subject of the license. The termination of the license agreements related to MN-166 would significantly and adversely affect our business. The termination of any of the remainder of our license agreements could materially and adversely affect our business.

If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunities.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the U.S. and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs. We cannot assure you that developments by others will not render our product candidates obsolete or noncompetitive. Many of our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer, more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any products that we are able to obtain approval for, if at all. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, research and development resources, including personnel and technology, clinical trial experience, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies.

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 and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates.

We will depend on strategic collaborations with third parties to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates if we are able to achieve such third-party arrangements.

A key aspect of our strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize selected product candidates. To date, we have not entered into any such collaborative arrangements, and we may not be able to enter into any collaborations or otherwise monetize these product candidates on acceptable terms, if at all.

By entering into a strategic collaboration with a partner, we may rely on the partner for financial resources and for development, regulatory and commercialization expertise. Even if we are successful in entering into a strategic collaboration for one of our product candidates, our partner may fail to develop or effectively commercialize the product candidate because such partner:

does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;

decides to pursue a competitive potential product developed outside of the collaboration;

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cannot obtain the necessary regulatory approvals;

determines that the market opportunity is not attractive; or

cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We also face competition in our search for partners from other biotechnology and pharmaceutical companies worldwide, many of whom are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting partners and entering into collaborations on acceptable terms for these product candidates or otherwise monetizing these product candidates, we may not be able to complete development of or obtain regulatory approval for such product candidates. In such event, our ability to generate revenues from such products and achieve or sustain profitability would be significantly hindered.

The terms under which we raise additional capital or debt financing may harm our business and may significantly dilute stockholders ownership interests.

If we raise additional funds through collaborations or licensing arrangements with third parties, we may need to relinquish some rights to our product candidates, including commercialization rights, which may hinder our ability to generate revenues and achieve or sustain profitability. If we raise additional funds by issuing equity securities, including as part of a debt financing, stockholders may experience substantial dilution. Debt financing, if available, may involve significant cash payment obligations and restrictive covenants and other financial terms that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

The sale of additional common stock to Aspire Capital may cause substantial dilution to our existing shareholders and/or the price of our common stock to decline.

Pursuant to a common stock purchase agreement with Aspire Capital Fund, LLC (Aspire) dated August, 20, 2012, we may sell additional shares of our common stock to Aspire over a period of up to 24 months. Depending upon market liquidity at the time, sales of shares of our common stock under the agreement may cause the trading price of our common stock to decline and may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to Aspire in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We rely on third parties to conduct our clinical trials, and we may incur additional development costs, experience delays in the commencement and completion of clinical trials, and be unable to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We rely extensively on CROs, medical institutions, clinical investigators, contract laboratories and other service providers to perform important functions related to the conduct of our clinical trials, the collection and analysis of data and the preparation of regulatory submissions. Although we design and manage our current clinical trials to ensure that each clinical trial is conducted in accordance with its investigational plan and protocol, we do not have the ability to conduct all aspects of our clinical trials directly for our product candidates.

The FDA requires us and our CROs to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately

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informed of the potential risks of participating in clinical trials. Our reliance on CROs does not relieve us of these responsibilities and requirements. The CROs, medical institutions, clinical investigators, contract laboratories and other service providers that we employ in the conduct of our clinical trials are not our employees, and we cannot control the amount or timing of resources that they devote to our product development programs. If any of these third parties fails to devote sufficient care, time and resources to our product development programs, if its performance is substandard, or if any third party is inspected by the FDA and found not to be in compliance with GCPs, it will delay the completion of the clinical trial in which they are involved and the progress of the affected development program. The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the clinical trials and the subsequent collection and analysis of data. Any failure of the CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, the CROs, clinical investigators and other service providers may have relationships with other commercial entities, some of which may have competitive products under development or currently marketed, and our competitive position could be harmed if they assist our competitors. If any of these third parties does not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates. In addition, while we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

We rely on third-party manufacturers to produce our product candidates, which may result in delays in our clinical trials and the commercialization of products, as well as increased costs.

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of our product candidates for clinical trials or commercial purposes in the foreseeable future. We contract with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials, and we plan to contract with third-party manufacturers to produce sufficient quantities of any product candidates approved by the FDA or other regulatory authorities for commercial sale. While we believe that there are competitive sources available to manufacture our product candidates, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty.

Reliance on third-party manufacturers limits our ability to control certain aspects of the manufacturing process and therefore exposes us to a variety of significant risks, including risks related to our ability to commercialize any products approved by regulatory authorities or conduct clinical trials, reliance on such third parties for regulatory compliance and quality assurance, and the refusal or inability of a third-party manufacturer to supply our requirements on a long-term basis. In addition, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel and compliance with federal, state and foreign regulations. Also, our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to timely produce our product candidates for clinical trials and commercial sale may be interrupted, which could result in delayed clinical trials or receipt of regulatory approval and lost or delayed revenues.

We may not be able to establish or maintain any commercial manufacturing and supply arrangements on commercially reasonable terms that we require for purposes of commercializing a product. Any failure by us to secure or maintain any such required commercial supply agreements could result in interruption of supply and lost or delayed revenues, which would adversely affect our business. Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA or other regulatory approval of the product candidate or may impair our ability to manufacture commercial quantities, which would adversely affect our business. For example, our manufacturers will need to produce specific batches

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of a product candidate to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our third-party manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data for the product candidate, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize such product candidate.

Our manufacturers are obligated to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs and, in some cases, International Convention on Harmonization, or ICH, standards. A failure of any of our third-party manufacturers to establish and follow cGMPs and/or ICH standards and to document their adherence to such practices may lead to significant delays in our ability to timely conduct and complete clinical trials, obtain regulatory approval of product candidates or launch of our products into the market. In addition, changing third-party manufacturers is difficult. For example, a change in third-party manufacturer for a particular product candidate requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming and, in some cases, our manufacturers may not provide us with adequate assistance to transfer the manufacturing processes and procedures for our product candidates to new manufacturers or may possess intellectual property rights covering parts of these processes or procedures for which we may need to obtain a license. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of regulatory approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the API and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the API and finished product for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

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Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on a number of factors, including:

- demonstration of efficacy;
- changes in the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources and may never be successful.

If our products are not accepted by the market or if users of our products are unable to obtain adequate coverage of and reimbursement for our products from government and other third-party payers, our revenues and profitability will suffer.

Our ability to commercialize our products successfully will depend in significant part on pricing and cost effectiveness, including our ability to produce a product at a competitive price and our ability to obtain appropriate coverage of and reimbursement for our products and related treatments from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payers are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payers will consider our products cost-effective or provide coverage of and reimbursement for our products, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payers may conclude that our products are less safe, less clinically effective or less cost-effective than existing products, and third-party payers may not approve our products for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for our products from third-party payers, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of our products could cause our sales to suffer. Even if third-party payers make reimbursement available, payment levels may not be sufficient to make the sale of our products profitable.

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Market acceptance and sales of our current or future product candidates will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures, both in the U.S. and other key international markets. For example, continuing health care reform in the U.S. will control or significantly influence the purchase of medical services and products, and may result in inadequate coverage of and reimbursement for our products. Many third-party payers are pursuing various ways to reduce pharmaceutical costs, including the use of formularies. The market for our products depends on access to such formularies, which are lists of medications for which third-party payers provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third-party payers, including government payers, are instituting could have a material adverse effect on our ability to operate profitably.

Internationally, the success of our product candidates, if approved, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. Negotiating prices with governmental authorities can delay commercialization by 12 months or more. Reimbursement policies may adversely affect our ability to sell our product candidates, if approved, on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, which may impact the reimbursement rates and timing to launch product candidates. Such pricing practices may affect our ability to achieve profitability or expected rates of growth in revenue or results of operations, which in turn could adversely affect our business, financial condition and results of operations.

If we fail to obtain and maintain approval from regulatory authorities in international markets for any of our current or future product candidates for which we have rights in international markets, our market opportunities will be limited and our business will be adversely impacted.

Sales of our product candidates outside of the U.S. will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of our product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials. In many countries outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

If we fail to identify and license or acquire other product candidates, we will not be able to expand our business over the long term.

Because we do not have internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive, and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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Moreover, product candidate acquisitions that we do complete involve numerous risks, including:

- difficulties in integrating the development program for the acquired product candidate into our existing operations;
- diversion of financial and management resources from existing operations;
- risks of entering new markets or technologies and of receiving regulatory approval;
- inability to generate sufficient revenues to offset acquisition costs; and
- delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

If we are not successful in identifying and licensing or acquiring other product candidates over the long term, we will not be able to grow our revenues with sales from new products beyond those revenues, if any, from any approved products derived from our existing product candidates, and we may fail to achieve or sustain profitability.

We are dependent on our management team, Yuichi Iwaki, M.D., Ph.D., and experienced scientific staff, and if we are unable to retain, motivate and attract key personnel, our product development programs may be delayed and we may be unable to develop successfully or commercialize our product candidates.

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued services with us, whether through employment, service on our board of directors or a consulting agreement. We are also substantially dependent on the continued services of clinical development personnel because of the highly technical nature of our product development programs. We are not presently aware of any plans of our executive officers or key personnel to retire or leave employment with the company. Following termination of employment, these individuals may engage in other businesses that may compete with us.

If we acquire or license new product candidates, our success will depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our product development programs depend on our ability to attract and retain highly experienced clinical development and regulatory personnel. However, we face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our corporate headquarters is located. Our short operating history and the uncertainties attendant to being a development stage biopharmaceutical company could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives. In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These third parties are not our employees and may have commitments to, or 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 our product candidates.

Although we have employment agreements with key members of management, each of our employees, subject to applicable notice requirements, may terminate his or her employment at any time. We do not carry key person insurance covering members of senior management. If we lose any of our key management personnel, we may not be able to find suitable replacements, which would adversely affect our business.

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If we are unable to establish sales, marketing and distribution capabilities, whether independently or with third parties, we will be unable to successfully commercialize our product candidates.

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in obtaining regulatory approvals for any of our product candidates or acquiring other approved products, we will need to establish sales, marketing and distribution capabilities on our own or with partners in order to commercialize an approved product. The acquisition or development of an effective sales and marketing infrastructure will require a significant amount of our financial resources and time and could negatively impact our commercialization efforts, including delay of a product launch. We may be unable to establish and manage a sufficient or effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore hindering our ability to generate revenues and achieve or sustain profitability. In addition, if we are unable to develop internal sales capabilities, we will need to contract with third parties or establish a partnership to market and sell the product. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate any product revenues, may generate increased expenses and may never become profitable. In addition, although we intend to establish strategic collaborations to market any products approved for sale by regulatory authorities outside of the U.S., we may be required to market our product candidates outside of the U.S. directly if we are unable to establish such collaborations. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the U.S. and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries, pricing of prescription drugs is subject to government control, and we expect to continue to see proposals to implement similar controls in the U.S. to continue. Another example of proposed reform that could affect our business is drug reimportation into the U.S. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or our ability to raise capital or to obtain strategic partnerships or licenses. More recently, the Patient Protection and Affordable Care Act imposed numerous reforms that may impact the costs, legal requirements and potential success of our operations.

We may be sued for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

The development and commercialization of drug products entails significant product liability risks. Product liability claims may arise from use of any of our product candidates in clinical trials and the commercial sale of any approved products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

withdrawal of clinical trial participants;

termination of clinical trial sites or entire clinical trial programs;

decreased demand for our product candidates;

impairment of our business reputation;

costs of related litigation;

substantial monetary awards to patients or other claimants;

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loss of revenues; and

the inability to commercialize our product candidates.

We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time; however, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. In addition, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale clinical trials, and in the event that any of our product candidates is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. In addition, our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Successful product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one of our product candidates.

We may need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.

We have 12 full-time employees as of the date of this report. If we are successful in securing a strategic collaboration or raising additional capital, our management, personnel, systems and facilities currently in place may not be adequate to support the company s needs. For example, we may hire additional personnel in clinical development, regulatory affairs and business development to further strengthen our core competencies or choose to develop sales, marketing and distribution capabilities for certain of our product candidates. Our need to effectively manage our operations, growth and product development programs requires that we:

manage our clinical trials effectively;

manage our internal development efforts effectively while carrying out our contractual obligations to licensors and other third parties;

ensure that our consultants, CROs and other service providers successfully carry out their contractual obligations, provide high quality results and meet expected deadlines; 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, which may impact our ability to timely achieve our development and commercialization goals, if at all.

We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

Our quarterly operating results have fluctuated in the past and are likely to continue to do so in the future. Some of the factors that could cause our operating results to fluctuate from period to period include:

the status of development of our product candidates and, in particular, the advancement or termination of activities related to our product development programs and the timing of any milestone payments payable under our licensing agreements;

the execution of other collaboration, licensing and similar arrangements and the timing of payments we may make or receive under these arrangements;

variations in the level of expenses related to our product development programs;

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the unpredictable effects of collaborations during these periods;

the timing of our satisfaction of applicable regulatory requirements, if at all;

the rate of expansion of our clinical development and other internal research and development efforts;

the costs of any litigation;

the effect of competing technologies and products and market developments; and

general and industry-specific economic conditions.

We believe that quarterly or yearly comparisons of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

Our management has broad discretion over the use of our cash, and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as well as rules and regulations implemented by the SEC, The Nasdaq Stock Market, or Nasdaq, and Japanese securities laws, and incur significant legal, accounting and other expenses as a result. These rules impose various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and may make it more difficult and expensive for us to renew our director and officer liability insurance, and may result in imposition of reduced policy limits and coverage.

The Sarbanes-Oxley Act requires that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Our listing obligations under the Jasdaq Market (formerly the Hercules Market until its closure in 2010) of the Osaka Securities Exchange, or OSE, also require that we comply either with Section 404 of the Sarbanes-Oxley Act or equivalent regulations in Japan and we elected to comply with Section 404. As a result, we are required to perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404. We are subject to attestation by our registered public accounting firm on our report regarding internal control over financial reporting for the year ended December 31, 2012 under Japanese securities laws. Our efforts to

comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. We cannot be certain that a material weakness will not be identified when we test the effectiveness of our controls in the future. If a material weakness is identified, we could be subject to sanctions or investigations by Nasdaq, the SEC, the OSE or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

Additionally, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas

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such as say on pay and proxy access. To maintain high standards of corporate governance and public disclosure, we intend to invest all reasonably necessary resources to comply with such compliance programs and rules and all other evolving standards. These investments may result in increased general and administrative costs and a diversion of our management s time and attention from strategic revenue generating and cost management activities.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs, including delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

A variety of risks associated with operating our business and marketing our products internationally could materially adversely affect our business.

A significant amount of our business activity is outside of the United States. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including, but not limited to:

- compliance with differing or unexpected regulatory requirements for our products;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of our product candidates in Europe, increased dependence on the commercialization efforts of our distributors or strategic partners;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;

compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;

workforce uncertainty in countries where labor unrest is more common than in the U.S.;

changes in diplomatic and trade relationships; and

challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

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Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

There is the risk that our patents (both those owned by us and those in-licensed) may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing approval for one or more of our product candidates, particularly our in-licensed patents. Also, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Composition of matter patents on APIs may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. We do not have compound patent protection for the API in our MN-166 and MN-001 product candidates, although we do have patent protection for a particular crystalline polymorph of MN-001 and we have composition of matter protection on ibudilast analogs. As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same API as found in our MN-166 and MN-001 product candidates so long as such competitors do not infringe any methods of use, methods of manufacture, formulation or, in the case of MN-001, specific polymorph patents that we hold or have exclusive rights to through our licensors. For example, we currently rely on method of use patents for MN-166.

It is our policy to consult with our licensors in the maintenance of granted patents we have licensed and in their pursuit of patent applications that we have licensed, but each of our licensors generally remains primarily responsible for or in control of the maintenance of the granted patents and prosecution of the applications. We have limited control, if any, over the amount or timing of resources that each licensor devotes on our behalf, and a licensor may not assign as great a priority to prosecution of these patent applications as we would if we were undertaking such prosecution ourselves. As a result of this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that our licensed patents will be maintained and that any additional patents will ever mature from our licensed applications. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We typically rely on our licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we generally do not maintain control over the payment of annuities, we cannot be certain that our licensors will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. For example, certain annuities were not paid in a timely manner with respect to foreign patents licensed under MN-002 (the active metabolite of MN-001) and, as a result, our patent rights may be impaired in those territories. In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

The patent protection of our product candidates and technology involves complex legal and factual questions. Most of our license agreements give us a right, but not an obligation, to enforce our patent rights. To the extent it is necessary or advantageous for any of our licensors cooperation in the enforcement of our patent rights, we cannot control the amount or timing of resources our licensors devote on our behalf or the priority they place on enforcing our patent rights. We may not be able to protect our intellectual property rights against third party infringement, which may be difficult to detect, especially for infringement of patent claims for methods of manufacturing. Additionally, challenges may be made to the ownership of our intellectual property rights, our ability to enforce them or our underlying licenses, which in some cases have been made under foreign laws and may provide different protections than that of U.S. law.

We cannot be certain that any of the patents or patent applications owned by us or our licensors related to our product candidates and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

- obtain and maintain patents to protect our product candidates;

obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;

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protect our trade secrets and know-how;

operate without infringing the intellectual property and proprietary rights of others;

enforce the issued patents under which we hold rights; and

develop additional proprietary technologies that are patentable.

The degree of future protection for our proprietary rights is uncertain. For example:

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

we or our licensor 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 none of our pending patent applications will result in issued patents;

any patents under which we hold rights may not provide us with a basis for maintaining market exclusivity for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, not infringed or unenforceable under U.S. or foreign laws; or

any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party s relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. There are many patents relating to chemical compounds and methods of use.

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If our compounds or their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches for unexpired patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that unexpired, third-party patents containing claims covering our product candidates, their methods of use or manufacture do not exist. Moreover, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, and because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates and which could have a material effect in developing and commercializing one or more of our product candidates. The owner of a patent that is arguably infringed can bring a civil action seeking to enjoin an accused infringer from importing, making, marketing, distributing, using or selling an infringing product. We may need to resort to litigation to enforce our intellectual property rights or to seek a declaratory judgment concerning the scope, validity or enforceability of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of actual damages, royalties, lost profits, potential enhanced damages and attorneys fees, if any infringement for which we are found liable is deemed willful, or a case against us is determined by a judge to be exceptional;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- having to enter into license arrangements that may not be available on reasonable or commercially acceptable terms; or
- significant cost and expense, as well as distraction of our management from our business.

As a result, we could lose our ability to develop and commercialize current or future product candidates.

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

Risks Related to the Securities Markets and Investment in Our Common Stock

Our stock price may be volatile, and you may not be able to resell our shares at a profit or at all.

Despite the listing of our common stock on the Nasdaq Global Market and the Jasdaq Market of the Osaka Securities Exchange in Japan, trading volume in our securities has been light and an active trading market may not develop for our common stock. In December 2012, our average trading volume was approximately 28,000 shares per day on the Nasdaq Global Market and approximately 63,000 shares per day on the Jasdaq Market.

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The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. For example, since the date of our initial public offering in Japan on February 8, 2005 through December 31, 2012, our common stock has traded as high as approximately $42.00 and as low as approximately $1.30. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the development status of our product candidates, including clinical trial results and determinations by regulatory authorities with respect to our product candidates;
- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- FDA or foreign regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- announcements of technological innovations, new commercial products or other material events by us or our competitors;
- disputes or other developments concerning our intellectual property rights;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual and anticipated fluctuations in our quarterly or annual operating results;
- price and volume fluctuations in the overall stock markets;
- any potential delisting of our securities;
- changes in, or failure to meet, securities analysts or investors expectations of our financial performance;
- additions or departures of key personnel;
- discussions of our business, management, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;
- litigation or public concern about the safety of our potential products;
- public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques; or

regulatory developments in the U.S. and in foreign countries.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock.

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 in the past experienced significant stock price volatility. 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.

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Future sales of our common stock may cause our stock price to decline and may make it difficult to sell your shares.

Sales of substantial amounts of our common stock, or the availability of such common stock for sale, could adversely affect the prevailing market prices for our common stock. If this occurs and continues, it could impair our ability to raise additional capital through the sale of securities should we desire to do so. In addition, it may be difficult, or even impossible, to find a buyer for shares of our common stock.

We have also registered all common stock that we may issue under our current employee benefits plans and upon exercise of warrants. As a result, these shares can be freely sold in the public market upon issuance, subject to the terms of the underlying agreements governing the grants and the restrictions of the securities laws. In addition, our directors and officers may in the future 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.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and the removal and replacement of our directors and management more difficult.

Our restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock or adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of blank check preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our Restated Certificate of Incorporation or Amended and Restated Bylaws except with $66\,^{2}/_{3}$ percent stockholder approval; and
- provide for a classified board of directors with staggered terms.

We also may be subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for three years unless the holder s acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively 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. In any

event, these provisions may delay or prevent a third party from acquiring us. Any such delay or prevention could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We leased approximately 5,089 square feet of office space at our headquarters at 4350 La Jolla Village Drive, Suite 950, San Diego, California under a lease that expired on February 28, 2013. On February 27, 2013, we entered into a sublease agreement effective March 1, 2013 (the Sublease) with Denali Advisors, LLC, the sublessor, to which Irvine Company, the master landlord, has provided its consent. The Sublease is for 5,219 square feet, and is for the Company s new headquarters located at 4275 Executive Square, Suite 650, La Jolla, California, 92037. The Sublease has a term of 4 years and 9 months and provides that the Company will pay Irvine Company a monthly base rent of $10,699 for the premises during the first year. In addition to our headquarters, we also lease 1,726 square feet of office space in Tokyo, Japan under a lease that expires in May 2013 and provides for six month extensions thereafter. We have no laboratory, research or manufacturing facilities, and we currently do not plan to purchase or lease any such facilities, as such services are provided to us by third-party service providers. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. Legal Proceedings

On March 3, 2011, we received a letter, in which certain allegations were made, from a former employee who had been terminated in January 2011 pursuant to our planned reduction-in-force. On July 8, 2011, the former employee filed a lawsuit in the Superior Court of the State of California, County of San Diego, asserting certain claims related to the Company s work environment and the employee s termination, and on December 12, 2011 the court granted our motion to compel arbitration. On August 1, 2012, the arbitrator stayed all proceedings to allow the plaintiff time to obtain new counsel. The plaintiff has since obtained new counsel and the arbitrator has continued the stay to allow our legal counsel and the plaintiff s new counsel to work out some final details regarding documents and property previously held by the plaintiff s former counsel. Based on our current assessment, we do not expect its outcome to have a material adverse effect on our business, financial condition and results of operations.

We may become involved in various other disputes and legal proceedings which arise in the ordinary course of business. Our assessment of the likely impact of our pending litigation may change over time. An adverse result in any of these matters may occur which could harm our business and result in a material liability.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the Jasdaq Market under the symbol 4875 and on the Nasdaq Global Market under the symbol MNOV. Our stock had been traded on the Hercules Market since February 8, 2005 (through the Hercules Market s closure in 2010) and now is currently traded on the Jasdaq Market and on the Nasdaq Global Market since December 7, 2006.

The following table sets forth the high and low sale prices per share of our common stock as reported on the Nasdaq Global Market.

	Common Stock Price	
	High	**Low**
Fiscal year ended December 31, 2011		
First quarter	$ 5.90	$ 2.56
Second quarter	$ 2.72	$ 1.94
Third quarter	$ 3.08	$ 1.88
Fourth quarter	$ 2.44	$ 1.60
Fiscal year ended December 31, 2012		
First quarter	$ 3.38	$ 1.62
Second quarter	$ 3.95	$ 1.29
Third quarter	$ 2.45	$ 1.56
Fourth quarter	$ 2.19	$ 1.49

Holders of Common Stock

As of the date of this filing there were approximately 6,300 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future. We expect to retain our future earnings, if any, to fund the growth and development of our business.

Use of Proceeds

On March 23, 2011, we consummated a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of $3.00 per unit for gross proceeds of $8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of $3.56 per share. The warrants are indexed to our stock and do not permit net-cash settlement. On March 29, 2011, we received net proceeds of approximately $7.7 million, after underwriter discount and underwriter expenses and no warrants exercised.

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In October 2011, pursuant to a stock purchase agreement by and between us and Kissei, Kissei purchased for $7.5 million (i) an aggregate of 800,000 shares of our common stock, par value $0.001 per share, at a price of $2.50 per share, which approximated the fair value of our common stock at the time of the transaction, and (ii) 220,000 shares of our Series B Convertible Preferred Stock, or Series B Preferred, par value $0.01 per share, at a price of $25.00 per share, which approximated the fair value of our preferred stock on an as converted basis at the time of the transaction.

On August 20, 2012, we entered into a Common Stock Purchase Agreement with Aspire pursuant to which the Company may sell to Aspire, and Aspire would be obligated to purchase, up to an aggregate of $20 million of our common stock over the two year term of the agreement including $1 million in common stock purchased by Aspire in connection with execution of the agreement. Daily sales of our common stock to Aspire are subject to certain limitations and the per share sales price is based on closing stock prices at or near each transaction date. No more than 3,231,096 shares of our common stock can be issued under this agreement, including the 363,636 shares issued to Aspire in consideration of entering into the agreement. Our net proceeds will depend on the frequency and number of shares of our common stock sold to Aspire and the per share purchase price of each transaction. As of December 31, 2012, the Company had completed sales to Aspire totaling 856,060 shares of common stock at prices ranging from $1.65 to $1.93 per share, generating gross proceeds of $1.5 million. Between August 21, 2012 and the date of this report, we have generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire including proceeds of $1.5 million on the sale 800,000 shares of our common stock subsequent to December 31, 2012.

We have used and intend to continue to use the net proceeds from the above transactions to fund our product development programs and for general corporate purposes.

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding the securities authorized for issuance under our equity compensation plans can be found under Item 12 of this Annual Report on Form 10-K.

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Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since February 8, 2005, which is the date our common stock first began trading on the Hercules Market of the Osaka Securities Exchange, to two indices: the Hercules Total Index and the Hercules Standard Index., through December 31, 2009. The graph assumes an initial investment of $100 on February 8, 2005, and that all dividends were reinvested.

	2/8/2005	12/30/2005	12/29/2006	12/28/2007	12/30/2008	12/30/2009
MediciNova, Inc.	$ 100	$ 36	$ 42	$ 14	$ 5	$ 19
Hercules Total Index	$ 100	$ 153	$ 73	$ 48	$ 20	$ 23
Hercules Standard Index	$ 100	$ 162	$ 86	$ 59	$ 25	$ 26

* No cash dividends have been declared or paid on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

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Performance Graph

Due to the closure of the Hercules Market of the Osaka Securities Exchange and the inability to retrieve our stock s performance from the Hercules Market in 2010, the following graph illustrates a comparison of the total cumulative stockholder return on our common stock since March 31, 2010, to the Jasdaq Market (total index). The graph assumes an initial investment of $100 on March 31, 2010, and that all dividends were reinvested.

	3/31/2010	12/30/2010	12/30/2011	12/30/2012
MediciNova, Inc.	$ 100	$ 60	$ 22	$ 22
Jasdaq Total Index	$ 100	$ 98	$ 90	$ 103

* No cash dividends have been declared or paid on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

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The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since December 7, 2006 which is the date our common stock first began trading on the Nasdaq Global Market, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on December 7, 2006, and that all dividends were reinvested.

* No cash dividends have been declared or paid on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

	12/7/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/30/2011	12/31/2012
MediciNova, Inc.	$ 100	$ 38	$ 13	$ 58	$ 39	$ 14	$ 14
NASDAQ Biotechnologies Index	$ 100	$ 101	$ 88	$ 102	$ 117	$ 131	$ 173
NASDAQ Composite Index	$ 100	$ 109	$ 65	$ 93	$ 109	$ 107	$ 124

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Item 6. Selected Financial Data.

The selected financial data set forth below is derived from our audited consolidated financial statements and may not be indicative of future operating results. The following selected financial data should be read in conjunction with the Consolidated Financial Statements and notes thereto and Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K. Amounts are in thousands, except per share amounts.

	Years ended December 31,	
	2012	2011
Statements of Operations Data:		
Revenues	$ 803	$
Operating expenses:		
Research and development	5,013	7,784
General and administrative	6,735	8,324
Total operating expenses	11,748	16,108
Operating loss	(10,945)	(16,108)
Other expense	(30)	(81)
Interest expense		(1,595)
Other income, net	25	62
Loss before income taxes	(10,950)	(17,722)
Income Taxes	(11)	(12)
Net loss	(10,961)	(17,734)
Net loss applicable to common stockholders	$ (10,961)	$ (17,734)
Basic and diluted net loss per share	$ (0.66)	$ (1.20)
Shares used to compute basic and diluted net loss per share	16,522,929	14,813,156

	As of December 31,	
	2012	2011
Balance Sheet Data:		
Cash, cash equivalents and current investment securities	$ 4,011	$ 15,093
Working capital	3,384	12,010
Total assets	19,568	30,787
Deficit accumulated during the development stage	(296,234)	(285,272)
Total stockholders equity	14,880	23,498

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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 consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption Item 1A. Risk Factors.

Overview

Background

We are a development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs with a commercial focus on the U.S. market. We were incorporated in Delaware in September 2000.

We have incurred significant net losses since our inception. For the year ended December 31, 2012, we had a net loss of $11.0 million. At December 31, 2012, from inception, our accumulated deficit was $296.2 million, including $50.4 million of non-cash stock-based compensation charges. We expect to incur substantial net losses for the next several years as we continue to develop certain of our existing product development programs, and over the long-term if we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own. As of December 31, 2012, we had available cash and cash equivalents of $4.0 million and working capital of $3.4 million. We expect to have approximately $3 million in available cash as of March 31, 2013, and, assuming we raise additional capital, we expect to spend approximately $6 million from April 1, 2013 through December 31, 2013 to execute our strategic plan and fund operations. As of the date of this report, we have working capital sufficient to fund operations through June 30, 2013. These factors raise substantial doubt about the Company s ability to continue as a going concern.

Between August 21, 2012 and the date of this report we have generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire Capital Fund LLC (Aspire) including proceeds of $1.5 million on the sale 800,000 shares of our common stock subsequent to December 31, 2012. We have the right, subject to the terms of the Common Stock Purchase Agreement, to cause Aspire to acquire up to 3,231,096 shares for total gross proceeds not to exceed $20 million (including the 2,019,696 shares issued or sold to Aspire to date for $3.0 million), subject to daily dollar limitations and subject to the maximum dollar amount we can sell from time to time under our registration statement on Form S-3. We expect to sell additional shares under this agreement during 2013. We are also pursuing other opportunities to raise capital through the sale of our common stock or through other strategic initiatives. There can be no assurances that there will be adequate financing available to us on acceptable terms, or at all. If the Company is unable to obtain additional financing, we may have to sell one or more of our programs or cease operations.

We are currently focusing our development activities on MN-166, an ibudilast-based drug candidate for the treatment of neurological disorders, and obtaining additional funding to advance clinical trial development of MN-221, a novel, highly selective $ß_2$ -adrenergic receptor agonist being developed for the treatment of acute exacerbations of asthma and COPD.

Including MN-166 and MN-221 and our other product development programs, we have acquired licenses to eight compounds for the development of ten product candidates which include clinical development for the treatment of acute exacerbations of asthma, MS and other central nervous system (CNS) disorders, bronchial asthma, interstitial cystitis (IC), solid tumor cancers, generalized anxiety disorders/insomnia, preterm labor and urinary incontinence.

We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. The joint venture agreement

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provides for the joint venture company, Zhejiang Sunmy Bio-Medical Co., Ltd. (Zhejiang Sunmy), to develop and commercialize MN-221 in China. A sublicense will be required under which Zhejiang Sunmy will license MN-221 from us. In accordance with the joint venture agreement, in March 2012 we paid $680,000 for our 30% interest in Zhejiang Sunmy. The other parties to the joint venture agreement provided funding for their combined 70% interest. We have not entered into the sublicense of MN-221 with the joint venture company as of the date of this report. There is no assurance the sublicense will be executed and there is no assurance that Zhejiang Sunmy will be able to proceed with the development of MN-221 in China. A. Zhejiang Sunmy is a variable interest entity for which we are not the primary beneficiary as we do not have a majority of the board seats and we will not have power to direct or significantly influence the actions of the entity. We therefore account for the activities of Zhejiang Sunmy under the equity method whereby we absorb any loss or income generated by Zhejiang Sunmy according to our percentage ownership. At December 31, 2012 we reflect a long-term asset on our consolidated balance sheet which represents our investment in Zhejiang Sunmy, net of our portion of any generated loss or income.

Upon completion of proof-of-concept Phase 2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical or biotech companies who seek late stage product candidates, such as MN-221, to support further clinical development and product commercialization. Depending on decisions we may make as to further clinical development, we may seek to raise addition capital. We may also pursue potential partnerships and potential acquirers of license rights to our programs in markets outside the U.S.

Underwritten Firm Commitment Public Offering

In March 2011 we completed a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of $3.00 per unit for gross proceeds of $8.25 million. Each unit consists of one share of common stock and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of $3.56 per share. The warrants are indexed to our stock and do not permit net-cash settlement. On March 29, 2011, we received net proceeds of $7.7 million, after underwriter discount and underwriter expenses and no warrants exercised. In accordance with the authoritative guidance, the warrants were classified as equity instruments as they contain no provision which may require cash settlement.

At-The-Market Issuance Sales Agreement

On May 5, 2011, we entered into an at-the-market (or ATM) issuance sales agreement, or sales agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which we could issue and sell shares of our common stock having an aggregate offering price of up to $15.0 million from time to time through MLV as our sales agent. The issuance and sale of these shares by us under the sales agreement, if any, would be subject to the effectiveness of our shelf registration statement on Form S-3 (File No. 333-163116), initially filed with the Securities and Exchange Commission on November 13, 2009. Effective October 23, 2011, we terminated the ATM between us and MLV. No shares of common stock were issued under the ATM.

Kissei Stock Purchase

In October 2011, pursuant to a stock purchase agreement by and between us and Kissei Pharmaceutical Co., Ltd., or Kissei, Kissei purchased for $7.5 million (i) an aggregate of 800,000 shares of our common stock, par value $0.001 per share at a price of $2.50 per share, which approximated the fair value of our common stock at the time of the transaction, and (ii) 220,000 shares of our Series B Convertible Preferred Stock, par value $0.01 per share, at a price of $25.00 per share, which approximated the fair value of our preferred stock on an as converted basis at the time of the transaction. The purchase agreement contains customary representations, warranties and covenants and a standstill

agreement from Kissei that terminates if Kissei beneficially owned less than three percent of our outstanding voting stock. Each share of the Series B Preferred Stock is convertible into

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10 shares of common stock. The Series B Preferred ranks pari passu (on an as-if-converted-to-common-stock basis) with the common stock in liquidation and dividend rights. The holders of the Series B Preferred do not have voting rights, and the consent of a majority of the outstanding Series B Preferred is required for certain actions of the Company.

Kissei Services Agreement

In October 2011 we entered into an agreement with Kissei to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of $2.5 million. We assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, which was research and development services. Under the terms of the agreement, we are responsible for all costs to be incurred in the performance of these services. As such, we are recognizing as revenue the $2.5 million payment as the research and development services are performed. Certain of these research and development services were completed in 2012 and the remaining services are expected to be delivered and completed after 2013.

Common Stock Purchase Agreement

On August 20, 2012, we entered into a common stock purchase agreement with Aspire pursuant to which the Company may sell to Aspire, and Aspire would be obligated to purchase, up to an aggregate of $20 million of our common stock over the two year term of the agreement including $1 million in common stock purchased by Aspire in connection with execution of the agreement. Daily sales of our common stock to Aspire are subject to certain limitations and the per share sales price is based on closing stock prices at or near each transaction date. No more than 3,231,096 shares of our common stock can be issued under this agreement, including the 363,636 shares issued to Aspire in consideration of entering into the agreement. Our net proceeds will depend on the frequency and number of shares of our common stock sold to Aspire and the per share purchase price of each transaction. As of December 31, 2012, the Company had completed sales to Aspire totaling 856,060 shares of common stock at prices ranging from $1.65 to $1.93 per share, generating gross proceeds of $1.5 million. Between August 21, 2012 and the date of this report, we have generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire including proceeds of $1.5 million on the sale 800,000 shares of our common stock subsequent to December 31, 2012.

Lease of Corporate Headquarters

We leased approximately 5,089 square feet of office space at our headquarters at 4350 La Jolla Village Drive, Suite 950, San Diego, California under a lease that expired on February 28, 2013. On February 27, 2013, we entered into a sublease agreement effective March 1, 2013 (the Sublease) with Denali Advisors, LLC, the sublessor, to which Irvine Company, the master landlord, has provided its consent. The Sublease is for 5,219, square feet, and is for the Company s new headquarters located at 4275 Executive Square, Suite 650, La Jolla, California, 92037. The Sublease has a term of 4 years and 9 months and provides that the Company will pay Irvine Company a monthly base rent of $10,699 for the premises during the first year.

Revenues and Cost of Revenues

We recognized approximately $803,000 of revenue for the year ending December 31, 2012 and no revenues in the two-year period ended December 31, 2011. Revenue was recorded in 2012 related to the Kissei services agreement based on the development services we performed during that period. All expenses incurred during 2012 related to these services were recorded as research and development expenses. Other than

the revenue recorded in 2012, our revenues to date have been from development services revenues under service agreements pursuant to which we billed consulting fees and our pass-through clinical contract costs. The primary costs associated with these revenues were clinical contract costs we incurred and passed-through to our customers.

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Research and Development

Our research and development expenses consist primarily of the license fees related to our product candidates, salaries and related employee benefits, costs associated with the preclinical and clinical development of our product development programs, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. We use external service providers to manufacture our compounds to be used in clinical trials and for the majority of the services performed in connection with the preclinical and clinical development of our product candidates. Research and development expenses include fees paid to consultants, contract research organizations, contract manufacturers and other external service providers, including professional fees and costs associated with legal services, patents and patent applications for our intellectual property. Internal research and development expenses include costs of compensation and other expenses for research and development personnel, supplies, facility costs and depreciation. Research and development costs are expensed as incurred.

The following table summarizes our research and development expenses for the periods indicated for each of our product development programs. To the extent that costs, including personnel costs, are not tracked to a specific product development program, such costs are included in the Unallocated category (in thousands):

Product		Year ended December 31,	
Candidate	**Disease/Indication**	**2012**	**2011**
MN-221	Acute exacerbations of asthma/COPD	$ 3,578	$ 5,677
MN-166	Neurological disorders including opioid withdrawal, methamphetamine addiction, chronic MOH pain and MS	661	804
MN-001	Bronchial asthma	171	93
MN-029	Solid tumors	101	97
MN-001	Interstitial cystitis	34	33
MN-246	Urinary incontinence	7	3
MN-447	Thrombotic disorders	6	41
MN-305	Generalized anxiety disorder/insomnia	2	1
MN-221	Preterm labor		5
MN-462	Thrombotic disorders		
Unallocated		453	1,031
Total research and development		$ 5,013	$ 7,785

We are currently focusing our development activities on MN-166, an ibudilast-based drug candidate for the treatment of neurological disorders, and obtaining additional funding to advance clinical trial development of MN-221, a novel, highly selective ß$_2$ -adrenergic receptor agonist being developed for the treatment of acute exacerbations of asthma and chronic obstructive pulmonary disease, or COPD. In May 2012 we announced the preliminary trial results of the Phase 2 MN-221-CL-007 clinical trial for the treatment of acute exacerbations of asthma, and in August 2012 we announced preliminary trial results of an additional Phase 1b/2a COPD MN-221 CL-012 clinical trial. On October 22, 2012 we met with the FDA to review future development of this product candidate. The FDA identified the risk/benefit profile of MN-221 as a focal point for further development of MN-221 and advised that a clinical outcome, such as a reduction in hospitalizations, would need to be a pivotal trial primary endpoint. We have decided that future MN-221 development will be designed according to the feedback received from the FDA. Our research and development expenses may increase in connection with new clinical trials related to MN-166. We have determined that future MN-221 clinical trial development will be partner-dependent from a funding perspective.

We will continue to limit our expenditures on the remainder of our existing product candidates to only those activities deemed necessary to maintain our license rights or maximize the value of such product candidates while pursuing a variety of initiatives to monetize such product development. As a result, we expect that research and development expenses will remain low in future periods for our other product candidates.

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General and Administrative

Our general and administrative costs primarily consist of salaries, benefits and consulting and professional fees related to our administrative, finance, human resources, business development, legal, information systems support functions, facilities and insurance costs. General and administrative costs are expensed as incurred.

Our general and administrative expenses may increase in future periods if we are required to expand our infrastructure based on the success of our product development programs and in raising capital to support our product development programs or otherwise in connection with increased business development activities related to partnering, out-licensing or product disposition.

Other Income and Expense

Other income primarily consists of interest earned on our cash, cash equivalents and investments. In 2011, other expense primarily consists of accretion related to the Convertible Notes and the amortization of debt issuance costs paid to third parties and $1.6 million of interest on our debt. In 2012, other expense primarily consists of losses from the joint venture and net foreign exchange losses related to vendor invoices denominated in foreign currencies. We held no debt and had no interest expense in 2012.

Critical Accounting Policies and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities. We review our estimates on an ongoing basis, including those related to our significant accruals. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our most critical accounting estimates include our recognition of revenue which impacts revenue and deferred revenue, of research and development expenses which impacts operating expenses and accrued liabilities, and stock-based compensation which impacts operating expenses. We review our estimates and assumptions periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that the following accounting policies are critical to the judgments and estimates used in preparation of our consolidated financial statements.

Revenue

In October 2011 we entered into an agreement with Kissei to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of $2.5 million. We assessed the deliverables in accordance with the authoritative guidance and concluded the

existence of one deliverable, which was research and development services. The $2.5M was initially recorded as deferred revenue. Revenue was recorded in 2012 as the research and development services were delivered.

Research and Development Expenses

Research and development costs are expensed as incurred based on certain contractual factors such as estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, accruals are adjusted. To date, our accrued research and development expenses have not differed significantly from the actual expenses incurred.

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Stock-Based Compensation

We grant options to purchase our common stock to our employees and directors under our Amended and Restated 2004 Stock Incentive Plan. Additionally, we have outstanding stock options that were granted under our 2000 General Stock Incentive Plan. The benefits provided under both of these plans requires stock-based compensation for an award of equity instruments, including stock options and employee stock purchase rights issued to employees to be recognized as a cost in the consolidated financial statements. The cost of these awards is measured according to the grant date fair value of the stock award and is recognized on a straight-line basis over the period during which an employee is required to provide service in exchange for the award, which is usually the vesting period. We occasionally issue employee performance based stock options, the vesting of which is subsequently based on a determination made by the Company s board of directors as to the achievement of certain corporate objectives. The grant date of such awards is the date on which our board of directors makes its determination. For periods preceding the grant date, the cost of these awards is measured according to their fair value at each reporting date. In the absence of an observable market price for the stock award, the grant date fair value of the award would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the award, the expected term of the award, the current price of the underlying shares, the expected volatility of the underlying share price, the expected dividends on the underlying shares and the risk-free interest rate.

Valuation of our stock option grants require us to estimate certain variables, such as estimated volatility and expected life. If any of our estimations change, such changes could have a significant impact on the stock-based compensation amount we recognize.

Goodwill and Purchased Intangibles

Goodwill is recorded when the consideration paid for an acquisition exceeds the fair value of the identified net tangible and intangible assets of acquired businesses. The allocation of purchase price for acquisitions require extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets as a portion of the purchase price can only be allocated to goodwill in a business combination. Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to annual impairment tests. The amounts and useful lives assigned to intangible assets that have finite useful lives require the use of estimates and the exercise of judgment. These judgments can significantly affect our net operating results. We recorded goodwill and IPR&D of $9.6 million and $4.8 million, respectively, as of December 31, 2012 and 2011.

Our annual test date for goodwill and purchased indefinite life intangibles impairment is December 31 or more frequently if we believe indicators of impairment are present. We periodically re-evaluate the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of our long-lived assets. The criteria used for these evaluations include management s estimate of the asset s continuing ability to generate income from operations and positive cash flows in future periods as well as the strategic significance of any intangible assets in our business objectives. If assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board, or FASB, issued updated accounting guidance that clarifies existing fair value measurements and disclosures, and eliminates differences between GAAP and International Financial Reporting Standards to make convergence guidance more understandable. This guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

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In September 2011, the FASB, issued guidance to simplify how entities test for goodwill impairment. The updated guidance permits an assessment of qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit in which goodwill resides is less than its carrying value. For reporting units in which this assessment concludes it is more likely than not that the fair value is more than its carrying value, the updated guidance eliminates the requirement to perform further goodwill impairment testing. This new guidance is effective for fiscal years beginning after December 15, 2011. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

Effective January 1, 2012, the Company adopted guidance issued by the FASB, concerning presentation and disclosure only for the presentation of comprehensive (loss) income. The adoption of this guidance did not have a material impact on the Company s consolidated financial position or results of operations, other than its impact on the presentation of comprehensive (loss) income.

In August 2012, the FASB issued updated guidance to 2011 guidance that permits an assessment of the qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit in which goodwill resides is less than its carrying value. This updated guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

Results of Operations

Comparison of the Years ended December 31, 2012 and 2011

Revenues

Revenue for the year ended December 31, 2012 was approximately $803,000. There was no revenue for the year ended December 31, 2011. The revenue recorded in 2012 related to the development services we performed under the Kissei services agreement during that period.

Research and Development

Research and development expenses for the year ended December 31, 2012 were $5.0 million, a decrease of $2.8 million compared to $7.8 million for the year ended December 31, 2011. This decrease in research and development expenses primarily related to a decrease of $3.4 million in spending on MN-221 primarily due to the completion of the CL-007 clinical trial in March 2012, partially offset by an increase in spending of $1.3 million for our MN-221 CL-012 clinical trial, and decreases in unallocated employee compensation, occupancy and legal costs totaling $0.6 million.

General and Administrative

General and administrative expenses were $6.7 million for the year ended December 31, 2012, a decrease of $1.6 million compared to $8.3 million for the year ended December 31, 2011. This decrease in general and administrative expenses was due primarily to $1.2 million decrease in employee compensation expense including $0.6 million related to stock-based compensation, and a decrease in professional legal and accounting fees of $0.4 million.

Other Expense

Other expense for the year ended December 31, 2012 was approximately $30,000, as compared to approximately $80,000 for the year ended December 31, 2011. In 2011, other expense primarily consisted of accretion related to convertible notes and amortization of debt issuance costs paid to third parties. In 2012, other expense consisted of losses from the joint venture accounted for under the equity method according to our percentage ownership, and net foreign exchange losses related to vendor invoices denominated in foreign currencies.

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Interest Expense

Interest expense for the year ended December 30, 2011 was $1.6 million and consisted of interest on our debt under the effective interest method and write-off of debt related costs pursuant to the early repayment of our debt with Oxford. In 2012, we held no debt and had no interest expense.

Other Income

Other income for the year ended December 31, 2012 was approximately $25,000, as compared to approximately $60,000 for the year ended December 31, 2011. The decrease is due to a decrease in interest income on lower cash equivalents.

Liquidity and Capital Resources

We incurred losses of $11.0 million and $17.7 million for the years ended December 31, 2012, and 2011 respectively. At December 31, 2012, from inception, our accumulated deficit was $296.2 million, including $50.4 million of non-cash stock-based compensation charges. We have used net cash of $11.9 million and $13.3 million to fund our operating activities for the years ended December 31, 2012 and 2011, respectively**.** Our operating losses to date have been funded primarily through the private placement of our equity securities, the public sale of our common stock, long-term debt, development agreements with partners and the exercise of founders warrants, net of treasury stock repurchases.

In March 2011 we announced a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of $3.00 per unit for gross proceeds of $8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment.

In October 2011, pursuant to a stock purchase agreement by and between us and Kissei Pharmaceutical Co., Ltd., or Kissei, Kissei purchased (i) an aggregate of 800,000 shares of our common stock, par value $0.001 per share at a price of $2.50 per share, and (ii) 220,000 shares of our Series B Convertible Preferred Stock, par value $0.01 per share, at a price of $25.00 per share. In October we received gross proceeds of $7.5 million related to this purchase agreement.

In October 2011, we entered into an agreement with Kissei to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of $2.5 million. We are responsible for all costs incurred and to be incurred in the performance of these services. The amount received from Kissei, net of the amount recorded as revenue, is included on the balance sheet as deferred revenue and will be recognized as revenue as we perform the remaining services. Revenue recorded in 2012 was $0.8 million and no revenue was recorded in 2011.

On August 20, 2012 we entered into a common stock purchase agreement with Aspire, pursuant to which the Company may sell to Aspire, and Aspire would be obligated to purchase, up to an aggregate of $20 million of our common stock over the two year term of the agreement

including $1 million in common stock purchased by Aspire in connection with execution of the agreement. Daily sales of our common stock to Aspire are subject to certain limitations and the per share sales price is based on closing stock prices at or near each transaction date. No more than 3,231,096 shares of our common stock can be issued under this agreement, including the 363,636 shares issued to Aspire in consideration of entering into the agreement. Our net proceeds will depend on the frequency and number of shares of our common stock sold to Aspire and the per share purchase price of each transaction. We may, on any business day over the term of the agreement, direct Aspire to purchase up to 50,000 shares, up to a maximum of $500,000 per business day. The purchase price shall be the lower of (i) the lowest sale price of the Company s common stock on the date of the sale, or (ii) the average of the three lowest closing stock prices during the 12 consecutive business days ending on the business day immediately preceding the

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purchase date. In addition, we may on any business day over the term of the agreement, direct Aspire to make a volume-weighted average purchase (VWAP) of stock not to exceed 15% (which limitation may be increased up to 30% by the mutual agreement of the parties) of the aggregate shares of our stock traded on the next business day, the purchase price of which shall be the lower of the closing price on the date of the sale, or 95% of the next business day s Nasdaq volume weighted average price, subject to a minimum market price threshold established by us and certain other exceptions. We initially issued 363,636 shares of our common stock to Aspire as consideration for entering into the agreement. As of December 31, 2012, the Company had completed sales to Aspire totaling 856,060 shares of common stock at prices ranging from $1.65 to $1.93 per share, generating gross proceeds of $1.5 million. Between August 21, 2012 and the date of this report, we have generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire including proceeds of $1.5 million on the sale 800,000 shares of our common stock subsequent to December 31, 2012. The agreement with Aspire provides Aspire certain termination rights, including rights under an event of default as defined therein, under which the Company may not require and Aspire would not be obligated to purchase any shares of our common stock. The Company and Aspire may also not effect any sales under the agreement on any purchase date where the closing price of our common stock is less than $1.00 per share.

Between August 21, 2012 and the date of this report we have generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire including proceeds of $1.5 million on the sale 800,000 shares of our common stock subsequent to December 31, 2012. We have the right, subject to the terms of the Common Stock Purchase Agreement, to cause Aspire to purchase up to approximately 1,300,000 additional shares for total gross proceeds not to exceed $20 million (including the $3.0 million sold to Aspire to-date) subject to daily dollar limitations and subject to the maximum dollar amount we can sell from time to time under our registration statement on Form S-3. We expect to sell additional shares under this agreement during 2013. We are also pursuing other opportunities to raise capital through the sale of our common stock or through other strategic initiatives. There can be no assurances that there will be adequate financing available to us on acceptable terms, or at all. If the Company is unable to obtain additional financing, we may have to sell one or more of our programs or cease operations.

Our future funding requirements will depend on many factors, including, but not limited to:

- progress in, and the costs of, future planned clinical trials and other research and development activities;
- the scope, prioritization and number of our product development programs;
- our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements, and to complete acquisitions of additional product candidates;
- the time and costs involved in obtaining regulatory approvals;
- the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;
- the costs associated with expanding our management, personnel, systems and facilities;
- the costs associated with any litigation;

the costs associated with the operations or wind-down of any business we may acquire;

the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and

the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obtain regulatory approval to market our product candidates.

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Other Significant Contractual Obligations

The following summarizes our scheduled long-term contractual obligations that may affect our future liquidity as of December 31, 2012 (in thousands):

Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	$ 145	$ 108	$ 37	$	$
Research and development services(1)	$ 2,354	$ 4	$ 2,350		
Total(2)	$ 2,499	$ 112	$ 2,387	$	$

(1) In October 2011, we entered into an agreement with Kissei to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of $2.5 million. We are responsible for all costs to be incurred in the performance of these services. The estimated remaining costs to be incurred in the performance of all such remaining services are included above.

(2) We also enter into agreements with third parties to conduct our clinical trials, manufacture our product candidates, perform data collection and analysis and other services in connection with our product development programs. As our payment obligations under these agreements depend upon the progress of our product development programs, we are unable at this time to estimate the future costs we might incur under these agreements.

Off-Balance Sheet Arrangements

At December 31, 2012, we did not have any relationship with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance variable interest, or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we did not engage in trading activities involving non-exchange traded contracts. As a result, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We do not have relationships and transactions with persons and entities that derive benefits from their non-independent relationship with us or our related parties except as disclosed herein.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our primary exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. The primary objective of our investment activities is to preserve principal. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments and we do not use interest rate derivative instruments to manage exposure to interest rate changes. We mitigate default risk by investing in investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments due to their relatively short term nature.

Cash and cash equivalents as of December 31, 2012 were $4.0 million and were primarily invested in money market interest bearing accounts and money market funds. A hypothetical 10% adverse change in the average interest rate on our cash and cash equivalents would have had no material effect on net loss for the year ended December 31, 2012.

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Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of

MediciNova, Inc.

We have audited the accompanying consolidated balance sheets of MediciNova, Inc. (a development stage company) as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders equity, and cash flows for the years then ended, and for the period from September 26, 2000 (inception) through December 31, 2012. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements for the period January 1, 2009 through December 31, 2010, were audited by other auditors whose report dated March 31, 2011 expressed an unqualified opinion on those statements. The financial statements for the period January 1, 2009 through December 31, 2010 includes total net loss of $40.6 million. Our opinion on the statements of operations and comprehensive loss, stockholders equity, and cash flows for the period September 26, 2000 (inception) through December 31, 2012, insofar as it relates to amounts for the period January 1, 2009 through December 31, 2010, is based solely on the report of other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of MediciNova, Inc., (a development stage company) at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for the years then ended and the period from September 26, 2000 (inception) through December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has a history of recurring losses from operations and an accumulated deficit that raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), MediciNova Inc. s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 28, 2013

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 4,010,530	$ 15,093,124
Prepaid expenses and other current assets	411,592	614,540
Total current assets	4,422,122	15,707,664
Goodwill	9,600,241	9,600,241
In-process research and development	4,800,000	4,800,000
Investment in joint venture	667,204	650,000
Property and equipment, net	78,474	29,425
Total assets	$ 19,568,041	$ 30,787,330
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 491,853	$ 718,882
Accrued expenses	314,652	1,515,815
Accrued compensation and related expenses	228,124	599,087
Current deferred revenue	3,163	863,510
Total current liabilities	1,037,792	3,697,294
Deferred tax liability	1,956,000	1,956,000
Long-term deferred revenue	1,694,257	1,636,490
Total liabilities	4,688,049	7,289,784
Stockholders equity:		
Preferred stock, $0.01 par value; 3,000,000 and 500,000 shares authorized at December 31, 2012 and December 31, 2011; 220,000 shares issued at December 31, 2012 and December 31, 2011	2,200	2,200
Common stock, $0.001 par value; 100,000,000 and 30,000,000 shares authorized at December 31, 2012 and December 31, 2011; 17,407,311 and 16,127,615 shares issued at December 31, 2012 and December 31, 2011, respectively, and 17,403,125 and 16,088,015 shares outstanding at December 31, 2012 and December 31, 2011, respectively	17,407	16,128
Additional paid-in capital	312,293,225	309,998,251
Accumulated other comprehensive loss	(67,957)	(56,845)
Treasury stock, at cost; 4,186 shares at December 31, 2012 and 39,600 shares at December 31, 2011	(1,131,086)	(1,189,705)
Deficit accumulated during the development stage	(296,233,797)	(285,272,483)
Total stockholders equity	14,879,992	23,497,546
Total liabilities and stockholders equity	$ 19,568,041	$ 30,787,330

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years ended December 31,		Period from September 26, 2000 (inception) to December 31,
	2012	2011	2012
Revenues	$ 802,580	$	$ 2,360,807
Operating expenses:			
Cost of revenues			1,258,421
Research and development	5,013,092	7,784,719	167,054,655
General and administrative	6,734,844	8,323,715	112,257,368
Total operating expenses	11,747,936	16,108,434	280,570,444
Operating loss	(10,945,356)	(16,108,434)	(278,209,637)
Impairment charge on investment securities			(1,735,212)
Other expense	(29,605)	(81,292)	(389,230)
Interest expense		(1,595,093)	(3,605,818)
Other income	24,791	62,316	19,145,183
Loss before income taxes	(10,950,170)	(17,722,503)	(264,794,714)
Income taxes	(11,144)	(11,573)	(75,961)
Net loss	(10,961,314)	(17,734,076)	(264,870,675)
Accretion to redemption value of redeemable convertible preferred stock			(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock			(31,264,677)
Net loss applicable to common stockholders	(10,961,314)	$ (17,734,076)	$ (296,233,797)
Basic and diluted net loss per common share	$ (0.66)	$ (1.20)	
Shares used to compute basic and diluted net loss per share	16,522,929	14,813,156	
Net loss applicable to common stockholders	$ (10,961,314)	$ (17,734,076)	$ (296,233,797)
Other comprehensive loss, net of tax:			
Foreign currency translation adjustments	(11,112)	(1,143)	(67,957)
Comprehensive loss	$ (10,972,426)	$ (17,735,219)	$ (296,301,754)

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Convertible preferred stock		Common stock							
	Shares	Amount	Shares	Amount	Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
Issuance of common stock for cash to founders at $1.00 per share in September		$	50,000	$ 50	$ 49,950	$	$	$	$	$ 50,000
Issuance of Series A convertible preferred stock at $10 per share in October	500,000	5,000			4,995,000					5,000,000
Net loss and comprehensive loss									(201,325)	(201,325)
Balance at December 31, 2000	500,000	5,000	50,000	50	5,044,950				(201,325)	4,848,675
Issuance of Series A convertible preferred stock at $10 per share in August	500,000	5,000			4,995,000					5,000,000
Net loss									(1,794,734)	(1,794,734)
Balance at December 31, 2001	1,000,000	10,000	50,000	50	10,039,950				(1,996,059)	8,053,941
Net loss									(6,931,476)	(6,931,476)
Balance at December 31, 2002	1,000,000	10,000	50,000	50	10,039,950				(8,927,535)	1,122,465
Issuance of Series B convertible preferred stock at $100 per share, net of issuance costs of $1,093,453, in March, April, May and December	107,500	1,075			9,655,472					9,656,547
Net loss									(6,209,130)	(6,209,130)
Balance at December 31, 2003	1,107,500	11,075	50,000	50	19,695,422				(15,136,665)	4,569,882
Issuance of Series B convertible preferred stock at $100 per share, net of issuance costs of $1,208,896, in January, February, March, April and May	183,650	1,837			17,154,267					17,156,104
Stock-based compensation related to founders warrants					34,069,916					34,069,916
Deferred employee stock-based compensation					1,419,300	(1,419,300)				
Amortization of deferred employee stock-based						224,579				224,579
Deemed dividend resulting from beneficial conversion feature on Series C					31,264,677				(31,264,677)	

redeemable convertible preferred stock								
Accretion to redemption value of redeemable convertible preferred stock							(78,756)	(78,756)
Net loss							(48,272,603)	(48,272,603)
Balance at December 31, 2004	1,291,150	12,912	50,000	50	103,603,582	(1,194,721)	(94,752,701)	7,669,122

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

	Convertible preferred stock		Common stock							
	Shares	Amount	Shares	Amount	Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
Issuance of common stock in initial public offering at $38.80 per share in February			3,000,000	3,000	104,483,895					104,486,895
Issuance of common stock upon partial exercise of over-allotment option at $38.80 per share in March			157,300	157	5,557,616					5,557,773
Issuance costs for registration statement filed on behalf of restricted stockholders					(165,476)					(165,476)
Conversion of redeemable convertible preferred stock into common stock in February			2,766,785	2,767	43,499,998					43,502,765
Conversion of convertible preferred stock into common stock in February	(1,291,150)	(12,912)	3,911,500	3,911	9,001					
Stock-based compensation related to acceleration of option vesting upon employee termination and subsequent reissuance of a fully vested option					127,875					127,875
Amortization of deferred employee stock-based compensation, net of cancelations						311,282				311,282
Cancelation of stock options issued to employees and related deferred compensation					(84,000)	84,000				
									(19,689)	(19,689)

Accretion to redemption value of redeemable convertible preferred stock								
Purchase of treasury stock at $11.10 per share in December						(55,445)		(55,445)
Net loss							(25,692,135)	(25,692,135)
Other comprehensive loss					(15,188)			(15,188)
Balance at December 31, 2005	9,885,585	9,885	257,032,491	(799,439)	(15,188)	(55,445)	(120,464,525)	135,707,779
Cashless warrant exercises of 260,000 in February, April and August	260,000	260	(260)					
Warrant exercises of 275,000 shares at $1.00 per share in March and August	275,000	275	274,725					275,000
Write off balance of deferred employee stock-based compensation as of 12/31/05			(799,439)	799,439				
Option exercises of 1,400 shares at $10.00 per share in May and August	1,400	2	13,998					14,000

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

	Convertible preferred stock		Common stock		Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
	Shares	Amount	Shares	Amount						
Amortization of deferred employee stock-based compensation					2,090,182					2,090,182
Purchase of treasury stock from $10.30 $13.10 per share in February, March, May, June, July, September and October								(1,382,425)		(1,382,425)
Net loss									(35,689,611)	(35,689,611)
Other comprehensive loss							(34,017)			(34,017)
Balance at December 31, 2006			10,421,985	10,422	258,611,697		(49,205)	(1,437,870)	(156,154,136)	100,980,908
Cashless warrant exercises of 650,047 in January and September			650,047	650	(650)					
Issuance of common stock in a public offering at $12.00 per share in February			1,000,000	1,000	10,638,600					10,639,600
Employee stock-based compensation					3,939,416					3,939,416
Issuance of shares under an employee stock purchase plan at $6.72								33,782		33,782
Net loss			(5)						(48,903,244)	(48,903,244)
Other comprehensive loss							(82,261)			(82,261)
Balance at December 31, 2007			12,072,027	12,072	273,189,063		(131,466)	(1,404,088)	(205,057,380)	66,608,201
Employee stock-based compensation					3,172,712					3,172,712
Issuance of shares under an employee stock purchase plan at $2.33 average								86,726		86,726
Comprehensive loss:										
Net loss									(21,924,829)	(21,924,829)
Other comprehensive income							101,722			101,722
Balance at December 31, 2008			12,072,027	12,072	276,361,775		(29,744)	(1,317,362)	(226,982,209)	48,044,532
Employee stock-based compensation					2,371,636					2,371,636
Option exercises			100,483	98	406,259					406,357
Fair value of redemption feature of Avigen purchase					9,513,042					9,513,042

Issuance of shares under an employee stock purchase plan at $2.21 average					81,967		81,967
Net loss						(20,368,890)	(20,368,890)
Other comprehensive loss				(35,170)			(35,170)
Balance at December 31, 2009	12,172,510	12,170	288,652,712	(64,914)	(1,235,395)	(247,351,099)	40,013,474

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

	Convertible preferred stock		Common stock						
	Shares	Amount	Shares	Amount	Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
Employee stock-based compensation					2,000,935					2,000,935
Option exercises			44,948	49	166,550					166,599
Issuance of shares for Convertible Notes			265,409	265	1,804,515					1,804,780
Fair value of warrant issued in conjunction with Loan Agreement					859,208					859,208
Issuance of shares under an employee stock purchase plan at $6.56 average								37,460		37,460
Net loss									(20,187,308)	(20,187,308)
Other comprehensive loss							9,212			9,212
Balance at December 31, 2010			12,482,867	12,484	293,483,920		(55,702)	(1,197,935)	(267,538,407)	24,704,360
Employee stock-based compensation					1,372,748					1,372,748
Option exercises			32,836	31	76,232					76,263
Issuance of shares for Convertible Notes			11,246	12	76,461					76,473
Issuance of shares under an employee stock purchase plan								8,230		8,230
Issuance of units in a public offering at $3.00 per unit net of issuance costs of $715,112, each unit consisting of one share of common stock and one warrant to purchase one share of common stock.			2,800,666	2,801	7,684,085					7,686,886
Issuance of series B convertible preferred stock at $25 per share, net of issuance costs of $144,146	220,000	2,200			5,353,654					5,355,854
Issuance of common stock at $2.50 per share, net of issuance costs of $48,049			800,000	800	1,951,151					1,951,951
Net loss									(17,734,076)	(17,734,076)
Other comprehensive loss							(1,143)			(1,143)
Balance at December 31, 2011	220,000	2,200	16,127,615	16,128	309,998,251		(56,845)	(1,189,705)	(285,272,483)	23,497,546

Employee stock-based compensation			709,650		709,650
Option exercises	60,000	60	137,670		137,730
Issuance of shares under an employee stock purchase plan				58,619	58,619
Issuance of common stock under a common stock purchase agreement	1,219,696	1,219	1,347,654		1,348,873

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

	Convertible preferred stock		Common stock							
	Shares	Amount	Shares	Amount	Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
Fair value of warrant issued					100,000					100,000
Net loss									(10,961,314)	(10,961,314)
Other comprehensive loss							(11,112)			(11,112)
Balance at December 31, 2012	220,000	$ 2,200	17,407,311	$ 17,407	$ 312,293,225	$	$ (67,957)	$ (1,131,086)	$ (296,233,797)	$ 14,879,922

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,		Period from September 26, 2000 (inception) to December 31,
	2012	2011	2012
Operating activities:			
Net loss	$ (10,961,314)	$ (17,734,076)	$ (264,870,675)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	709,650	1,372,748	50,390,931
Amortization of Kissei upfront payment	(802,580)		1,697,420
Depreciation and amortization	69,528	41,869	2,014,052
Amortization of premium/discount on investment securities, convertible debt, debt discount and issuance costs		752,124	(1,099,365)
Impairment charge, net on investment securities and ARS Put			1,735,212
(Gain)/loss on disposal of assets	823		11,460
Impairment of sublease			35,259
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	266,927	164,563	(310,664)
Accounts payable, income tax payable, accrued expenses and deferred rent	(776,508)	(656,196)	545,034
Accrued compensation and related expenses	(370,964)	250,333	131,983
Restricted assets		(17)	5,982
Deferred revenue		2,500,000	2,500,000
Net cash used in operating activities	(11,864,438)	(13,308,652)	(209,712,471)
Investing activities:			
Cash paid for acquired business, net of acquired cash			(2,829,785)
Purchases of investment securities			(377,205,766)
Maturities or sales of investment securities			377,918,240
Acquisition of property and equipment	(83,378)	(6,085)	(2,360,968)
Investment in joint venture	(680,000)		(680,000)
Proceeds from sales of property and equipment			256,845
Net cash used in investing activities	(763,378)	(6,085)	(4,901,434)
Financing activities:			
Proceeds from issuance of common stock and units, net of issuance costs	1,486,603	9,715,100	132,665,225
Proceeds from issuance of convertible preferred stock, net of issuance costs		5,355,854	85,572,825
Proceeds from ARS loan			17,605,485
Net proceeds from debt			14,670,000
Proceeds from conversion of convertible notes		76,473	1,881,253
Purchase of treasury stock, net of employee stock purchases	58,619	8,230	(1,164,868)
Repayment of debt		(15,000,000)	(15,000,000)
Repayment of ARS loan			(17,605,485)
Net cash provided by (used in) financing activities	1,545,222	155,657	218,624,435
Net increase / (decrease) in cash and cash equivalents	(11,082,594)	(13,159,080)	4,010,530
Cash and cash equivalents, beginning of period	15,093,124	28,252,204	

Cash and cash equivalents, end of period	$ 4,010,530	$ 15,093,124	$ 4,010,530
Supplemental disclosure of investing activities and financing activities:			
Proceeds from issuance of warrants	$	$ 2,882,258	$ 2,882,258
Conversion of convertible preferred stock into common stock upon initial public offering	$	$	$ 43,515,677
Restricted assets, cash unrestricted upon conversion of convertible notes	$	$ 76,473	$ 1,881,815
Supplemental disclosures of cash flow information:			
Income taxes paid	$ 10,951	$ 12,010	$ 69,601
Interest paid	$	$ 1,088,926	$ 2,487,343

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

(a development stage company)

Notes to Consolidated Financial Statements

1. The Company, Basis of Presentation and Summary of Significant Accounting Policies

The Company

We were incorporated in the state of Delaware in September 2000. We are a development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs with a commercial focus on the U.S. market. We are currently focusing our development activities on MN-166, an ibudilast-based drug candidate for the treatment of neurological disorders, and obtaining additional funding to advance clinical trial development of MN-221, a novel, highly selective ß$_2$ -adrenergic receptor agonist being developed for the treatment of acute exacerbations of asthma and chronic obstructive pulmonary disease, or COPD.

As a development stage company, we have consumed substantial amounts of capital since our inception. We do not have material commitments for capital expenditures. We do conduct clinical trials which are administered by third-party CROs and there is a significant degree of estimation involved in quantifying the expense associated with clinical trial activity. We accrue costs for work performed by CROs based on the achievement of contracted milestone activities and on internal estimates of activities using patient enrollment and contractual or estimated rates during the period. Our R&D expense and cash payments in future periods could potentially be impacted if we were not to receive complete and accurate information from the CRO or other third parties on a timely basis or correctly estimate the outcome of contract negotiations, activity levels and enrollment rates.

We have had, and will continue to have an ongoing need to raise additional cash from outside sources to fund our operations. Our business will continue to require us to incur substantial research and development expenses and management plans to continue financing operations with equity issuances, debt arrangements or a combination thereof.

We incurred losses of $11.0 million and $17.7 million for the years ended December 31, 2012 and 2011 respectively. We have a history of recurring losses from operations and have an accumulated deficit of $296.2 million as of December 31, 2012. Additionally, we have used net cash of $11.9 million and $13.3 million to fund our operating activities for the years ended December 31, 2012 and 2011, respectively**.** To date, these operating losses have been funded primarily through the private placement of our equity securities, the public sale of our common stock, long-term debt and the exercise of founders warrants.

As of December 31, 2012, we had available cash and cash equivalents of $4.0 million and working capital of $3.4 million. We presently estimate that we have sufficient working capital to fund operations through June 30, 2013. The Company will require additional cash funding to continue to execute its strategic plan and fund operations through December 31, 2013. These factors raise substantial doubt about the Company s ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a

going concern. This basis of accounting contemplates the recovery of the Company s assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Between August 21, 2012 and the date of this report, the Company has generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire Capital Fund LLC (Aspire) including proceeds of $1.5 million on the sale 800,000 shares of its common stock subsequent to December 31, 2012 (see Note 7). We have the right, subject to the terms of the Common Stock Purchase Agreement, to cause Aspire to acquire up to

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3,231,096 shares for total gross proceeds not to exceed $20 million (including the 2,019,696 shares issued or sold to Aspire to date for $3.0 million), subject to daily dollar limitations and subject to the maximum dollar amount we can sell from time to time under our registration statement on Form S-3. We expect to sell additional shares under this agreement during 2013. We are also pursuing other opportunities to raise capital through the sale of our common stock or through other strategic initiatives. There can be no assurances that there will be adequate financing available to us on acceptable terms, or at all. If the Company is unable to obtain additional financing, we may have to seek buyers for one or more of our programs or cease operations.

Basis of Presentation

Our primary activities since incorporation have been recruiting personnel, conducting research and development, performing business and financial planning and raising capital. Accordingly, in connection with preparation of the consolidated financial statements we operate under one reporting segment and are considered to be in the development stage, in accordance with the authoritative guidance for development stage entities.

During the first quarter of 2005, we completed our initial public offering, or IPO, of 3,000,000 shares of common stock in Japan for proceeds of $104.5 million, net of underwriting discounts and commissions and offering costs. In December 2006, we were listed on the Nasdaq Global Market. Accordingly, we are a public company in both the U.S. and Japan, as our stock is traded on both the Nasdaq Global Market and the Jasdaq Market (formerly the Hercules Market of the Osaka Securities Exchange until its closure in 2010).

Avigen Transaction. On December 18, 2009, we acquired 100% of the outstanding shares of Avigen, a biopharmaceutical company whose potential product candidate, MN-166, is a therapeutic for Central Nervous System, or CNS, disorders. Under the terms of the transaction, Avigen shareholders, at their election, received an amount per share either in cash, Convertible Notes or a combination thereof, upon closing. Avigen shareholders holding approximately 17% of the Avigen common stock outstanding at the closing date elected to receive cash in the amount of approximately $1.19 per share. The remaining Avigen shareholders received the corresponding value of Convertible Notes. Holders of the Convertible Notes could convert their notes into our common stock at an initial conversion price of $6.80 per share through May 31, 2011. At the maturity of the Convertible Notes, the remaining holders would be paid the same per share amount as the Avigen shareholders that elected to receive cash at the closing, plus accrued interest. All Avigen shareholders were also entitled to receive approximately $0.04 per share, which was paid in two increments in 2010, and rights under contingent payment rights issued. In March 2011 we paid $0.02 per share to former Avigen shareholders related to the management transition plan Contingent Payment Rights (CPR).

Avigen Management Transition Plan (MTP). On March 11, 2011, a designated representative from Avigen notified us of the termination of the Avigen MTP, with the final distribution to occur on or about March 31, 2011. In connection with the termination of the Avigen MTP and pursuant to the related contingent payment rights agreement, the remaining funds were distributed to American Stock Transfer & Trust Company, LLC, or AST, and AST was instructed to distribute the funds to the Avigen shareholders on a pro rata basis (approximately $0.02 per share) based on the shares of Avigen common stock held immediately prior to the effective time of the Merger.

Joint Venture. We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. The joint venture agreement provides for the joint venture company, Zhejiang Sunmy Bio-Medical Co., Ltd. (Zhejiang Sunmy),to develop and commercialize MN-221 in China. A sublicense agreement will be required under which Zhejiang Sunmy will license MN-221 from us. In accordance with the joint venture agreement, in March 2012 we paid $680,000 for a 30% interest in Zhejiang Sunmy. The other parties to the joint venture agreement provided funding for their combined 70% interest. We have not entered into the sublicense of MN-221 with Zhejiang Sunmy as of the date of this filing. Zhejiang Sunmy is a variable interest entity for which we are not the primary beneficiary as we do not have a majority of the board seats and we will not have power to direct or

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significantly influence the actions of the entity. We therefore account for the activities of Zhejiang Sunmy under the equity method whereby we absorb any loss or income generated by Zhejiang Sunmy according to our percentage ownership. At December 31, 2012 we reflect a long-term asset on our consolidated balance sheet which represents our investment in Zhejiang Sunmy, net of our portion of any generated loss or income.

Principles of Consolidation

The consolidated financial statements include the accounts of MediciNova, Inc. and its wholly-owned subsidiaries. MediciNova, Inc. and its subsidiaries are collectively referred to herein as we, our or us.

On December 13, 2006, MediciNova (Europe) Limited, a wholly-owned subsidiary of MediciNova, Inc., was incorporated under the laws of England and Wales and established for the purpose of facilitating the clinical development of the Company s product candidates for the European marketplace. MediciNova (Europe) Limited s functional currency is the U.S. dollar, the reporting currency of its parent.

On January 4, 2007, MediciNova Japan, Inc., a wholly-owned subsidiary of MediciNova, Inc., was incorporated under the laws of Japan and established to strengthen business development and investor and public relations activities in Japan and other Asian countries. MediciNova Japan, Inc. s functional currency is the Japanese yen.

On August 17, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of MediciNova, Inc. was incorporated under the General Corporation Law of the State of Delaware for the purpose of facilitating the merger with Avigen.

All intercompany transactions and investments in our subsidiaries have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and other highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents at December 31, 2012 consisted of money market funds.

Deferred Revenue and Revenue Recognition

In October 2011, we entered into an agreement with Kissei Pharmaceutical Co., Ltd., or Kissei, to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of $2.5 million. Under the terms of the agreement we are responsible for all costs to be incurred in the performance of these services. Certain of these research and development services were completed in 2012 and the remaining services are expected to be delivered and completed after 2013. We assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, research and development services. As such, we are recognizing as revenue the $2.5 million payment as the research and development services are performed. The amount received from Kissei, net of the amount recorded as revenue, is included on the balance sheet as deferred revenue and will be recognized as revenue as we perform the remaining services. Revenue recorded in 2012 was $0.8 million. No revenue was recorded in 2011.

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At-The-Market Issuance Sales Agreement

On May 5, 2011, we entered into an at-the-market, or ATM, issuance sales agreement, or sales agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which we could issue and sell shares of our common stock having an aggregate offering price of up to $15.0 million from time to time through MLV as our sales agent. The issuance and sale of these shares by us under the sales agreement, if any, would be subject to the effectiveness of our shelf registration statement on Form S-3 (File No. 333-163116), initially filed with the Securities and Exchange Commission on November 13, 2009.

Effective October 23, 2011, we terminated the ATM between us and MLV. No shares of common stock were issued under the ATM.

Concentrations and Credit Risk

We maintain cash balances at various financial institutions and such balances commonly exceed the $250,000 amount insured by the Federal Deposit Insurance Corporation. We also maintain money market funds at various financial institutions which are not federally insured although are invested primarily in U.S. government securities. We have not experienced any losses in such accounts and management believes that we do not have significant credit risk with respect to such cash and cash equivalents.

Goodwill and Purchased Intangibles

Goodwill is recorded when the consideration paid for an acquisition exceeds the fair value of the identified net tangible and intangible assets of acquired businesses. The allocation of purchase price for acquisitions require extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets as a portion of the purchase price can only be allocated to goodwill in a business combination. Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to annual impairment tests. The amounts and useful lives assigned to intangible assets that have finite useful lives require the use of estimates and the exercise of judgment. These judgments can significantly affect our net operating results. We recorded goodwill and IPR&Dof $9.6 million and $4.8 million, respectively, as of December 31, 2012 and 2011.

Our annual test date for goodwill and purchased indefinite life intangibles impairment is December 31 or more frequently if we believe indicators of impairment are present. We periodically re-evaluate the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of our long-lived assets. The criteria used for these evaluations include management s estimate of the asset s continuing ability to generate income from operations and positive cash flows in future periods as well as the strategic significance of any intangible assets in our business objectives. If assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets.

Fair Value

Financial instruments, including cash equivalents, accounts payable and accrued liabilities, are carried at cost, which we believe approximates fair value given their short-term nature. We are required to measure certain assets and liabilities at fair value, either upon initial measurement or for subsequent accounting or reporting. We use fair value in the initial measurement of net assets acquired in a business combination and when accounting for and reporting on investment securities and certain financial instruments or assets. We estimate fair value using an exit price approach, which requires, among other things, that we determine the price that would be received to sell an asset or paid to transfer a liability in an orderly market of market participants, considering the highest and best use of assets and, for liabilities, assuming the risk of non-performance will be the same before and after the transfer. Many, but not all, of our financial instruments are carried at fair value.

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The judgments made in determining an estimate of fair value can materially impact our results of operations.

Equipment

Property and equipment, net, which consists of leasehold improvements, furniture and equipment and software, is stated at cost. Leasehold improvements, furniture and equipment, and software are depreciated using the straight-line method over the estimated useful lives of the related assets. The useful life for furniture, equipment (other than computers) and software is five years, computers is three years and leasehold improvements are amortized over the lesser of the useful life or the term of the lease.

Research and Development

Research and development expenses consist of costs incurred to further our research and development activities and include salaries and related employee benefits, costs associated with clinical trials, costs associated with non-clinical activities such as regulatory activities, research-related overhead expenses, and fees paid to external service providers who conduct certain research and development activities on our behalf. We use external service providers and vendors to conduct clinical trials, to manufacture product candidates to be used in clinical trials and to provide various other products and services related to our product development programs. Research and development expenses also include fees for licensed technology for which technological feasibility has not been established and there are no alternative uses. Research and development costs are expensed as incurred or accrued based on certain contractual provisions such as those for estimates of work performed, milestones achieved and patient enrollment. As actual costs become known, accruals are adjusted if necessary. To date, our accrual estimates have not differed significantly from the actual costs incurred.

Income Taxes

In accordance with the authoritative guidance for income taxes under ASC 740, a deferred tax asset or liability is determined based on the difference between the financial statement and the tax basis of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. We provide a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

The Company recognizes the impact of a tax position in the financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense.

We are subject to taxation in the U.S., California and foreign jurisdictions, of which currently no years are under examination. Our tax years for 2000 and forward are subject to examination by the U.S. and state tax authorities due to the carry-forward of unutilized net operating losses and research and development credits. During each of the two years in the period ended December 31, 2012, income tax expense relates to intercompany service income earned by our Japanese subsidiary, MediciNova Japan, Inc.

Stock-Based Compensation

We award options to purchase our common stock to our employees and directors and under our Amended and Restated 2004 Stock Incentive Plan (the 2004 Plan), the successor to our 2000 General Stock Incentive Plan (the 2000 Plan). The cost of these employee awards is measured according to the grant date fair value of the stock award and is recognized on a straight-line basis over the period during which an employee is required to provide service in exchange for the award, which is usually the vesting period. We occasionally issue employee performance based stock options, the vesting of which is subsequently based on a determination made by the

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Company s board of directors as to the achievement of certain corporate objectives. The grant date of such awards is the date on which our board of directors makes its determination. For periods preceding the grant date, the cost of these awards is measured according to their fair value at each reporting date. Stock options awarded to non-employees were recorded at their fair value as determined in accordance with the authoritative guidance for equity under ASC 505.

Under the MediciNova, Inc. 2007 Employee Stock Purchase Plan, or ESPP, 300,000 shares of our common stock have been reserved for issuance. In addition, the shares reserved will automatically increase by a number equal to the lesser of: (i) 15,000 shares, (ii) 1% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year or (iii) such lesser amount as determined by the Board. The ESPP permits full-time employees to purchase our common stock through payroll deductions (which cannot exceed 15% of each employee s compensation) at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month offering period.

The exercise price of stock options granted during the years ended December 31, 2012 and 2011 were equal to market value on the date of grant. During the years ended December 31, 2012 and 2011, options to purchase 750,000 and 1,431,000 shares of common stock, respectively, were granted. For the year ended December 31, 2012, 35,414 shares were issued under the ESPP, leaving 249,578 shares available for future issuance. Stock-based compensation expense for such stock options and employee stock purchase place are reflected in total operating expense for each respective year. The estimated fair value of each stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for stock option grants:

	Year Ended December 31,	
	2012	2011
Stock Options		
Risk-free interest rate	0.67%	0.70%
Expected volatility of common stock	83.26%	78.79%
Dividend yield	0.00%	0.00%
Expected option term (in years)	5.31	5.36
Employee Stock Purchase Plan		
Risk-free interest rate	0.30%	0.27%
Expected volatility of common stock	79.5%	77.97%
Dividend yield	0.00%	0.00%
Expected option term (in years)	0.5	0.5

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our employee stock options. The expected volatility is based on the historical volatility of our stock since listing on the Nasdaq Global Market in December 2006. We have not paid nor do we anticipate paying dividends on our common stock in the foreseeable future. The expected term of employee stock options is based on the simplified method as provided by the authoritative guidance on stock compensation, as we concluded that our historical stock option exercise experience does not provide a reasonable basis for us to estimate the expected term.

The weighted-average fair value of each stock option granted during the years ended December 31, 2012 and 2011, estimated as of the grant date using the Black-Scholes option valuation model, was $1.33 per option and $1.25 per option, respectively.

For the years ended December 31, 2012 and 2011, stock-based compensation expense related to stock options and the employee stock purchase plan was $0.7 million and $1.4 million, respectively, and was recorded as a component of general and administrative expense ($0.4 million and $1.1 million, respectively) and research

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and development expense ($0.3 million and $0.3 million, respectively). During the years ended December 31, 2012 and 2011, there were 60,000 and 32,836 stock options exercised, respectively, from which proceeds of $0.1 million and $0.08 million, respectively, were received.

As of December 31, 2012, there was $1.0 million of unamortized compensation cost related to unvested stock option awards which is expected to be recognized over a remaining weighted-average vesting period of 1.2 years, on a straight-line basis.

Net Loss Per Share

Net loss per common share is presented as basic and diluted net loss per common share. Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Potentially dilutive outstanding securities excluded from diluted net loss per common share because of their anti-dilutive effect:

	December 31,	
	2012	**2011**
Convertible preferred stock, as converted	2,200,000	2,200,000
Stock options	3,328,981	3,092,671
Warrants	3,128,686	2,998,686
Total	8,657,667	8,291,357

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board, or FASB, issued updated accounting guidance that clarifies existing fair value measurements and disclosures, and eliminates differences between GAAP and International Financial Reporting Standards to make convergence guidance more understandable. This guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

In September 2011, the FASB, issued guidance to simplify how entities test for goodwill impairment. The updated guidance permits an assessment of qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit in which goodwill resides is less than its carrying value. For reporting units in which this assessment concludes it is more likely than not that the fair value is more than its carrying value, the updated guidance eliminates the requirement to perform further goodwill impairment testing. This new guidance is effective for fiscal years beginning after December 15, 2011. The adoption of this guidance did not have a material impact on the Company s consolidated financial statements.

Effective January 1, 2012, the Company adopted guidance issued by the FASB, concerning presentation and disclosure only for the presentation of comprehensive (loss) income. The adoption of this guidance did not have a material impact on the Company s consolidated financial position or results of operations, other than its impact on the presentation of comprehensive (loss) income.

In August 2012, the FASB issued updated guidance to 2011 guidance that permits an assessment of the qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit in which

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goodwill resides is less than its carrying value. This updated guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

2. Fair Value Measurements

As defined in the authoritative guidance for fair value measurements and disclosures under ASC 820, fair value is based on the price that would be received to sell an asset or would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability and consistency of fair value measurements, ASC 820 prescribes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels which are described below:

Level 1:	Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities at the measurement date.
Level 2:	Inputs are quoted prices for similar items in active markets or inputs are quoted prices for identical or similar items in markets that are not active.
Level 3:	Inputs are unobservable due to little or no market data availability and inputs are usually developed by management or a third-party which reflect those inputs that a market participant would use. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The following table presents our financial instruments measured at fair value on a recurring basis classified by the fair value measurements and disclosures valuation hierarchy (in thousands):

	As of December 31, 2012			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 1,720	$ 1,720	$	$

	As of December 31, 2011			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 1,690	$ 1,690	$	$

At December 31, 2012, cash equivalents (instruments with maturities of three months or less at the date of purchase) were primarily invested in money market accounts, the fair value of which is based on Level 1 criteria in which their carrying amount is a reasonable estimate of their fair value based on daily quoted market prices. At December 31, 2012 and 2011 we did not hold financial instruments measured at fair value on a non-recurring basis.

3. Long-term Debt

In May 2010, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance Corporation, or Oxford, under which we borrowed $15.0 million at a stated interest rate of 12.87 percent. Our obligations under the Loan Agreement were secured by a first priority security interest in substantially all of our assets, other than our intellectual property, and we also agreed not to pledge or otherwise encumber our intellectual property assets. Our obligations under the Loan Agreement were guaranteed on a senior secured basis by Avigen. The Loan Agreement also contained certain restrictive covenants.

Pursuant to the Loan Agreement, we issued to Oxford a warrant to purchase up to 198,020 shares of our common stock, par value $0.001 per share. The warrant is exercisable, immediately, in whole or in part, has a per share exercise price of $6.06 and may be exercised on a cashless basis. The warrant will terminate on the earlier

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of May 10, 2017 or the closing date of a merger or consolidation transaction in which we are not the surviving entity. In addition, the warrant and debt instrument were immediately separable and issued separately. We accounted for the warrant as a component of stockholders equity as the agreement required settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

We accounted for the interest on the debt using the effective interest method wherein we treated the debt issuance costs paid directly to Oxford and the relative fair value of the warrants issued to Oxford as a discount on the debt, and we treated the debt issuance costs paid to third parties (primarily legal fees) as an other asset in our consolidated balance sheet. The amortization of the debt discount was recorded as interest expense and the amortization of the debt issuance costs paid to third parties was recorded as other expense in our consolidated statement of operations and comprehensive loss.

On March 31, 2011, we entered into an agreement with Oxford under which we made an early repayment of the loan in-full and wherein Oxford waived the prepayment penalty of approximately $437,000.

The table below summarizes the long-term debt activity:

	Year Ended December 31, 2011					
	Carrying Value 12/31/2010	Amortization (Interest Expense)	Amortization (Other Expense)	Payments	Write-Off Debt Related Costs	Carrying Value 12/31/2011
Other Assets:						
Debt issuance costs paid to third parties	$ 124,722	$	$ (21,426)	$	$ (103,296)	$
Liability:						
Loan	$ (15,000,000)	$	$	$ 15,000,000	$	$
Deferred interest charge	$ (134,491)	$ (504,207)		$ 450,000	$ 188,698	$
	$ (15,134,491)	$ (504,207)	$	$ 15,450,000	$ 188,698	$
Contra Liability:						
Relative fair value of warrants issued to lender(1)	$ 595,342	$ (102,274)	$	$	$ (493,068)	$
Debt issuance costs paid to lender	$ 103,934	$ (17,855)		$	$ (86,079)	$
	$ 699,276	$ (120,129)	$	$	$ (579,147)	$

(1) The relative fair value of the warrants issued to the lender was calculated using a Black-Scholes valuation model. The risk-free interest rate assumption was 2.86 percent based upon observed risk-free interest rates appropriate for the expected term of the warrants. The expected volatility assumption was 76 percent consistent with the volatility of our common stock based on the historical volatility of our stock since listing on the Nasdaq Global Market in December 2006. We have not paid and do not anticipate paying dividends on our common stock since our inception, and therefore, the dividend yield assumption was zero. The expected term assumption was seven years, which is the contractual life of the warrants. The fair value of the warrants using the Black-Scholes valuation model was calculated to be $4.34 per share.

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4. Balance Sheet Details

Property and Equipment

Property and equipment, net, consist of the following:

	December 31,	
	2012	2011
Leasehold improvements	$ 170,386	$ 172,648
Furniture and equipment	351,992	561,332
Software	228,397	221,380
	750,775	955,360
Less accumulated depreciation and amortization	(672,301)	(925,935)
	$ 78,474	$ 29,425
Depreciation expense	$ 33,507	$ 41,869

Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2012	2011
Research and development costs	$ 152,046	$ 615,792
Professional services fees	68,102	100,823
Joint venture capital contribution payable		650,000
Other	94,504	149,200
	$ 314,652	$ 1,515,815

5. Related Party Transactions

We entered into a stock purchase agreement dated September 26, 2011 with Kissei, under which on October 13, 2011 Kissei purchased for $7.5 million an aggregate of 800,000 shares of our common stock and 220,000 shares of our Series B Convertible Preferred Stock. On the same day, we entered into a letter agreement with Kissei pursuant to which we agreed to renegotiate in good faith the existing levels of the milestone payment amounts and royalty rates under our license agreement for MN-221 and agreed upon a new price for clinical supplies of API. On October 13, 2011 we entered into a services agreement with Kissei to perform two separate studies relating to MN-221 in exchange for $2.5

million paid to us in October, 2011. We are responsible for all costs to be incurred in the performance of these studies. The amount received from Kissei, net of the amount recorded as revenue through December 31, 2012, is included on the balance sheet at December 31, 2012 as deferred revenue and will be recognized as revenue in future periods as we perform the remaining services.

6. Commitments and Contingencies

Facility Lease

On July 6, 2011, we entered into a fifth amendment (the Fifth Lease Amendment) of our lease agreement (the Lease), with 4350 La Jolla Village LLC (the Landlord). The Fifth Lease Amendment amended and extended the Lease term from August 31, 2011 to May 31, 2012. The Fifth Lease Amendment provided that we

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pay the Landlord a monthly base rent of $12,468 for the premises during the nine-month extension period. On March 19, 2012, we entered into a sixth amendment of the Lease (the Sixth Lease Amendment), which extended the lease term through February 28, 2013, and provided that we pay the Landlord a monthly base rent of $12,672 for the premises during the term of the Sixth Lease Amendment. See Notes to Consolidated Financial Statements-Note 11. Subsequent Events, for information regarding a change in our headquarters and a new sublease agreement. In June 2005, we leased office space in Tokyo, Japan under a non-cancelable operating lease that expires in May 2013 and provides for six month extensions thereafter. Rent expense for the years ended December 31, 2012 and 2011 was $286,762 and $529,114, respectively, and rent expense, net of sub-lease income for the period from September 26, 2000 (inception) to December 31, 2012 was $5.0 million.

Future minimum payments as of December 31, 2012 are as follows:

Years ending December 31:	
2013	$ 77,039
Total minimum payments	$ 77,039

License Agreements

Since our inception, we have entered into eight license agreements with pharmaceutical companies which cover our current product candidates. In general, we seek to obtain exclusive licenses to the patent rights and know-how for all indications under the agreements within our licensed territories and to procure patent protection for our anticipated products, or obtain such protection from the relevant patents owned by our licensors. Under our license agreements we generally are required to make an upfront payment and additional payments upon the achievement of specific development and/or regulatory approval milestones. We are also generally obligated to pay royalties under the agreements until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis.

The amounts expended under these agreements and charged to research and development expense from September 26, 2000 (inception) to December 31, 2012 was $9,850,000. No such amounts have been expended during the years ended December 31, 2012 or 2011. As of December 31, 2012, future potential milestone payments totaled $94.1 million, and there are no minimum royalties required under any of the license agreements. We are unable at this time to estimate with certainty the timing on when these milestone payments will occur as these payments are dependent upon the progress of our product development programs.

Legal Proceedings

On March 3, 2011, we received a letter, in which certain allegations were made, from a former employee who had been terminated in January 2011 pursuant to our planned reduction-in-force. On July 8, 2011, the former employee filed a lawsuit in the Superior Court of the State of California, County of San Diego, asserting certain claims related to the Company s work environment and the employee s termination, and on December 12, 2011 the court granted our motion to compel arbitration. On August 1, 2012 the arbitrator stayed all proceedings to allow the plaintiff time to obtain new counsel. The plaintiff has since obtained new counsel and the arbitrator has continued the stay to allow our legal counsel and the plaintiff s new counsel to work out some final details regarding documents and property previously held by the plaintiff s former counsel. Based on our current assessment, we do not expect its outcome to have a material adverse effect on our business, financial condition and results of operations.

7. Stockholders Equity

Initial Public Offering in Japan

On February 8, 2005, we completed an IPO of 3,000,000 shares of common stock in Japan and received aggregate proceeds of $104,486,895, net of underwriting discounts and commissions and offering expenses. In

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addition, on March 8, 2005, we closed the sale of an additional 157,300 shares of our common stock pursuant to the partial exercise by our underwriters of an over-allotment option which resulted in aggregate proceeds to us of $5,557,773, net of underwriting discounts and commissions. In connection with our IPO, redeemable convertible and convertible preferred stock outstanding as of February 8, 2005 was automatically converted into 6,678,285 shares of common stock.

Public Offering in the U.S.

On February 1, 2007, we completed a public offering of 1,000,000 shares of common stock in the U.S. at a purchase price of $12.00 per share and received aggregate net proceeds of approximately $10,639,600, net of underwriting discounts and commissions and offering expenses.

Redeemable Convertible Preferred Stock

On September 2, 2004, we sold 27,667,856 shares of Series C redeemable convertible preferred stock at a purchase price of $1.62 per share for total net proceeds of $43,404,320, net of issuance costs. The Series C preferred stock was sold at a price per share below our IPO price. Accordingly, pursuant to the authoritative guidance for debt under ASC 470, we recorded a deemed dividend on the Series C preferred stock of $31,264,677, which is equal to the number of shares of Series C preferred stock sold multiplied by the difference between the estimated fair value of the underlying common stock and the Series C preferred stock conversion price per share. The deemed dividend increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share and was reported as a charge to accumulated deficit and a credit to additional paid-in capital, with no net impact on total stockholders equity.

Convertible Notes

At the closing of the Avigen transaction, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into the indenture. Under the terms of a separate trust agreement (the Trust Agreement), $29.4 million, which represented the initial principal amount of the Convertible Notes, was deposited with a trust agent for the benefit of the holders and us.

Prior to their maturity on June 18, 2011, holders of the Convertible Notes could submit irrevocable conversion notices instructing the trustee to convert such Convertible Notes into shares of our common stock at an initial conversion price of $6.80 per share. Following each conversion date we would issue the number of whole shares of common stock issuable upon conversion and the trustee would in turn release to us the respective amount of restricted cash to cover the stock issuance. Prior to the maturity of the Convertible Notes, approximately $1.9 million of the convertible notes were converted to 276,655 shares of our common stock. All remaining Convertible Notes matured on June 18, 2011 and the principal was repaid in full.

Firm Underwritten Public Offering

On March 23, 2011, we consummated a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of $3.00 per unit for gross proceeds of $8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common

stock. The shares of common stock and warrants are immediately separable and were issued separately. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of $3.56 per share. The warrants are indexed to our stock and do not permit net-cash settlement. On March 29, 2011, we received net proceeds of $7.7 million, after underwriter discount and underwriter expenses and no warrants exercised. In accordance with the authoritative guidance, the warrants were classified as equity instruments as they contain no provisions which may require cash settlement.

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Oxford Warrant

In May 2010, pursuant to the Loan Agreement with Oxford, we issued to Oxford a warrant to purchase up to 198,020 shares of our common stock at an exercise price of $6.06 per share. The warrant will terminate on the earlier of May 10, 2017 or the closing date of a merger or consolidation transaction in which we are not the surviving entity. In addition, the warrant and debt instrument are immediately separable and were issued separately. We therefore accounted for the warrant as a component of stockholders equity as the agreement requires settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

Kissei Stock Purchase

In October 2011, pursuant to a stock purchase agreement by and between us and Kissei, Kissei purchased for $7.5 million (i) an aggregate of 800,000 shares of our common stock, par value $0.001 per share, at a price of $2.50 per share, which approximated the fair value of our common stock at the time of the transaction, and (ii) 220,000 shares of our Series B Convertible Preferred Stock, or Series B Preferred, par value $0.01 per share, at a price of $25.00 per share, which approximated the fair value of our preferred stock on an as converted basis at the time of the transaction. The purchase agreement contains customary representations, warranties and covenants and a standstill agreement from Kissei that terminates if Kissei beneficially owns less than three percent of our outstanding voting stock. Each share of the Series B Preferred is convertible into 10 shares of common stock. The Series B Preferred ranks pari passu (on an as-if-converted-to-common-stock basis) with the common stock in liquidation and dividend rights. The holders of the Series B Preferred do not have voting rights, and the consent of a majority of the outstanding Series B Preferred is required for certain actions of the Company.

Common Stock Purchase Agreement

On August 20, 2012, we entered into a common stock purchase agreement with Aspire pursuant to which the Company may sell to Aspire, and Aspire would be obligated to purchase, up to an aggregate of $20 million of our common stock over the two year term of the agreement including $1 million in common stock purchased by Aspire in connection with execution of the agreement. Daily sales of our common stock to Aspire are subject to certain limitations and the per share sales price is based on closing stock prices at or near each transaction date. No more than 3,231,096 shares of our common stock can be issued under this agreement, including the 363,636 shares issued to Aspire in consideration of entering into the agreement. Our net proceeds will depend on the frequency and number of shares of our common stock sold to Aspire and the per share purchase price of each transaction. We may, on any business day over term of the agreement, direct Aspire to purchase up to 50,000 shares, to a maximum of $500,000 per business day. The purchase price shall be the lower of the lowest sale price of the Company s common stock on the date of the sale, or the average of the three lowest closing stock prices during the 12 consecutive business days ending on the business day immediately preceding the purchase date. In addition, MediciNova may on any business day over the term of the Agreement, direct Aspire to make a volume-weighted average purchase (VWAP) of stock not to exceed 15% (which limitation may be increased up to 30% by the mutual agreement of the parties) of the aggregate shares of our stock traded on the next business day, the purchase price of which shall be the lower of the closing price on the date of the sale, or 95% of the next business day s Nasdaq volume weighted average price, subject to a minimum market price threshold established by us and certain other exceptions. We initially issued 363,636 shares of our common stock to Aspire as consideration for entering into the agreement. As of December 31, 2012, the Company had completed sales to Aspire totaling 856,060 shares of common stock at prices ranging from $1.65 to $1.93 per share, generating gross proceeds of $1.5 million. Between August 21, 2012 and the date of this report, we have generated proceeds of $3.0 million under the Common Stock Purchase Agreement with Aspire including proceeds of $1.5 million on the sale 800,000 shares of our common stock subsequent to December 31, 2012. The agreement with Aspire provides Aspire certain termination rights, including rights under an event of default as defined therein, under which the Company may not require and Aspire would not be obligated to purchase any shares of our common stock. The Company and Aspire may also not effect any sales under the agreement on any purchase date where the closing price of our common stock is less than $1.00 per share.

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Warrant For Services

On August 22, 2012, we issued a warrant in exchange for investor relations services to purchase up to 130,000 of our common shares at a price of $1.88 per share, the closing price of our common stock on that date. The warrant contains provisions whereby the warrant becomes exercisable for specified shares of our common stock as a result of our stock achieving certain share price targets within a 15 month period beginning on August 22, 2012. The warrant expires in five years. The warrant is valued at its fair value of approximately $100,000 on August 22, 2012, is classified as equity and as a prepaid expense, and is being amortized over the one year period beginning August 22, 2012.

Stock Options

We grant options to our employees, directors and consultants under our 2004 Plan, the successor to the 2000 Plan.

2000 General Stock Incentive Plan

In September 2000, we adopted the 2000 Plan under which incentive stock options could be granted to our employees and nonstatutory stock options and other stock-based awards could be granted to employees, directors and consultants. Stock options have been granted with an exercise price of $10.00 per share and vest 25% after the first year of service from the grant date, with the remaining shares vesting in equal monthly installments over the subsequent 36 months of service. An employee may exercise stock options prior to vesting in which case we have the right to repurchase the unvested shares at the original exercise price if the employee is terminated before vesting in all shares occurs.

Following the vesting period, options are exercisable until the earlier of 90 days after the employee s termination with us or the ten-year anniversary of the initial grant, subject to adjustment under certain conditions. We have the right to purchase all of those shares that the employees have or will acquire under these stock options. The purchase price for any vested shares repurchased will be the greater of the fair market value of such shares on the date of purchase or the aggregate exercise price for such shares.

At December 31, 2012, stock options to purchase a total of 4,000 shares of common stock were outstanding under the 2000 Plan at a weighted average exercise price of $10.00 per share. No additional stock options have been or will be issued under the 2000 Plan. However, stock options previously granted under the 2000 Plan will remain outstanding until the earlier of expiration or exercise.

2004 Stock Incentive Plan

In connection with our IPO, we adopted the 2004 Plan, which serves as the successor program to the 2000 Plan. The 2004 Plan became effective upon the completion of our IPO in February 2005 and was amended and restated in February 2007.

The 2004 Plan is administered by the compensation committee of our board of directors and provides for the grant of (i) options to purchase shares of common stock; (ii) restricted stock; (iii) stock appreciation rights; and (iv) stock units. Incentive stock options may only be granted to employees. Nonstatutory stock options and other stock-based awards may be granted to employees, non-employee directors and consultants.

The number of shares reserved for issuance under the 2004 Plan will be increased on the first day of each of our fiscal years from 2006 through 2014, with the first such increase occurring on January 1, 2006, by the lesser of: (i) 100,000 shares; (ii) 3% of our outstanding common stock on the last day of the immediately preceding fiscal year; or (iii) the number of shares determined by our board of directors. In addition, in February 2007 and June 2008, the total number of shares available for grant under the 2004 Plan was increased by 300,000 and 1,000,000, respectively.

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Options granted to optionees other than non-employee directors will generally vest monthly over a four-year period, beginning on the vesting commencement date. The exercise price of an incentive stock option shall not be less than 100% of the fair market value at the time of grant and the exercise price of a nonstatutory stock option shall not be less than 85% of the fair market value at the time of grant.

The 2004 Plan terminates ten years after its initial adoption by the board of directors, unless terminated earlier by the board of directors. The board of directors may amend or terminate the plan at any time, subject to stockholder approval where required by applicable law.

A summary of our stock option activity and related information as of December 31, 2012 is as follows:

	Number of Option Shares	Weighted Average Exercise Price
Outstanding at January 1, 2012	3,092,671	$ 5.52
Granted	750,000	$ 2.01
Exercised	(60,000)	$ 2.30
Cancelled	(453,690)	$ 4.57
Outstanding at December 31, 2012	3,328,981	$ 4.92
Exercisable at December 31, 2012	2,089,963	$ 6.32

The weighted average contractual life of options outstanding at December 31, 2012 was 7.2 years and the weighted average contractual life of exercisable options at December 31, 2012 was 6.1 years. There was no aggregate intrinsic value of stock options outstanding and options exercisable, during the year ended December 31, 2012.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2012:

Common Stock under the employee stock purchase program	249,578
Common stock reserved for issuance upon exercise of warrant	3,128,686
Common stock options outstanding (under the 2000 Plan and 2004 Plan)	3,328,981
Common stock options authorized for future grant (under the 2004 Plan)	466,752
	7,173,997

8. Income Taxes

The significant components of our deferred income taxes at December 31, 2012 and 2011 are as follows:

	12/31/12	12/31/11
Deferred Tax Assets:		
Net operating loss carryforwards	83,783,000	79,215,000
Capitalized licenses	1,822,000	2,067,000
Research tax credits	7,145,000	7,124,000
Stock Options	570,000	395,000
Other, net	862,000	988,000
Total Deferred Tax Assets	94,182,000	89,789,000
Deferred Tax Liabilities		
In process R&D	(1,956,000)	(1,956,000)
Total Deferred Tax Liabilities	(1,956,000)	(1,956,000)
Net deferred tax assets	92,226,000	87,833,000
Valuation Allowance	(94,182,000)	(89,789,000)
Net Deferred Tax Liability	(1,956,000)	(1,956,000)

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We have established a valuation allowance against our deferred tax assets due to the uncertainty that such assets will be realized. We periodically evaluate the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred tax assets will be realizable, the valuation allowance will be reduced.

At December 31, 2012, we had federal and California net operating loss, or NOL, carryforwards of approximately $205.7 million and $205.1 million, respectively. The federal net operating loss carryforwards begin to expire in 2020, and the California net operating loss carryforwards begin to expire in 2013. At December 31, 2012, we also had federal and California research tax credit carryforwards of approximately $6.2 million and $1.4 million, respectively. The federal research tax credit carryforwards begin to expire in 2024, and the California research tax credit carryforward does not expire and can be carried forward indefinitely until utilized.

The above NOL carryforward and the research tax credit carryforwards are subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred which will limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. Multiple ownership changes have occurred in previous years which created annual limitations on our ability to utilize NOL and tax credit carryovers. Such limitations will result in approximately $7.3 million and $1 million of tax benefits related to federal and state NOL and tax credit carryforwards, respectively, that will expire unused. Accordingly, the related NOL and research credit carryforwards are not reflected in the deferred tax assets or the corresponding valuation allowance above. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, related to our operations in the U.S. will not impact our effective tax rate.

A reconciliation of the federal statutory income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,	
	2012	2011
Federal statutory income tax rate	35.0%	35.0%
State income taxes, net of federal benefit	5.8	5.5
Tax credits		1.6
Change in valuation allowance	(40.1)	(37.1)
Permanent differences	(0.7)	(5.0)
Other		
Provision for income taxes	0.0%	0.0%

We file income tax returns in the United States, California and foreign jurisdictions. Due to our losses incurred, we are essentially subject to income tax examination by tax authorities from our inception to date. Our policy is to recognize interest expense and penalties related to income tax matters as tax expense. At December 31, 2012, there are no unrecognized tax benefits, and we do not have any significant accruals for interest related to unrecognized tax benefits or tax penalties.

9. Employee Savings Plan

We have an employee savings plan available to substantially all employees. Under the plan, an employee may elect salary reductions which are contributed to the plan. The plan provides for discretionary contributions by us, which totaled $96,415, $97,929, and $1,196,091 for the years

ended December 31, 2012, 2011 and the period from September 26, 2000 (inception) to December 31, 2012, respectively.

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10. Quarterly Financial Data (Unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for fiscal 2012 and 2011 are as follows (in thousands, except per share data):

	Year Ended December 31, 2012			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Revenues	191	494	84	34
Total operating expenses	4,064	2,781	2,446	2,455
Net loss	(3,867)	(2,281)	(2,379)	(2,434)
Net loss applicable to common stockholders	(3,867)	(2,281)	(2,379)	(2,434)
Basic and diluted net loss per common share(1)	(0.24)	(0.14)	(0.14)	(0.14)

	Year Ended December 31, 2011			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Total operating expenses	4,976	3,722	3,907	3,503
Net loss	(5,656)	(4,681)	(3,894)	(3,503)
Net loss applicable to common stockholders	(5,656)	(4,681)	(3,894)	(3,503)
Basic and diluted net loss per common share(1)	(0.45)	(0.31)	(0.25)	(0.22)

(1) Loss per share is computed independently for each of the quarters presented. The sum of the quarterly net loss per share will not necessarily equal the total for the year.

11. Subsequent Events

Lease Amendment

On February 27, 2013, we entered into a sublease agreement effective March 1, 2013 (the Sublease) with Denali Advisors, LLC, the sublessor, to which Irvine Company, the master landlord, has provided its consent. The Sublease is for the Company s new headquarters located at 4275 Executive Square, Suite 650, La Jolla, California, 92037. The Sublease has a term of 4 years and 9 months and provides that the Company will pay Irvine Company a monthly base rent of $10,699 for the premises during the first year.

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Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as defined in the Rules 13(a)-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission s rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2012, our disclosure controls and procedures were effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our procedures or our internal controls will prevent or detect all errors and all fraud. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of our controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for es