MEDICINOVA INC
Form 10-K
March 27, 2014
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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, 2013

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 or Organization)	**(I.R.S. Employer Identification No.)**
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: None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 $48,678,000 based on the closing price of the registrant s common stock on The NASDAQ Global Market of $2.63 per share on June 28, 2013. 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, 2014 was 24,070,943.

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 2014 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, 2013

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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; the potential impact of uncertainties in the credit and capital markets or a future deterioration of these markets on our cash reserves; 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 biopharmaceutical company focused on developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs and a commercial focus on the U.S. market. We are currently focusing our development activities on MN-166 (Ibudilast) for the treatment of neurological disorders, MN-221 (Bedoradrine) for the treatment of acute exacerbations of asthma, MN-001 (Tipelukast) for the treatment of NASH (nonalcoholic steatohepatitis), and MN-029 (Denibulin) for the treatment of solid tumors.

MN-166 (Ibudilast) is currently in development for several different neurological disorders. 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 have successfully partnered with investigators from the NeuroNEXT consortium and funded by the National Institute on Neurological Diseases and Stroke (NINDS), to

resume a clinical development program for the treatment of primary and secondary progressive MS. In the area of addiction, in 2012, investigators at UCLA completed enrollment of a Phase 1b clinical trial of MN-166 in methamphetamine (MA)-dependent volunteers, funded by the National Institute on

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Drug Abuse (NIDA) and the results were presented at the Annual Meeting of the College on Problems of Drug Dependence (CPDD) in June 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 MA addiction. In collaboration with UCLA, this clinical trial commenced in 2013. In 2010, investigators at Columbia University and the New York State Psychiatric Institute (NYSPI) completed a double blinded, placebo controlled, Phase 1b/2a opioid withdrawal clinical trial that was funded by NIDA. Investigators at Columbia and the NYSPI 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. The same research group at Columbia University/NYSPI was previously granted an award from NIDA to evaluate the effects of ibudilast in marijuana dependence. They postulate that there is considerable overlap between endogenous opioid and cannabinoid systems, and because ibudilast has been shown to alleviate opioid withdrawal symptoms in opioid-dependent rats (Hutchinson *et al*., 2009) and humans (Cooper *et al*., in preparation), examination of ibudilast in marijuana-dependent subjects warrants evaluation. In August 2013, we announced that researchers at UCLA were granted approval and funding by National Institute on Alcoholism and Alcohol Abuse (NIAAA) of a Phase 1 clinical trial studying the use of MN-166 for the treatment of alcohol dependence. The study is expected to commence the second quarter of 2014.

In 2012, we completed a Phase 2 clinical trial of MN-221 for the treatment of acute exacerbations of asthma treated in the emergency room and conducted an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) in October 2012. We plan to conduct the MN-221 program according to the feedback received from the FDA following the EOP2 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 identify a partner for financial support before further clinical development is commenced. In early 2014, we began preparing a clinical trial in MN-001 for the treatment of Nonalcoholic Steatohepatitis (NASH) in the U.S.

We have acquired licenses to MN-166, MN-221, MN-001, and MN-029 for the development of four product candidates which include clinical development for the treatment of progressive MS, various addictions, acute exacerbations of asthma, NASH, and solid tumor cancers. We are pursuing our option to return four compounds, MN-246, MN-305, MN-447 and MN-462, to their respective Licensors in order to maximize our ability to pursue development of MN-166, MN-221, MN-001, and MN-029.

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 MN-166 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 are funding portions of the consortium sponsored trials. For example, we have increased our financial participation in the Secondary and Primary Progressive Ibudilast NeuroNEXT Trial in Multiple Sclerosis

(SPRINT-MS) Phase 2 clinical trial of MN-166 for the treatment of progressive MS.

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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 2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical companies who seek late stage product candidates, such as MN-166, MN-221, MN-001 and MN-029, to support further clinical development and product commercialization.

Our Product Candidates and 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 (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)

Ibudilast (MN-166) is a novel, first-in-class, anti-inflammatory and neuroprotective agent. Ibudilast inhibits macrophage migration inhibitory factor (MIF) and certain phosphodiesterases (PDEs). While it has been in use for more than 20 years in Japan and Korea for the treatment of asthma and post-stroke dizziness, we are developing ibudilast for the treatment of chronic neuropathic pain, drug dependence, and MS particularly primary and secondary progressive MS in the U.S. and Europe. We licensed MN-166 from Kyorin Pharmaceuticals (Kyorin) in 2004.

We have filed patent applications for multiple uses of ibudilast for the treatment of neurological conditions, as well as patent applications on analogs that have the potential to be second generation molecules. Some of the patent estate has received allowance in the U.S. and foreign countries.

Primary and Secondary Progressive Multiple Sclerosis: MS is a complex disease with predominantly unknown etiology and affects approximately 2.3 million people worldwide, according to the National Multiple Sclerosis Society. There are no therapies generally considered safe and efficacious in primary progressive MS (PPMS) or secondary progressive MS (SPMS) in the absence of relapses. There is a great need for a safe, effective, and conveniently administered therapy for patients with PPMS and SPMS without overt inflammation. Ibudilast (MN-166) may meet these needs. Based on promising results from a Phase 2a trial in Central and Eastern Europe completed in 2008, investigators from the NeuroNEXT consortium, a NIH-funded Phase 2 clinical trial network, have begun to evaluate ibudilast in PPMS and SPMS patients in the U.S. SPRINT-MS is a Phase 2, randomized, placebo-controlled trial evaluating the safety and tolerability of ibudilast (up to 100 mg/day) over two years in PPMS and SPMS patients. Recruitment and enrollment of a planned 240 patients at 28 medical centers in the U.S. commenced in late 2013 and the trial is expected to be completed in approximately three years.

Methamphetamine addiction: MA is a central nervous system stimulant drug that is similar in structure to amphetamine. It is a Schedule II drug, meaning that it has high abuse potential and low therapeutic potential. According to the SAMHSA 2012 National Survey on Drug Use and Health, there are approximately 440,000 current MA abusers age 12 and older in the U.S. According to the Rand Corporation, the national estimate of the

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economic burden of MA use, based on the most recent year for which data are available, is approximately $23.4 billion. Currently, there is no treatment for MA dependence. Based on non-clinical results with ibudilast s effects in an animal model of MA relapse, investigators at UCLA conducted a Phase 1b trial funded by NIDA to examine the safety and preliminary efficacy of ibudilast in non-treatment-seeking, MA-dependent users in an inpatient trial that was completed in 2012. Subsequently, UCLA investigators received NIDA grant funding for a Phase 2 trial that commenced in 2013 for evaluation of ibudilast in MA-dependent users in an outpatient trial setting.

We were granted Fast Track designation from the FDA for ibudilast for the treatment of MA dependence in February 2013. Fast track designation 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.

Opioid withdrawal: According to the Substance Abuse and Mental Health Services Administration s (SAMHSA) 2012 National Survey on Drug Use and Health, there are approximately 2.0 million people age 12 and above with nonmedical pain reliever dependence or abuse and approximately 467,000 people age 12 and above with heroin dependence or abuse in the U.S. Access to prescription opioids has recently become more difficult due to more stringent policies on prescribing opioids. An unintended consequence of this policy is increased use of heroin. It is attractive to prescription opioid addicts for two main reasons: heroin is cheaper and more accessible. Heroin poses serious health issues, such as risk of HIV and Hepatitis C infection, overdose and death (Knopf, 2012). The economic costs of nonmedical use of prescription opioids in the U.S. in 2006 (Hansen *et al.*, 2011) was estimated to total more than $50 billion annually; lost productivity and crime accounted for 94% of the total economic burden. There is an urgent, significant unmet medical need for a safe, effective non-addictive, non-opioid therapy for the treatment of prescription opioid and heroin addiction. In 2010, investigators at Columbia University and NYSPI completed a Phase 1b/2a to evaluate the ability of ibudilast to reduce opioid withdrawal symptoms in humans in a double-blind, randomized, placebo-controlled in-unit trial. The trial was funded by NIDA. Subsequently, investigators at Columbia/NYSPI commenced a Phase 2a clinical trial of ibudilast for the treatment of opioid prescription drugs.

Chronic Medication Overuse Headache: Investigators at University of Adelaide began evaluation of ibudilast s ability to decrease the frequency, severity and duration of headaches in patients diagnosed with chronic medication overuse headache (MOH) in a randomized, double-blind, placebo-controlled, pilot study in which patients receive 80 mg/day for eight weeks. This study commenced in 2011 and was expected to be completed by mid-2013, however the Investigator decided to finalize the trial using recruitment numbers short of the enrollment goal initially established. We are yet to receive the results of the trial and we do not expect to obtain access to the study results other than through the resulting publication, if any.

Alcohol addiction: According to SAMHSA s 2012 National Survey on Drug Use and Health, there are approximately 17.7 million people with alcohol dependence or abuse age 12 and older in the U.S. The Centers for Disease Control and Prevention (CDC) reports that alcohol abuse costs the U.S. $224 billion annually, based on information collected from several national studies reporting on the costs of alcohol overuse in 2006, the latest year for which complete data are available. Currently, medicines approved by the FDA to treat alcohol dependence include Antabuse®, Vivitrol®, and Campral®. However, the search for a safe and effective drug remains elusive due to limited success of these FDA-approved compounds (Witkiewitz *et al*., 2012). In a non-clinical trial (Bell *et al*., 2013), ibudilast was examined in rats and mice and was found to reduce alcohol drinking in alcohol-preferring P rats and high-alcohol drinking (HAD1) rats by 50%, and in mice made dependent on alcohol at doses which had no effect on non-dependent mice. Concurrently, investigators at UCLA received funding from the NIAAA to initiate a Phase 2a study to evaluate ibudilast in a randomized, double-blind, placebo-controlled within-subject crossover design to determine the safety,

tolerability and initial human

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laboratory efficacy of ibudilast in a sample of 24 non-treatment seeking individuals with either alcohol abuse or dependence. Participants will be treated with ibudilast and placebo. The study was initiated in early 2014.

Marijuana dependence: According to the SAMHSA s 2012 National Survey on Drug Use and Health, there are approximately 4.3 million people with marijuana and hashish dependence or abuse age 12 and older in the U.S. There is no available medical treatment for marijuana dependence. Researchers at Columbia University/NYSPI postulate that there is considerable overlap between endogenous opioid and cannabinoid systems, and because ibudilast has been shown to alleviate opioid withdrawal symptoms in opioid-dependent rats (Hutchinson *et al.*, 2009) and humans (Cooper *et al.*, in preparation), examination of ibudilast in marijuana-dependent subjects warrants evaluation. This study is expected to initiate enrollment during the first half of 2014.

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. We licensed MN-221 from Kissei Pharmaceutical Co., Ltd. (Kissei) in February 2004. Current inhaled beta-agonist treatments for asthma exacerbations are limited by bronchoconstriction or insufficient airflow due to inflammation and airway constriction, which reduces the amount of inhaled drug that can get into the lungs. In addition, the amount of inhaled treatments a patient can tolerate is limited due to the potential for cardiovascular side effects (*e.g.* increased heart rate).

MN-221 is designed to treat acute exacerbations of asthma via intravenous (i.v.) infusion, bypassing constricted airways to deliver the drug directly to the lungs. Preclinical studies showed MN-221 to have a high affinity for the ß$_2$-adrenergic receptor, found primarily in the lungs, and a much lower affinity for the ß$_1$-adrenergic receptor found primarily in cardiac tissue. MN-221 s improved delivery to the lungs and its cardiac safety profile may help fill an unmet need for patients with acute exacerbations of asthma, helping them to breathe easier and avoid a costly hospital stay.

Acute Exacerbation of Asthma: According to the most recent data available from the U.S. National Center for Health Statistics, there were 1.75 million emergency department visits, 439,000 hospitalizations, and 3,404 deaths due to asthma in 2010. According to the U.S. 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. Nearly 10% of hospitalized patients have life-threatening asthma that requires admission to the intensive care unit (ICU).

We completed a Phase 2b randomized, double-blind, placebo-controlled clinical trial (N=175) evaluating MN-221 in patients with acute exacerbations of asthma in the emergency department setting. MN-221 did not statistically meet the primary endpoint, improvement in FEV_1 (Forced Expiratory Volume in One Second) compared to placebo. However, MN-221 showed a significant benefit over placebo for FEV_1 (liters) Area Under the Curve ($AUC_{Hr\ 0\text{-}1,0\text{-}2,0\text{-}3}$) 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. Moreover, there was a 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.

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 and that any future MN-221 clinical trial development for asthma will be partner-dependent from a funding perspective.

MN-001 (Tipelukast)

MN-001 is a novel, orally bioavailable small molecule compound which demonstrates anti-inflammatory activity in preclinical models. It is postulated that inhibition of the 5-LO pathway exerts anti-inflammatory

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actions, which has implications in various inflammatory diseases such as arthritis, osteoarthritis, allergy and asthma (Martinez-Clemente *et al*., 2011). Recently, 5-LO has been postulated as a pathogenic factor in liver injury (Titos *et al*., 2010). MN-001 is thought to exert an inhibitory effect on 5-LO and the 5-LO/LT pathway, which is considered a novel target for fatty liver disease. We licensed MN-001 from Kyorin in 2002.

Previously, we evaluated MN-001 for its potential clinical efficacy in asthma and completed a Phase 2 study in asthma with positive results. This compound has been exposed to more than 600 subjects. MN-001 was considered generally safe and well-tolerated.

We completed a pre-clinical study evaluating MN-001 s potential clinical efficacy for the treatment of NASH. MN-001 administered orally once daily (10, 30, and 100 mg/kg for three weeks) was evaluated in the STAM (NASH-HCC) mouse model of NASH, as measured by liver biochemistry and histopathology, NAFLD activity score (NAS), and percent of fibrosis and gene expression. MN-001, in a dose-dependent manner, significantly reduced fibrosis area compared with placebo ($p<0.01$) as demonstrated by a reduction in liver hydroxyproline content, supporting MN-001 s anti-fibrotic properties. MN-001 significantly improved NAS ($p<0.01$). MN-001, in this animal model, improved NASH pathology by inhibiting hepatocyte damage ($p<0.01$) and ballooning ($p<0.01$). At the same time, MN-001 was also shown to reduce certain gene expression levels in the liver, thus implying that MN-001 prevents the formation of fibrosis in the NASH model. Collectively, these results provide compelling evidence that MN-001 warrants further evaluation for the treatment of NASH in humans. We are preparing to initiate a clinical trial for the treatment of NASH in the U.S.

MN-029 (Denibulin HCl)

MN-029 is a novel tubulin binding agent (TBA) under development for the treatment of solid tumors. It reverses inhibition of tubulin polymerization resulting in disruption of the cell cytoskeleton, thus causing the cancer cells to deform in shape and ultimately leading to extensive central necrosis of the solid tumor. We licensed MN-029 from Angiogene Pharmaceuticals, Ltd. (Angiogene) in 2002.

Several preclinical pharmacology studies have assessed the mechanism of action and anti-tumor activity of MN-029 *in vivo* in rodent models of breast adenocarcinoma, colon carcinoma, lung carcinoma and KHT sarcoma. In these studies, MN-029 damaged poorly formed tumor blood vessels by weakening tumor blood vessel walls and causing leakage, clotting and eventual vascular shutdown within the tumor, in addition to the direct effect over tumor cells. These studies suggest that MN-029 acts quickly and is rapidly cleared from the body, which may reduce the potential for some adverse effects commonly associated with chemotherapy. Shutdown of tumor blood flow in tumor models was confirmed through the use of dynamic contrast-enhanced magnetic resonance imaging. In two Phase I clinical studies we conducted, MN-029 was well-tolerated at doses that reduced tumor blood flow.

The first Phase 1 trial determined the safety, tolerability, and maximum tolerated dose (MTD) level of single doses of MN-029 given every three weeks in 34 subjects with refractory cancer. The MTD was determined to be 180 mg/m^2 and appeared to be safe as a single i.v. dose administered every three weeks for as many as 25 cycles. There were no clinically significant changes in routine laboratory assessments, vital signs, or ECG monitoring. The most commonly reported adverse events (AEs) were similar to others chemotherapies vomiting, nausea, diarrhea, and fatigue. There were a total of nine serious adverse events (SAEs) and study discontinuations due to AEs. In a preliminary evaluation of anti-tumor activity, no patient had a complete response or partial response; however stable disease was seen in 12 patients. MN-029 had a desired vascular effect in seven of 11 patients that were administered drug at dose levels of ^{3120} mg/m^2. Nine patients continued into extended cycles of treatment.

The second Phase 1 study was conducted to determine the safety, tolerability and MTD of single doses of MN-029 given every seven days for a total of three doses (Days 1, 8 and 15), followed by 13-day recovery (Days 16-28) in subjects with advanced/metastatic solid tumor cancer. Subjects who tolerated treatment with MN-029 could receive additional cycles. All 20 subjects reported at least one AE related to study drug. The most common

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AEs considered related to study drug were vomiting, nausea, arthralgia and headache. There were no clinically significant changes in routine laboratory assessments, vital signs or ECG monitoring. There was one SAE considered unrelated to study drug. Consistent with the previous Phase 1 trial, MN-029 up to dose levels of 180 mg/m^2 appeared to be safe and well tolerated. One subject had a partial response which lasted for 74 days. Stable disease was observed in seven subjects. The results suggested an effect of MN-029 on vascular perfusion, however, a larger sample size is warranted.

In October 2013, we announced that we have received a Notice of Allowance from the U.S. Patent and Trademark Office for a pending patent application which covers MN-029 di-hydrochloride. Once issued, the patent maturing from this allowed patent application is expected to expire no earlier than July 2032. The allowed claims cover a compound, pharmaceutical composition and method of treating certain cell proliferation diseases, including solid tumors, based on denibulin di-hydrochloride. We plan to pursue further development of MN-029 for the treatment of solid tumors.

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Table 1 Product Candidates and Programs Ibudilast (MN-166)

Indication	Clinical Study	Principal Investigator / Institution /Funding Agency(s)	Status
Multiple Sclerosis			
Primary and Secondary Progressive Multiple Sclerosis	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability and Activity of Ibudilast (MN-166) in Subjects with Progressive Multiple Sclerosis	Robert J. Fox, M.D., M.S., FAAN Cleveland Clinic National Institute on Neurological Diseases and Stroke MediciNova, Inc.	Ongoing
Addiction			
Methamphetamine Dependence	Randomized Trial of Ibudilast for Methamphetamine Dependence	Keith Heinzerling, M.D., MPH UCLA National Institute on Drug Abuse	Ongoing
Opioid Dependence	Effects of ibudilast (MN-166), a glial activation inhibitor, on oxycodone self-administration in opioid abusers	Sandra D. Comer, Ph.D. Columbia University/NYSPI National Institute on Drug Abuse MediciNova, Inc.	Ongoing
Alcohol Dependence	Development of Ibudilast (MN-166) as a Novel Treatment for Alcoholism	Lara Ray, Ph.D. UCLA National Institute on Alcohol Abuse and Alcoholism	Ongoing
Marijuana Dependence	Effect of Ibudilast on Marijuana Withdrawal and Relapse	Margaret Haney, Ph.D. Columbia University/NYSPI National Institute on Drug Abuse	Ongoing
Pain			
Chronic Medication Overuse Headache	Ibudilast in the Treatment of Medication Overuse Headache: A Double-Blind, Randomised,	Discipline of Pharmacology, University of Adelaide	Results Pending

Placebo-Controlled Pilot Study MediciNova, Inc.

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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 (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®R, from Taisho-Teva Pharmaceuticals (Taisho).

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.

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 five issued U.S. patents. We also have obtained licensed rights to 54 issued and pending foreign patents and applications corresponding to these U.S. patents and patent applications. In addition to these licensed rights, we hold 17 issued U.S. patents and have filed 14 additional U.S. patent applications. We also hold 71 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 for the development and commercialization of MN-166. Kyorin 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 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.

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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 for any reason with 90 days written notice to Kyorin 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.

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 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 $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 seven 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, does not include a potential extension under patent term restoration rules, and covers a method of treating PPMS or 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. Counterparts of this patent application have been granted in certain foreign jurisdictions. We have been granted a patent that covers the use of MN-166 (ibudilast) to enhance opioid analgesia in acute pain settings from the European Patent Office (EPO) and it expires no earlier than January 2028.

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, which does not include a potential extension under patent term restoration rules. 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 been granted a U.S. patent which covers the use of MN-221 for the treatment of acute exacerbations of asthma and it expires no earlier than November 2030. This

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patent includes claims covering the use of MN-221 (bedoradrine) in combination with a standard of care treatment regimen and covers different routes of administration, including intravenous, oral and inhalation. Counterparts of this patent application are pending in certain foreign jurisdictions. We have been granted a U.S. patent that covers the use of MN-221 for the treatment of irritable bowel syndrome and it expires no earlier than April 2031.

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 we 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 agreed 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 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 have been granted eight U.S. patents covering certain compositions, uses and manufacturing processes associated with MN-001 and MN-002. Patent applications corresponding to these U.S. patents were filed in certain foreign countries and some of the foreign patents have issued. 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 an exclusive, royalty-free, sub-licensable license to use the preclinical, clinical and regulatory databases to develop ophthalmic products incorporating MN-001 anywhere in the world and non-ophthalmic products incorporating MN-001 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 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 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.

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Under the license agreement, we have paid Kyorin $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.

MN-029

On June 19, 2002, we entered into an exclusive license agreement with Angiogene for the development and commercialization of the ANG-600 series of compounds. Angiogene 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 three 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. In addition to the licensed patents, we have been granted a U.S. patent which covers MN-029 (denibulin) di-hydrochloride and expires no earlier than July 2032. The allowed claims cover a compound, pharmaceutical composition and method of treating certain cell proliferation diseases, including solid tumors, based on denibulin di-hydrochloride.

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.

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 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 $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.

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.

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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 that patent 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 five-year new 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.

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 Multiple Sclerosis

Our MN-166 product candidate is in development for the treatment of progressive MS. Only one drug, mitoxantrone, is approved for treating this disease. However, mitoxantrone cannot be used on a long-term basis because of the potential for cardiac toxicity.

MN-166 for Drug Addiction

Our MN-166 product candidate has been in development for treatment of opioid withdrawal and MA 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

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antagonist naloxone). Other products approved for opioid dependence include Alkermes Vivitrol® (naltrexone monthly injection) and Orexo s Zubsolv® (buprenorphine and naloxone). We are aware of additional compounds in development for the treatment of opioid dependence at companies including Titan Pharmaceuticals 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 a_2 adrenergic receptor agonist like clonidine which may have somewhat less orthostatic hypotension limitations. There are no pharmaceuticals currently approved for the treatment of MA addiction.

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-001 for Nonalcoholic Steatohepatitis

Our MN-001 product candidate is being developed for the treatment of NASH. There are currently no therapeutic products approved for the treatment of NASH. There are ongoing studies to evaluate FDA-approved therapeutics not specifically indicated for NASH (*e.g.,* metformin, rosiglitazone) to determine their safety and efficacy in patients with NASH. We are aware of additional compounds in Phase 2 development for the treatment of NASH at companies including Intercept Pharmaceuticals and Raptor Pharmaceuticals. Other companies have compounds in Phase 1 development, as well.

MN-029 for Solid Tumor Cancer

Our MN-029 product candidate is being developed for the treatment of solid tumor cancer. In the past year, Genentech s Kadcyla®, a HER-2 antibody, microtubule inhibitor conjugate for HER-2-positive metastatic breast cancer, was approved for treatment in patients previously treated with trastuzumab and/or taxane. Bayer s Stivarga®, a kinase inhibitor for metastatic colorectal cancer, was approved for patients with advanced, unresectable (not subject to surgical removal), or metastatic gastrointestinal stromal tumor. We are aware of additional compounds in development for the treatment of solid tumor cancers at companies including Eli Lilly & Company, Hoffmann-La Roche and Novartis Pharmaceuticals.

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, or FDCA, 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

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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 nonclinical laboratory, animal studies, and formulation studies;
- submission of an 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 (NDA) accompanied by a substantial user fee;
- development of manufacturing processes which conform to FDA-mandated commercial good manufacturing practices (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.

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 approvals of our drugs. 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 product candidates.

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 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 product candidates. Moreover, positive results in preclinical tests or prior human studies do not necessarily predict positive results in subsequent clinical

trials.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any findings from tests in laboratory animals that suggest a significant risk for human subjects.

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

Phase 1: The potential drug is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism. If the investigational product is considered inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in the target population.

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Phase 2: The potential 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 potential drug is introduced into an expanded patient population at geographically dispersed clinical trial sites to further evaluate clinical efficacy and safety. The purpose of the Phase 3 trial is to conduct a risk/benefit analysis of the potential drug and provide an adequate basis for product labeling. It is common to have two adequate and well-controlled Phase 3 trials for the FDA to approve an NDA.

Prior to initiation of each clinical trial, an independent Institutional Review Board (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 (GCP) 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. In addition, we may suspend or discontinue a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

During the development of a new drug, we may request to meet with the FDA at times such as prior to submitting an IND, at the EOP2, and before an NDA is submitted, and meetings are not limited to these certain times. The purpose of the EOP2 meeting is to discuss the Phase 2 clinical trial results and present plans for a pivotal Phase 3 trial that, in our opinion, will support the approval of the new drug. Additional animal safety studies, formulation studies and pharmacology studies are concurrently conducted with the ongoing clinical trials. Also, in compliance with cGMP requirements, the process for manufacturing commercial quantities of the new drug is finalized, with the expectation that the quality, purity, and potency of the drug will meet standards. A sponsor may also request a Special Protocol Assessment (SPA), the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

Fast track designation: The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for marketing, including a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for

accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over

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existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

U.S. patent term restoration and marketing exclusivity: Depending upon the timing, duration and specifics of the FDA approval of a drug candidate, some U.S. patents covering the product candidates may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent terms for one or more of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company s NDA. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued Written Request for such a trial.

Regulation outside the United States: In addition to regulations in the U.S., we and our strategic alliance partners will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any

commercial sales and distribution of our products.

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Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application (CTA) must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we or our strategic alliance partners must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our strategic alliance partners fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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 11 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, 2013, we had a net loss of $4.0 million. At December 31, 2013, from inception, our accumulated deficit was $301.4 million, including $51.6 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 candidates, 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, 2013, we had available cash and cash equivalents of $6.7 million and working capital of $13.9 million. We expect to have approximately $13.8 million in available cash as of March 31, 2014, and we expect to spend approximately $4.3 million from April 1, 2014 through December 31, 2014 to execute our strategic plan and fund operations. There can be no assurances that there will be adequate financing available to us in the future on acceptable terms, or at all. If we are 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;

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 2014 relative to 2013 as we have reduced our employee costs and elected to rely primarily upon clinical trials conducted and funded by outside entities.

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Our estimate of cash requirements for future operating expenses assumes that we do not incur significant clinical development expenditures unless we 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 Sections 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.

Our business will continue to require us to incur substantial research and development expenses. 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. Although we received a $6 million milestone payment in January 2014, we 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.

We are largely dependent on the success of our MN-166 product candidate and other product candidates 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 primarily on the successful development and commercialization of our MN-166 product candidate, for the treatment of neurological disorders including MS, opioid withdrawal, methamphetamine addiction, chronic MOH, alcohol dependency and marijuana dependency. This product

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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.

Our attempts to develop MN-001 in NASH may detract from our efforts to develop other product candidates and may limit the effectiveness of our product development efforts as a whole.

In 2013, we determined to pursue development of MN-001 in NASH. These activities will divert financial and management resources from our other product development activities and may limit our ability to complete or continue those other programs.

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

We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Medfron Medical Technologies, 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 eight clinical trials for four of our product development programs. INDs were approved by the FDA and are active for seven of our product candidates.

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. 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;

- 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.

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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, if any, 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 candidate 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 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.

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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, if approved, 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 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.

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.

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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;
- 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;

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.

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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;

- 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; and

- the formulation or dosing regimen of a product candidate may result, unintentionally, in patient non-compliance, leading to low patient retention rates, incomplete data to conduct an adequate analysis, and failure to complete the trial.

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 four compounds for the development of eight 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 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 product candidates 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 equity 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.

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/or 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 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

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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 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

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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.

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;

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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.

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

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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.

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 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. 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 personnel. However, we face competition for experienced 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 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.

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

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

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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;

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.

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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;
- 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.

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 of the Tokyo Stock Exchange, or TSE, 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

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those controls, as required by Section 404. We are subject to attestation by our independent registered public accounting firm on our report regarding internal control over financial reporting for the year ended December 31, 2013 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 TSE 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 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 and natural disasters.

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;

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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.

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

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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;
- 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

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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. 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.

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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 Tokyo Stock 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 2013, our average trading volume was approximately 39,500 shares per day on The NASDAQ Global Market and approximately 65,000 shares per day on the JASDAQ Market.

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, 2013, 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;
- 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.

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Our common stock may be delisted on The NASDAQ Global Market or the JASDAQ Market of the Tokyo Stock Exchange.

In addition to the risks identified immediately above, the market price of our common stock, and your ability to sell your shares at a profit, or at all, may be affected by the delisting of our shares for failure to meet applicable listing standards. For example, price per share minimums are maintained by The NASDAQ Global Market, and our share price has, in the past, fallen below the required minimum. In addition, JASDAQ Market listing requirements currently mandate that listed companies achieve a profit or positive cash flow from operations within a five-year period. Failure to meet these or other listing requirements for either of the stock exchanges on which are common stock is listed could adversely affect the market price for our common stock and your ability to sell your shares at a profit, or at all.

The sale of additional common stock to Macquarie Capital (USA) Inc. may cause substantial dilution to our existing stockholders and/or the price of our common stock to decline.

Pursuant to the at-the-market equity distribution agreement with MCUSA dated October 16, 2013, we may sell additional shares of our common stock to MCUSA. 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 MCUSA, 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 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.

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.

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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% 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% 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We executed a sublease agreement for our headquarters 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 has a term of four years and nine months and provides that we will pay Irvine Company a monthly base rent of $10,699 for the premises during the first year. In June 2005, we leased office space in Tokyo, Japan under a non-cancelable operating lease with an original expiration date of May 2013 and an auto-renewal two-year extension, which we continued to lease for the remainder of 2013 through May 2015 with the acceptance of the extension. We have no laboratory, research or manufacturing facilities, and we

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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

We are not involved in any material legal proceedings as of the date of this report. We may become involved in various 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 listed on the JASDAQ Market of the Tokyo Stock Exchange and trades under the code 4875, and is listed on The NASDAQ Global Market and trades 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, 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
Fiscal year ended December 31, 2013		
First quarter	$ 3.67	$ 1.53
Second quarter	$ 4.70	$ 2.26
Third quarter	$ 2.76	$ 2.25
Fourth quarter	$ 3.10	$ 1.91

Holders of Common Stock

As of the date of this filing, there were approximately 7,800 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.

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

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, 2011, to the JASDAQ Market (total index). The graph assumes an initial investment of $100 on March 31, 2011, 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.

	3/31/2011	12/30/2011	12/28/2012	12/30/2013
MediciNova, Inc.	$ 100	$ 65	$ 63	$ 97
JASDAQ Total Index	$ 100	$ 94	$ 107	$ 201

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The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since March 31, 2011 to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on March 31, 2011, 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.

	3/31/2011	12/30/2011	12/31/2012	12/31/2013
MediciNova, Inc.	$ 100	$ 66	$ 64	$ 83
NASDAQ Biotechnologies Index	$ 100	$ 104	$ 137	$ 228
NASDAQ Composite Index	$ 100	$ 94	$ 109	$ 150

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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,	
	2013	2012
Statements of Operations Data:		
Revenues	$ 6,003	$ 803
Operating expenses:		
Research, development and patents	3,366	5,013
General and administrative	6,658	6,735
Total operating expenses	10,024	11,748
Operating loss	(4,021)	(10,945)
Other expense	(25)	(30)
Interest expense		
Other income, net	21	25
Loss before income taxes	(4,025)	(10,950)
Income Taxes	(4)	(11)
Net loss	(4,029)	(10,961)
Net loss applicable to common stockholders	$ (4,029)	$ (10,961)
Basic and diluted net loss per share	$ (0.19)	$ (0.66)
Shares used to compute basic and diluted net loss per share	20,697,440	16,522,929

	As of December 31,	
	2013	2012
Balance Sheet Data:		
Cash, cash equivalents, restricted cash and current investment securities	$ 6,700	$ 4,011
Working capital	13,922	3,384
Total assets	29,546	19,568
Accumulated Deficit	(301,387)	(297,320)
Total stockholders equity	25,426	14,880

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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 biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs and 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, 2013, we had a net loss of $4.0 million. At December 31, 2013, from inception, our accumulated deficit was $301.4 million, including $51.6 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.

We are 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,(Ibudilast) for the treatment of neurological disorders, MN-221(Bedoradrine), for the treatment of acute exacerbations of asthma, MN-001(Tipelukast) for the treatment of NASH (nonalcoholic steatohepatitis), and MN-029 (Denibulin) for the treatment of solid tumors.

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 and search for additional compounds to develop. A sublicense would be required under which Zhejiang Sunmy would 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, 2013 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.

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Revenues and Cost of Revenues

We recognized approximately $6,003,000 of revenue for the year ending December 31, 2013 and $803,000 in revenue for the ended December 31, 2012. In 2013 we recorded $6,000,000 in revenues earned through a licensing arrangement held by Avigen, Inc., or Avigen, which we acquired in December 2009. There were no expenses incurred during 2013 related to this milestone.

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. Under the terms of the agreement, we are responsible for all costs incurred and to be incurred in the performance of these services. Certain of the development services were completed in 2013 and 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, which was research and development services. The $2.5 million was initially recorded as deferred revenue. Revenue was recorded in 2013 and 2012 of $3,000 and $0.8 million, respectively, as the research and development services were delivered. All expenses incurred during 2013 and 2012 related to these services were recorded as research and development expenses.

Research, Development and Patent Expenses

Our research, development and patent 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, development and patent 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, development and patent costs are expensed as incurred.

The following table summarizes our research, development and patent 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 Candidate[1]	Disease/Indication	Year ended December 31, 2013	2012
MN-221	Acute exacerbations of asthma/COPD	$ 216	$ 3,578
MN-166	Neurological disorders including opioid withdrawal, methamphetamine addiction, chronic MOH pain and MS	1,999	661
MN-001	Bronchial asthma	242	171
MN-029	Solid tumors	43	101
MN-001	Interstitial cystitis	5	34
MN-246	Urinary incontinence	3	7
MN-447	Thrombotic disorders		6
MN-305	Generalized anxiety disorder/insomnia	17	2

MN-221	Preterm labor		
MN-462	Thrombotic disorders	1	
Unallocated		840	453
Total research, development and patents		$ 3,366	$ 5,013

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(1) We are pursuing our option to return four compounds, MN-246, MN-305, MN-447 and MN-462, to their respective Licensors in order to maximize our ability to pursue development of MN-166, MN-221, MN-001, and MN-029.

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 MN-166 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 are funding portions of the consortium sponsored trials. For example, we have increased our financial participation in the Secondary and Primary Progressive Ibudilast NeuroNEXT Trial in Multiple Sclerosis (SPRINT-MS) Phase 2 clinical trial of MN-166 for the treatment of progressive MS. 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 2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical companies who seek late stage product candidates, such as MN-221, MN-001 and MN-029, to support further clinical development and product commercialization.

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 2013 and 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 had no outstanding debt and had no interest expense in 2013 or 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

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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 research, development and patent expenses which impacts operating expenses and accrued liabilities, stock-based compensation which impacts operating expenses and goodwill and purchased intangibles. 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.

Research, Development and Patent Expenses

Research, development and patent 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, development and patent expenses have not differed significantly from the actual expenses incurred.

Stock-Based Compensation

We grant options to purchase our common stock to our employees and directors under our 2013 Stock Incentive Plan. Additionally, we have outstanding stock options that were granted under our Amended and Restated 2004 Stock Incentive Plan and 2000 General Stock Incentive Plan. The benefits provided under all 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 our 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 requires 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 in-process research and

development, or IPR&D, of $9.6 million and $4.8 million, respectively, as of December 31, 2013 and 2012.

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At least annually in the fourth quarter, or more frequently if indicators of impairment exists, we complete an impairment test for goodwill and purchased indefinite life intangibles. 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.

Results of Operations

Comparison of the Years ended December 31, 2013 and 2012

Revenues

We recognized approximately $6,003,000 of revenue for the year ending December 31, 2013 of which $6,000,000 was related to a license arrangement acquired in December 2009 and $3,000 was related to research and development services delivered during the year. There were no expenses incurred during 2013 related to the milestone. We recognized approximately $803,000 in revenue for the year ended December 31, 2012 related to research and development services delivered.

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 $2.5 million was initially recorded as deferred revenue. Revenue was recorded in 2012 and 2013 as the research and development services were delivered. All expenses incurred during 2013 and 2012 related to these services were recorded as research and development expenses.

Research, Development and Patent Expenses

Research, development and patent expenses for the year ended December 31, 2013 were $3.4 million, a decrease of $1.6 million compared to $5.0 million for the year ended December 31, 2012. This decrease in research, development and patent expenses primarily related to a decrease of $3.4 million in spending on MN-221 primarily due to the completion of the MN-221-CL-007 clinical trial, partially offset by an increase in costs related to the MN-166 clinical trials of $1.3 million and an increase in unallocated employee costs of $0.4 million.

General and Administrative

General and administrative expenses were $6.7 million for both the years ended December 31, 2013 and 2012.

Other Expense

Other expense for the year ended December 31, 2013 was approximately $25,000, as compared to approximately $30,000 for the year ended December 31, 2012. In 2012 and 2013, 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.

Other Income

Other income for the year ended December 31, 2013 was approximately $21,000, as compared to approximately $25,000 for the year ended December 31, 2012. In 2012 and 2013, other income consisted of interest income on our cash, cash equivalents, and restricted cash balances.

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Liquidity and Capital Resources

We incurred losses of $4.0 million and $11.0 million for the years ended December 31, 2013, and 2012, respectively. At December 31, 2013, from inception, our accumulated deficit was $301.4 million, including $51.6 million of non-cash stock-based compensation charges. We have used net cash of $10.6 million and $11.9 million to fund our operating activities for the years ended December 31, 2013 and 2012, 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 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, or Series B Preferred, at a price of $25.00 per share. In October we received gross proceeds of $7.5 million related to this purchase agreement. The purchase agreement contains 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 Stock 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, however, the consent of holders of a majority of the outstanding Series B Preferred is required for certain actions.

On August 20, 2012 we entered into a common stock purchase agreement with Aspire, pursuant to which we could elect to 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. The common stock purchase agreement with Aspire was terminated on October 17, 2013, and as of such date, we had completed sales to Aspire totaling 2,504,532 shares of common stock at prices ranging from $1.60 to $3.82 per share, generating gross proceeds of $5.4 million.

On May 9, 2013, we entered into a Securities Purchase Agreement with certain accredited investors pursuant to which we agreed to sell to the investors 1,158,730 shares of our common stock at a price of $3.15 per share and warrants to purchase an aggregate of 869,047 shares of our common stock with an exercise price of $3.15 per share (the Private Placement). The Private Placement closed on May 14, 2013. The warrants will expire on May 9, 2018 and may be exercised for cash or, if the current market price of our common stock is greater than the per share exercise price, by surrender of a portion of the warrant in a cashless exercise. The aggregate purchase price for the shares and the warrants sold in the Private Placement was $3.7 million and associated expenses incurred were $0.3 million. In connection with the purchase by one investor of 158,730 shares of our common stock and a warrant to purchase 119,047 shares of our common stock, on May 29, 2013 the investor provided $51,389 additional consideration for the shares and the warrant, and we entered into an amendment to the warrant with the investor to reflect an exercise price of $3.38 per share.

On April 17, 2013, we entered into an at-the-market equity distribution agreement with Macquarie Capital (USA) Inc., or MCUSA, pursuant to which we could sell our common stock through MCUSA from time to time up to an aggregate offering price of $6 million. As of July 25, 2013, we had completed all available sales to MCUSA under this agreement, generating gross and net proceeds of $6.0 million and $5.5 million, respectively, on sales of 1,936,237 shares of common stock at prices ranging from $2.44 to $4.10 per share.

On October 16, 2013, we entered into a second at-the-market equity distribution agreement with MCUSA pursuant to which we may sell our common stock through MCUSA from time to time up to an aggregate offering price of $10

million. Under the terms of this agreement, unless otherwise mutually agreed, no daily sale of an amount of shares of our common stock is to exceed the lower of $50,000 or 10% of the lower of the 5-day or 3-month average daily traded value of our common stock on NASDAQ (unless 10% of the lower of the 5-day or 3-month average daily traded value of our common stock on the JASDAQ Market of the Tokyo Stock Exchange

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(TSE) is greater, in which case the value from the TSE will be used) as of the date of the applicable issuance notice. The price per share is not to be less than the greater of $1.29 or the last available closing price of a share of common stock on NASDAQ. MCUSA agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices and applicable laws, rules and regulations to sell shares of our common stock and is to sell such shares by any method permitted by law deemed to be at the market. We agreed to pay MCUSA an aggregate commission rate of 7.0% of the gross proceeds of any common stock sold under this agreement. MCUSA is under no obligation to purchase shares pursuant to this agreement and there are no assurances that MCUSA will be successful in selling shares. Our proceeds will depend on the number of shares of our common stock sold to MCUSA and the per share purchase price of each transaction. The agreement with MCUSA provides both MCUSA and us the right to terminate the agreement in our sole discretion upon giving five business days written notice. As of December 31, 2013, we have generated gross and net proceeds of $0.27 million and $0.25 million, respectively, under this agreement on sales of 117,500 shares of our common stock at prices ranging from $2.15 to $2.58 per share. Between October 16, 2013 and the date of this report, we have generated gross and net proceeds of $3.5 million and $3.3 million, respectively, on the sale of 1,607,500 shares of our common stock under the at-the-market equity distribution agreement with MCUSA, including gross and net proceeds of $3.2 million and $3.0 million, respectively, on the sale of 1,490,000 shares of our common stock subsequent to December 31, 2013. We expect to sell additional shares under this agreement during 2014.

As of December 31, 2013, we had available cash and cash equivalents of $6.7 million and working capital of $13.9 million. We expect to have approximately $13.8 million in available cash as of March 31, 2014, and we expect to spend approximately $4.3 million from April 1, 2014 through December 31, 2014 to execute our strategic plan and fund operations. As of the date of this report, we believe we have working capital sufficient to fund operations through June 30, 2015. 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 we are 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, 2013 (in thousands):

Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	$ 774	$ 260	$ 514	$	$
Research and development services(1)	$ 2,351	$	$ 2,351		
Total(2)	$ 3,125	$ 260	$ 2,865	$	$

(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, and perform data collection, 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, 2013, 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.

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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. as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, stockholders equity, and cash flows for each of the two years in the period ended December 31, 2013. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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 also 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 provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of MediciNova, Inc., at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2013 in conformity with U.S. generally accepted accounting principles.

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, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) and our report dated March 27, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 27, 2014

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MEDICINOVA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2013	December 31, 2012
Assets:		
Current assets:		
Cash and cash equivalents	$ 6,700,493	$ 4,010,530
Receivable	6,008,553	
Prepaid expense and other current assets	1,673,560	411,592
Total Current Assets	14,382,606	4,422,122
Goodwill	9,600,241	9,600,241
In-process research and development	4,800,000	4,800,000
Investment in joint venture	680,982	667,204
Property and equipment, net	82,414	78,474
Total assets	$ 29,546,243	$ 19,568,041
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 33,894	$ 491,853
Accrued expenses and other current liabilities	240,148	314,652
Accrued compensation and other related expenses	186,393	228,124
Current deferred revenue		3,163
Total current liabilities	460,435	1,037,792
Long-term deferred rent	9,889	
Deferred tax liability	1,956,000	1,956,000
Long-term deferred revenue	1,694,163	1,694,257
Total liabilities	4,120,487	4,688,049
Stockholders equity:		
Preferred stock, $0.01 par value; 3,000,000 shares authorized at December 31, 2013 and 2012; 220,000 shares issued and outstanding at December 31, 2013 and 2012	2,200	2,200
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2013 and 2012; 22,495,443 and 17,407,311 shares issued at December 31, 2013 and 2012, respectively, and 22,495,443 and 17,403,125 shares outstanding at December 31, 2013 and 2012, respectively	22,495	17,407
Additional paid-in capital	326,868,578	312,293,225
Accumulated other comprehensive loss	(80,803)	(67,957)
Treasury stock, at cost; zero shares at December 31, 2013 and 4,186		(44,705)

shares at December 31, 2012		
Accumulated deficit	(301,386,714)	(297,320,178)
Total stockholders equity	25,425,756	14,879,992
Total liabilities and stockholders equity	$ 29,546,243	$ 19,568,041

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years ended December 31,	
	2013	**2012**
Revenues:		
License revenue	$ 6,000,000	$
Research and development service revenue	3,257	802,580
Operating expenses:		
Research, development and patents	3,365,808	5,013,092
General and administrative	6,657,989	6,734,844
Total operating expenses	10,023,797	11,747,936
Operating loss	(4,020,540)	(10,945,356)
Other expense	(24,518)	(29,605)
Other income	20,565	24,791
Loss before income taxes	(4,024,493)	(10,950,170)
Income taxes	(4,035)	(11,144)
Net loss applicable to common shareholders	(4,028,528)	(10,961,314)
Basic and diluted net loss per common share	$ (0.19)	$ (0.66)
Shares used to compute basic and diluted net loss per share	20,697,440	16,522,929
Net loss applicable to common stockholders	$ (4,028,528)	$ (10,961,314)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustments	(12,846)	(11,112)
Comprehensive loss	$ (4,041,374)	$ (10,972,426)

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Preferred stock		Common stock						
	Shares	Amount	Shares	Amount	Additional paid-in capital	Treasury Stock	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders equity
Balance at December 31, 2011	220,000	$ 2,200	16,127,615	$ 16,128	$ 309,998,251	$ (429,015)	$ (56,845)	$ (286,033,173)	$ 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						384,310		(325,691)	58,619
Issuance of common stock under a common stock purchase agreement			1,219,696	1,219	1,347,654				1,348,873
Fair value of warrant issued					100,000				100,000
Net loss								(10,961,314)	(10,961,314)
Foreign currency translation adjustments							(11,112)		(11,112)
Balance at December 31, 2012	220,000	2,200	17,407,311	17,407	312,293,225	(44,705)	(67,957)	(297,320,178)	14,879,992
Employee stock-based compensation					1,216,444				1,216,444
Option exercises			79,462	79	193,872				193,951
Issuance of shares under an employee			26,065	26	49,764	44,705		(38,008)	56,487

tock purchase lan									
ssuance of ommon stock nder ecurities urchase greements			4,860,939	4,861	12,682,264				12,687,125
Warrant xercises			121,666	122	433,009				433,131
Net loss								(4,028,528)	(4,028,528)
Foreign urrency ranslation djustments							(12,846)		(12,846)
Balance at December 31, 2013	220,000	$ 2,200	22,495,443	$ 22,495	$ 326,868,578	$	$ (80,803)	$ (301,386,714)	$ 25,425,756

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,	
	2013	**2012**
Operating activities:		
Net loss	$ (4,028,528)	$ (10,961,314)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	1,216,444	709,650
Amortization of Kissei upfront payment	(3,257)	(802,580)
Depreciation and amorization	100,487	69,528
(Gain) loss on disposal of assets	(4,307)	823
Change in value of equity method investment	(13,778)	
Changes in assets and liabilities:		
Prepaid expenses and other assets	(1,353,334)	266,927
Receivables	(6,008,553)	
Accounts payable, income tax payable, accrued expenses and deferred rent	(509,900)	(776,508)
Accrued compensation and related expenses	(41,730)	(370,964)
Net cash used in operating activities	(10,646,456)	(11,864,438)
Investing activities:		
Acquisitions of property and equipment	(41,554)	(83,378)
Investment in China Joint Venture		(680,000)
Proceeds from sales of property and equipment	4,800	
Net cash used in investing activities	(36,754)	(763,378)
Financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	13,363,997	1,486,603
Net proceeds from issuance of Treasury Stock under ESPP	6,697	58,619
Net cash provided by financing activities	13,370,694	1,545,222
Effects of foreign exchange on cash	2,479	
Net increase / (decrease) in cash and cash equivalents	2,689,963	(11,082,594)
Cash and cash equivalents, beginning of period	4,010,530	15,093,124
Cash and cash equivalents, end of period	$ 6,700,493	$ 4,010,530
Supplemental disclosure of cash flow information:		
Income taxes paid	$ 6,354	$ 10,951

See accompanying notes to consolidated financial statements.

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MEDICINOVA, INC.

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization and Business

The Company was incorporated in the state of Delaware in September 2000 and is a public company. The Company s common stock is listed in both the U.S. and Japan and trades on The NASDAQ Global Market and the JASDAQ Market of the Tokyo Stock Exchange. The Company is a 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. The Company is currently focusing its development activities on MN-166, (Ibudilast) for the treatment of neurological disorders, MN-221(Bedoradrine), for the treatment of acute exacerbations of asthma, MN-001(Tipelukast) for the treatment of NASH (nonalcoholic steatohepatitis), and MN-029 (Denibulin) for the treatment of solid tumors.

In December 2013, the Company received notice that a $6.0 million milestone had been achieved under its assignment of rights agreement with Genzyme Corporation, or Genzyme (see Note 2). Prior to 2013, the Company was in the development stage.

As of December 31, 2013, the Company had available cash and cash equivalents of $6.7 million and working capital of $13.9 million.

Principles of Consolidation

The consolidated financial statements include the accounts of MediciNova, Inc. and its wholly-owned subsidiaries MediciNova (Europe) Limited, MediciNova Japan, Inc. and Avigen, Inc. All intercompany transactions and balances are eliminated in consolidation. MediciNova (Europe) Limited was incorporated under the laws of England in 2006. As of December 31, 2013, there have been no significant transactions related to MediciNova (Europe) Limited. MediciNova Japan, Inc. was incorporated in Japan in 2007. On December 18, 2009, the Company acquired Avigen, Inc., a Delaware corporation (Avigen), and it became a wholly-owned subsidiary.

Segment Reporting

The Company operates in a single industry segment the discovery and development of small molecule therapeutics.

Use of Estimates

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

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, 2013 consisted of money market funds.

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Concentrations and Credit Risk

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

Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, receivables, accounts payable and accrued liabilities, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments.

Goodwill and Purchased Intangibles

The Company records goodwill and other intangible assets based on the fair value of the assets acquired. In determining the fair value of the assets acquired, the Company utilizes extensive accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired. The Company uses the discounted cash flow method to estimate the value of intangible assets acquired.

The Company assesses goodwill and indefinite lived intangible assets for impairment using fair value measurement techniques on an annual basis during the fourth quarter of the year, or more frequently if indicators of impairment exist. The Company periodically re-evaluates the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of its 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 the Company s 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.

Research, Development and Patents

Research and development costs are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, facilities and depreciation, research and development supplies, licenses and outside services. Such research and development costs totaled $2.7 million and $4.5 million for the years ended December 31, 2013 and 2012, respectively.

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. The Company includes all external costs related to the filing of patents on developments in Research, Development and Patents expenses. Such patent-related expenses totaled $0.7 million and $0.5 million for the years ended December 31, 2013 and 2012, respectively.

Stock-Based Compensation

The Company estimates the fair value of stock options using the Black-Scholes option pricing model on the date of grant. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally three to four years; however, certain provisions in the Company s equity compensation plans provide for shorter vesting periods under certain circumstances.

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Net Loss Per Share

The Company computes basic net loss per share using the weight average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under the Company s stock option agreements and warrants. Common share equivalents are excluded from the diluted net loss per share calculation because of their anti-dilutive effect. Due to the net income recorded for the fourth quarter of 2013, the Company considered the impact of using the two-class method for presenting net income per share given the participating nature of the Series B Convertible Preferred Stockholders noting the two-class method was not applicable.

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

	December 31,	
	2013	**2012**
Convertible preferred stock, as converted	2,200,000	2,200,000
Stock options	3,217,043	3,328,981
Warrants	3,761,067	3,128,686
Total	9,178,110	8,657,667

Recent Accounting Pronouncements

In December 2011, the Financial Accounting Standards Board (FASB) issued accounting guidance requiring an entity to disclose information about offsetting arrangements and the impact of these arrangements on the Company s financial position. The guidance is effective for interim and annual periods beginning on or after January 1, 2013. The adoption of this guidance did not have a material impact on the consolidated financial statements.

In February 2013, the Financial Accounting Standards Board issued an accounting standard update to require reclassification adjustments from other comprehensive income to be presented either in the financial statements or in the notes to the financial statements. This accounting standard became effective for the Company beginning in the first quarter of 2013, and its adoption did not have any impact on the financial statements.

In July 2013, the FASB issued guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. The Company intends to adopt this guidance during the first quarter of 2014, and does not believe the adoption of this standard will have a material impact on the consolidated financial statements.

2. Revenue Recognition

Revenue Recognition Policy

Revenues consist of milestone payments and research and development services. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which require substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement. Milestones that do not meet the criteria for accounting under the milestone method because the payments are solely contingent

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upon the performance of a third party are accounted for as contingent revenue. Research and development services are recognized as research costs are incurred over the period the services are performed. For all other revenue the Company recognizes revenues when all four of the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

Genzyme Corporation

In December 2005, Avigen and Genzyme entered into an Assignment Agreement (Genzyme Agreement) in which Genzyme acquired certain gene therapy intellectual property, programs and other related assets from Avigen in exchange for an initial $12.0 million payment, and Avigen could receive additional development milestone payments, sublicensing fees and royalty payments based on the successful development of products by Genzyme utilizing technologies previously developed by us. Avigen was subsequently acquired by the Company in December 2009 along with Avigen s rights and obligations under the Genzyme Agreement. If Genzyme fails to diligently pursue the commercialization or marketing of products using the assigned technology, as specified in the Genzyme Agreement, some of the rights assigned could revert back to the Company at a future date.

The development milestones outlined in the Genzyme Agreement do not meet the definition of a substantive milestone obligation under authoritative guidance on revenue recognition for milestone payments, as Genzyme is responsible for the development of the product and there is no further substantive service effort required by the Company. The Company determined that a non-substantive milestone in the Genzyme Agreement had been earned, and license revenue and a receivable of $6.0 million were recorded as no future performance obligation exists. The Company received payment of the amount receivable in January 2014.

Kissei Pharmaceutical Co., Ltd

In October 2011, the Company 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 the Company is responsible for all costs to be incurred in the performance of these services. Certain of these research and development services were completed in 2013 and 2012, and the remaining services are expected to be delivered and completed after 2013. The Company assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, research and development services. As such, revenue is being recognizing 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 long-term deferred revenue and will be recognized as revenue as the remaining services are performed. Revenue recorded was $3,000 and $0.8 million in 2013 and 2012, respectively.

3. Fair Value Measurements

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

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 near the measurement date; and

Level 3: Unobservable inputs due to little or no market data, which require the reporting entity to develop its own assumptions

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Cash equivalents, including money market accounts of $6.0 million and $3.9 million measured at fair value as of December 31, 2013 and 2012, respectively, are classified within Level 1.

4. Balance Sheet Details

Property and Equipment

Property and equipment, net, consist of the following:

	December 31,	
	2013	**2012**
Leasehold improvements	$ 16,854	$ 170,386
Furniture and equipment	257,945	351,992
Software	238,808	228,397
	513,607	750,775
Less accumulated depreciation and amortization	(431,193)	(672,301)
	$ 82,414	$ 78,474
Depreciation expense	$ 36,655	$ 33,507

The Company uses the straight-line method to record depreciation expense.

Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2013	**2012**
Research and development costs	$ 99,846	$ 152,046
Professional services fees	38,208	68,102
Other	102,094	94,504
	$ 240,148	$ 314,652

5. Related Party Transactions

On October 13, 2011, the Company entered into a services agreement with Kissei to perform two separate studies relating to MN-221 in exchange for $2.5 million paid to the Company in October 2011. The Company is 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, 2013, is included on the balance sheet at December 31, 2013 as deferred revenue and will be recognized as revenue in future periods as the Company performs the remaining services.

On May 9, 2013, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which the Company agreed to sell to the investors 1,158,730 shares of common stock and warrants to purchase an aggregate of 869,047 shares of common stock (the Private Placement). The Private Placement closed on May 14, 2013. The Private Placement included issuance of shares of common stock and a warrant to purchase shares of common stock to Fountain Erika LLC (Fountain Erika), an entity of which Tatsuo Izumi, a member of the Company s board of directors at that time, is a principal. The warrant was subsequently amended on May 29, 2013. Fountain Erika s acquisition of the shares of common stock and a warrant to purchase shares of the Company s common stock was at an at the market price.

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6. Commitments and Contingencies

Lease Commitments

The Company subleases its office space under an operating lease with an initial terms of four years and nine months, expiring in November 2017. Rent expense for the years ended December 31, 2013 and 2012 was $259,690 and $286,762, respectively. The difference between the minimum lease payments and the straight-line amount of total rent expense is recorded as deferred rent. Deferred rent at December 31, 2013 and 2012 was $9,889 and zero, respectively.

As of December 31, 2013, the total estimated future annual minimum lease payments under the Company s non-cancelable building and copier leases for the years ending after December 31, 2013 are as follows:

Years ending December 31:	
2014	$ 260,213
2015	206,441
2016	167,373
2017	139,608
Total minimum payments	$ 773,635

Product Liability

The Company s business exposes it to liability risks from its potential drug products. A successful product liability claim or series of claims brought against the Company could result in the payment of significant amounts of money and divert management s attention from running the business. The Company may not be able to maintain insurance on acceptable terms, or the insurance may not provide adequate protection in the case of a product liability claim. To the extent that product liability insurance, if available, does not cover potential claims, the Company would be required to self-insure the risks associated with such claims. The Company believes it carries reasonably adequate insurance for product liability.

License and Research Agreements

The Company has entered into in-licensing agreements with various pharmaceutical companies. Under the terms of these agreements, the Company has received licenses to research, know-how and technology claimed, in certain patents or patent applications. Under these license agreements, the Company is generally required to make upfront payments and additional payments upon the achievement of milestones and/or royalties on future sales of products 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.

No amounts have been expended under these agreements during the years ended December 31, 2013 or 2012. For products currently in development, future potential milestone payments based on product development are $10.0 million as of December 31, 2013. For all other products, future potential milestone payments related to development milestones and commercialization milestones totaled $84.1 million as of December 31, 2013. There are no minimum royalties required under any of the license agreements. The Company is unable to estimate with certainty the timing on when these milestone payments will occur as these payments are dependent upon the progress of the Company s product development programs.

Legal Proceedings

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not aware of any such proceedings or claims that it believes will have, individually or in aggregate, a material adverse effect on its business, financial condition or results of operations.

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7. Joint Venture

The Company 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 and pursue additional compounds to develop. A sublicense agreement would be required under which Zhejiang Sunmy would license MN-221 from the Company and, as of the date of this filing, no such sublicense agreement has been entered into. In accordance with the joint venture agreement, in March 2012 the Company 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. Zhejiang Sunmy is a variable interest entity for which the Company is not the primary beneficiary as the Company does not have a majority of the board seats and does not have power to direct or significantly influence the actions of the entity. The activities of Zhejiang Sunmy are accounted for under the equity method whereby the Company absorbs any loss or income generated by Zhejiang Sunmy according to the Company s percentage ownership. At December 31, 2013, the investment is reflected as a long-term asset on the Company s consolidated balance sheet which represents the investment in Zhejiang Sunmy, net of the Company s portion of any generated loss or income.

8. Stock-based Compensation

Stock Incentive Plans

In June 2013, the Company adopted the 2013 Equity Incentive Plan, or 2013 Plan, under which the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The 2013 Plan is the successor to the Company s Amended and Restated 2004 Stock Incentive Plan, or 2004 Plan, which was in turn the successor to the Company s 2000 General Stock Incentive Plan, or 2000 Plan (together, the Prior Plans). A total of 2,500,000 shares of common stock were initially reserved for issuance under the 2013 Plan, plus returning shares that may become available from time to time. Returning shares are shares that are subject to outstanding awards granted under the 2004 Plan that expire or terminate prior to exercise or settlement, are forfeited because of the failure to vest, are repurchased, or are withheld to satisfy tax withholding or purchase price obligations in connection with such awards. Although the Company no longer grants equity awards under the Prior Plans, all outstanding stock awards granted under the Prior Plans will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the Prior Plans, as applicable. As of December 31, 2013, 2,612,751 options remain available for future grant under the 2013 Plan.

Stock Options

Options granted under the 2013 Plan and Prior Plans have terms of ten years from the date of grant and generally vest over a three or four year period.

The exercise price of all options granted during the years ended December 31, 2013 and 2012 was equal to the market value of the Company s common stock on the date of grant.

A summary of stock option activity and related information as of December 31, 2013 is as follows:

	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2013	3,328,981	$ 4.92		
Granted	1,608,000	$ 3.42		
Exercised	(79,462)	$ 2.44		
Cancelled	(1,640,476)	$ 3.29		
Outstanding at December 31, 2013	3,217,043	$ 5.06	7.0	$ 144
Exercisable at December 31, 2013	2,196,688	$ 6.09	5.8	$ 144

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The aggregate intrinsic value of options exercised during 2013 and 2012 was $63,704 and $61,620, respectively. During the year ended December 31, 2013, there were 79,462 stock options exercised, from which proceeds of $0.2 million was received. During the years ended December 31, 2013 and 2012, options to purchase 1,608,000 and 750,000 shares of common stock, respectively, were granted.

Employee Stock Purchase Plan

Under the Company s 2007 Employee Stock Purchase Plan, or ESPP, 300,000 shares of common stock were originally reserved for issuance. In addition, the shares reserved automatically increase each year by a number equal to the lesser of: (i) 15,000 shares; (ii) 1% of the outstanding shares of 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 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.

For the year ended December 31, 2013, an aggregate of 30,251 shares were issued under the ESPP, leaving 234,327 shares available for future issuance.

Compensation Expense

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,	
	2013	2012
Stock Options		
Risk-free interest rate	1.02%	0.67%
Expected volatility of common stock	84.80%	83.26%
Dividend yield	0.00%	0.00%
Expected option term (in years)	5.68	5.31

The estimated fair value of employee stock purchase rights under the Company s ESPP 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,	
	2013	2012
Employee Stock Purchase Plan		
Risk-free interest rate	0.15%	0.30%
Expected volatility of common stock	89.66%	79.50%
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 employee stock options. The expected volatility is based on the historical volatility of the Company s common stock.

The Company has not paid nor does the Company anticipate paying dividends on its 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 the historical stock option exercise experience does not provide a reasonable basis to estimate the expected term.

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The weighted-average fair value of each stock option granted during the years ended December 31, 2013 and 2012, estimated as of the grant date using the Black-Scholes option valuation model, was $2.37 per option and $1.33 per option, respectively.

Stock-based compensation expense for stock option awards and ESPP shares are reflected in total operating expense for each respective year. For the years ended December 31, 2013 and 2012, stock-based compensation expense related to stock options and the ESPP was $1.2 million and $0.7 million, respectively, and was recorded as a component of general and administrative expense ($0.8 million and $0.4 million, respectively) and research and development expense ($0.4 million and $0.3 million, respectively).

As of December 31, 2013, there was $2.0 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 1.7 years, on a straight-line basis.

9. Stockholders Equity

Kissei Stock Purchase

In October 2011, pursuant to a stock purchase agreement by and between the Company and Kissei Pharmaceutical Co., Ltd., or Kissei, Kissei purchased (i) an aggregate of 800,000 shares of the Company s common stock, par value $0.001 per share at a price of $2.50 per share, and (ii) 220,000 shares of the Company s Series B Convertible Preferred Stock, par value $0.01 per share, at a price of $25.00 per share. In October 2011 the Company received gross proceeds of $7.5 million related to this purchase agreement. The purchase agreement contains a standstill agreement from Kissei that terminates if Kissei beneficially owns less than three percent of the Company s outstanding voting stock. Each share of the Series B Preferred Stock 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, however, the consent of holders of a majority of the outstanding Series B Preferred is required for certain actions.

Common Stock Purchase Agreement

On August 20, 2012, the Company entered into a common stock purchase agreement with Aspire pursuant to which the Company could elect sell to Aspire, and Aspire would be obligated to purchase, up to an aggregate of $20 million of common stock over the two-year term of the agreement including $1.0 million in common stock purchased by Aspire in connection with execution of the agreement. The common stock purchase agreement with Aspire was terminated on October 17, 2013, and as of such date, the Company had completed sales to Aspire totaling 2,504,532 shares of common stock at prices ranging from $1.60 to $3.82 per share, generating gross proceeds of $5.4 million.

At-The-Market Issuance Sales Agreements

On April 17, 2013, the Company entered into an at-the-market equity distribution agreement with Macquarie Capital (USA) Inc., or MCUSA, pursuant to which the Company could sell common stock through MCUSA from time to time up to an aggregate offering price of $6.0 million. As of July 25, 2013, the Company had completed all available sales to MCUSA under this agreement, generating gross and net proceeds of $6.0 million and $5.5 million, respectively, on sales of 1,936,237 shares of common stock at prices ranging from $2.44 to $4.10 per share.

On October 16, 2013, the Company entered into a second at-the-market equity distribution agreement with MCUSA pursuant to which the Company may sell common stock through MCUSA from time to time up to an aggregate

offering price of $10.0 million. Under the terms of this agreement, unless otherwise mutually agreed,

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no daily sale of an amount of shares of the Company s common stock is to exceed the lower of $50,000 or 10% of the lower of the 5-day or 3-month average daily traded value of the Company s common stock on NASDAQ (unless 10% of the lower of the 5-day or 3-month average daily traded value of the Company s common stock on the JASDAQ Market of the Tokyo Stock Exchange (TSE) is greater, in which case the value from the TSE will be used) as of the date of the applicable issuance notice. The price per share is not to be less than the greater of $1.29 or the last available closing price of a share of the Company s common stock on NASDAQ. MCUSA agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices and applicable laws, rules and regulations to sell shares of the Company s common stock and is to sell such shares by any method permitted by law deemed to be at the market. The Company agreed to pay MCUSA an aggregate commission rate of 7.0% of the gross proceeds of any common stock sold under this agreement. MCUSA is under no obligation to purchase shares pursuant to this agreement and there are no assurances that MCUSA will be successful in selling shares. Proceeds from sales of common stock will depend on the number of shares of common stock sold to MCUSA and the per share purchase price of each transaction. The agreement with MCUSA provides both MCUSA and the Company the right to terminate the agreement in our their discretion upon giving five business days written notice. As of December 31, 2013, the Company has generated gross and net proceeds of $0.27 million and $0.25 million, respectively, under this agreement on sales of 117,500 shares of the Company s common stock at prices ranging from $2.15 to $2.58 per share. Between October 16, 2013 and the date of this report, the Company has generated gross and net proceeds of $3.5 million and $3.3 million, respectively, on the sale of 1,607,500 shares of the Company s common stock under the at-the-market equity distribution agreement with MCUSA, including gross and net proceeds of $3.2 million and $3.0 million, respectively, on the sale of 1,490,000 shares of common stock subsequent to December 31, 2013.

Warrant for Services

On August 22, 2012, the Company issued a warrant in exchange for investor relations services to purchase up to 130,000 of common stock of the Company at a price of $1.88 per share, the closing price of the Company s common stock on that date. The warrant contained provisions whereby it became exercisable for a specified number of shares of common stock as a result of the stock achieving certain share price targets within a 15-month period beginning on August 22, 2012. As of December 31, 2013, the warrant was exercisable for 15,000 shares, and no further shares will vest. The warrant expires five years from the date of issuance. The warrant was valued at its fair value of approximately $100,000 on August 22, 2012, is classified as equity and was amortized over the one-year period beginning August 22, 2012.

Securities Purchase Agreement

On May 9, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors (the Purchase Agreement) pursuant to which the Company agreed to sell to the investors 1,158,730 shares of the Company s common stock at a price of $3.15 per share and warrants to purchase an aggregate of 869,047 shares of the Company s common stock with an exercise price of $3.15 per share (the Private Placement). The Private Placement closed on May 14, 2013. The warrants will expire on May 9, 2018 and may be exercised for cash or, if the current market price of common stock of the Company is greater than the per share exercise price, by surrender of a portion of the warrant in a cashless exercise. The aggregate purchase price for the shares and the warrants sold in the Private Placement was $3.7 million and associated expenses incurred were $0.3 million.

In connection with the purchase by one investor of 158,730 shares of common stock and a warrant to purchase 119,047 shares of common stock, on May 29, 2013 the investor provided $51,389 additional consideration for the shares and the warrant, and the Company entered into an amendment to the warrant with the investor to reflect an exercise price of $3.38 per share.

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The net proceeds for the shares and the warrants sold in the Private Placement of $3.4 million were allocated based on the relative fair value of each instrument. The fair value of the shares was based on the closing price of the Company s common stock on May 9, 2013, and the fair value of the warrants based on a Black-Scholes valuation model.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2013:

Common Stock reserved for issuance upon conversion of Series B Convertible Preferred Stock	2,200,000
Common Stock reserved for issuance under the ESPP	234,327
Common stock reserved for issuance upon exercise of warrants outstanding	3,761,067
Common stock reserved for issuance upon exercise of options outstanding (under the 2000 Plan, 2004 Plan and 2013 Plan)	3,217,043
Common stock reserved for future equity awards (under the 2013 Plan)	2,612,751
	12,025,188

Treasury Stock

During 2013 the Company determined that it had not been accounting for the resale of treasury stock to employees through the Company s ESSP correctly. The Company historically recorded the cash proceeds from the resale of treasury stock as a reduction to treasury stock. The Company was not properly accounting for the difference between the price per share the treasury stock was resold for and the price per share originally paid by the Company to purchase the shares. Based on a quantitative and qualitative analysis, the Company determined the error to be immaterial to the consolidated balance sheets and the consolidated statements of stockholders equity and the error did not impact the consolidated statements of operations or cash flows. To correct this error, the Company has decreased the opening balance of treasury stock and increased the balance of the accumulated deficit at December 31, 2011 in the statement of stockholders equity by $760,690 and corrected the resale activity in 2012 resulting in a decrease in treasury stock and an increase in accumulated deficit of $325,691 at December 31, 2012.

10. Income Taxes

A reconciliation of income (loss) before income taxes for domestic and foreign locations for the years ended December 31, 2013 and 2012 is as follows:

	Year Ended December 31,	
	2013	**2012**
United States	$ (4,048,522)	$ (10,986,343)
Foreign	24,029	36,173
Loss before income taxes	$ (4,024,493)	$ (10,950,170)

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A reconciliation of income tax expense for the years ended December 31, 2013 and 2012 is as follows:

	Year Ended December 31,	
Current:	2013	2012
Federal	$	$
State		
Foreign	4,035	11,144
Total current income tax expense	4,035	11,144
Deferred:		
Federal		
State		
Foreign		
Total deferred income tax expense		
Total income tax expense	$ 4,035	$ 11,144

The significant components of deferred income taxes at December 31, 2013 and 2012 are as follows:

	Year Ended December 31,	
Deferred tax assets:	2013	2012
Net operating loss carryforwards	$ 84,537,000	$ 83,092,000
Capitalized licenses	1,576,000	1,822,000
Research tax credits	7,448,000	7,145,000
Stock options	1,763,000	1,861,000
Other, net	1,454,000	1,554,000
Total deferred tax assets	96,778,000	95,474,000
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	94,822,000	93,518,000
Valuation allowance	(96,778,000)	(95,474,000)
Net deferred tax liability	$ (1,956,000)	$ (1,956,000)

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates 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, 2013, the Company has federal and California net operating losses, or NOL, carryforwards of approximately $207.7 million and $206.6 million, respectively. The federal NOL carryforwards begin to expire in 2020, and the California NOL carryforwards continue to expire in 2014. The Company expects that $108.2 million in California NOL carryforwards will expire by 2017 and the remaining $98.4 million in California NOL carryforwards will begin to expire in 2028. At December 31, 2013, the Company also had federal and California research tax credit carryforwards of approximately $6.5 million and $1.5 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. At December 31, 2013, the Company has both federal and California capital loss carryovers of approximately $1.7 million. The federal and California capital loss carryovers expire in 2015.

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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. The Company has not completed an IRC Section 382/383 analysis since 2011 regarding the limitation of net operating loss and research and development credit carryforwards. There is a risk that additional changes in ownership have occurred since the completion of the Company s analysis, which was through December 2011. If a change in ownership were to have occurred, additional NOL and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, related to the Company s operations in the U.S. will not impact the Company s effective tax rate.

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

	Year Ended December 31,	
	2013	2012
Federal statutory income tax rate	35.0%	35.0%
State income taxes, net of federal benefit	3.6	5.8
Tax credits	7.5	
Change in valuation allowance	(63.7)	(28.3)
Permanent differences	(0.3)	(0.1)
Stock compensation	20.0	(12.6)
Other	(2.2)	0.1
Provision for income taxes	(0.1)%	(0.1)%

The Company files income tax returns in the United States, California and foreign jurisdictions. Due to the Company s losses incurred, the Company is essentially subject to income tax examination by tax authorities from inception to date. The Company s policy is to recognize interest expense and penalties related to income tax matters as tax expense. At December 31, 2013, there are no unrecognized tax benefits, and there are not significant accruals for interest related to unrecognized tax benefits or tax penalties.

In preparing the 2013 financial statement footnote disclosures, the Company determined that the December 31, 2012 deferred tax asset for stock based compensation included an error and was understated by $1.3 million, and the valuation allowance was understated by the same amount. Also during 2013, the Company determined that it did not record a deferred tax asset related to the Kissei deferred revenue as of December 31, 2012. As a result, the December 31, 2012 other deferred tax asset was understated by $0.7 million, and the deferred tax asset for net operating losses was overstated by the same amount. Accordingly, the 2012 amounts have been changed for the purposes of presentation within the above table. These changes in the disclosed deferred tax assets and valuation allowance did not impact the consolidated balance sheets or the consolidated statements of stockholders equity, operations, or cash flows as the Company is in a net loss position with a full valuation allowance on their deferred tax assets.

11. Employee Savings Plan

The Company has 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 $87,710 and $96,415 for the years ended December 31, 2013 and 2012.

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12. Quarterly Financial Data (Unaudited)

The following table presents certain quarterly financial data for eight consecutive quarters ended December 31, 2013. The unaudited quarterly information has been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, includes all adjustments, necessary for a fair presentation of this data (in thousands, except per share data). As the shares of Series B Convertible Preferred Stock participate equally with the common shares upon payment of dividends, the two-class method is not applicable in the calculation of earnings per share for the fourth quarter of 2013 when net income was recorded.

	Year Ended December 31, 2013			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Revenues	$ 3	$	$	$ 6,000
Total operating expenses	2,421	2,788	2,242	2,573
Net income (loss)	(2,419)	(2,786)	(2,237)	3,413
Net income (loss) applicable to common stockholders	(2,419)	(2,786)	(2,237)	3,413
Basic net income (loss) per common share(1)	(0.14)	(0.14)	(0.10)	0.15
Diluted net income (loss) per common share(1)	(0.14)	(0.14)	(0.10)	0.14

	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)

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

13. Subsequent Events

On January 10, 2014, the Company received a payment of $6.0 million from Genzyme in relation to the development milestone earned in December 2013 as described in Note 2 of the financial statements.

On March 10, 2014, the Company announced that it entered into an agreement with Research Foundation for Mental Hygiene, Inc. to supply Ibudilast (MN-166) for their clinical study of Ibudilast in marijuana-dependent subjects. The study will be led by investigators from Columbia University.

Subsequent to December 31, 2013 through the date of this report, the Company generated gross and net proceeds of $3.2 million and $3.0 million, respectively, on the sale of 1,490,000 shares of common stock under the second at-the-market equity distribution agreement with MCUSA.

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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 Acting 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 Acting 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, 2013, our disclosure controls and procedures were effective.

Our management, including our Chief Executive Officer and Acting 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.

Changes in Internal Control over Financial Reporting

There was no change in internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) (COSO) in Internal Control Integrated Framework. Our management has concluded that, as of December 31, 2013, our internal control over financial reporting was effective based on these criteria.

Ernst & Young LLP, an independent registered public accounting firm, has audited our consolidated financial statements included in this Annual Report on Form 10-K and has issued an attestation report, included herein, on the effectiveness of our internal control over financial reporting as of December 31, 2013.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of

MediciNova, Inc.

We have audited MediciNova, Inc. s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (the COSO criteria). MediciNova, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

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

In our opinion, MediciNova, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of MediciNova, Inc. as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, stockholders equity and cash flows for each of the two years in the period ended December 31, 2013 of MediciNova, Inc. and our report dated March 27, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 27, 2014

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Item 9B. Other Information

Our stockholders approved the 2013 Equity Incentive Plan, or 2013 Plan, at the June 14, 2013 annual meeting. The terms of the 2013 Plan were described in our proxy statement on Schedule 14A that was filed with the SEC on April 29, 2013 and provided to stockholders. While the proxy statement correctly described the number of shares of common stock available for issuance as the sum of (1) 2,500,000 shares and (2) any Returning Shares (as defined), the copy of the 2013 Plan that was attached as an appendix to the proxy statement contained a scrivener s error and incorrectly stated the number of shares as 2,000,000. Additionally, while the Form 8-K filed with the SEC on June 17, 2013 to disclose the annual meeting voting results correctly described the number of shares of common stock available for issuance under the 2013 Plan as 2,500,000 shares plus Returning Shares, the copy of the 2013 Plan that was filed as Exhibit 99.1 to the Form 8-K contained the same scrivener s error and incorrectly stated the number of shares as 2,000,000. A corrected copy of the 2013 Plan is filed as an exhibit to this Annual Report on Form 10-K.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item and not set forth below will be contained in the sections titled Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance, Corporate Governance, Meetings and Committees of the Board, and Executive Officers in our definitive proxy statement for our 2014 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the conclusion of our fiscal year ended December 31, 2013 and is incorporated in this Annual Report on Form 10-K by reference.

We have adopted a Code of Ethics for Senior Officers, or Code of Ethics, that applies to our Chief Executive Officer, President, Acting Chief Financial Officer and key management employees (including other senior financial officers) who have been identified by our Board of Directors. We have also adopted a Code of Business Conduct that applies to all of our officers, directors, employees, consultants and representatives. Each of the Code of Ethics and Code of Business Conduct are available on our website at *www.medicinova.com* under the Corporate Governance section of our Investor Relations page. We will promptly post on our website (i) any waiver, if and when granted, to any provision of the Code of Ethics or Code of Business Conduct (for executive officers or directors) and (ii) any amendment to the Code of Ethics or Code of Business Conduct.

Item 11. Executive Compensation

The information required by this item will be contained in the section titled Executive Compensation in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Certain of the information required by this item will be contained in section titled Security Ownership of Certain Beneficial Owners and Management the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

The following table provides information as of December 31, 2013 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Stockholders(1)	3,215,043	$ 5.06	2,847,078
Equity Compensation Plans Not Approved by Stockholders(2)	2,000	$ 10.00	
Total	3,217,043	$ 5.06	2,847,078

(1) Consists of the Amended and Restated 2004 Stock Incentive Plan, the 2013 Equity Incentive Plan and the 2007 Employee Stock Purchase Plan, or ESPP. Under the ESPP, the shares reserved 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.

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(2) Consists solely of the MediciNova, Inc. 2000 General Stock Incentive Plan, or 2000 Plan, which was terminated upon the completion of our initial public offering on February 8, 2005, and no additional shares of common stock are available for the grant of new awards. Under the 2000 Plan, incentive stock options to purchase shares of our common stock could be granted to our employees, and nonstatutory stock options and other stock-based awards could be granted to employees, directors and consultants. Options granted under the 2000 Plan have terms of ten years from the date of grant and generally vested over three or four-year periods.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be contained in the sections titled Certain Relationships and Related Transactions and Corporate Governance in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in the section titled Ratification of Appointment of Independent Registered Public Accounting Firm in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) *Documents filed as part of this report.*

1. *Financial Statements.* The following financial statements of MediciNova, Inc. and Report of Ernst & Young LLP, an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

2. *Financial Statement Schedules*. None.

3. *Exhibits*.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 of the Registrant s Quarterly Report on Form 10-Q filed August 9, 2012).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 of the Registrant s Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).
3.3	Certificate of Designation, Preferences and Rights of the Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant s Current Report on Form 8-K filed September 27, 2011).
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant s Annual Report on Form 10-K (File No. 001-33185) filed February 15, 2007).
4.2	Amended and Restated Registration Rights Agreement, dated September 2, 2004, by and among the Registrant, its founders and the investors named therein (incorporated by reference to Exhibit 4.2 of the Registrant s Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).
4.3	Warrant, dated May 10, 2010, issued to Oxford Finance Corporation (incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K filed May 14, 2010).
4.4	Form of Warrant to Purchase Common Stock, dated March 29, 2011, issued to Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 4.1 of the Registrants Current Report 8-K filed March 24, 2011).

4.5	Warrant, dated August 22, 2012, issued to Redington, Inc., as amended (incorporated by reference to Exhibit 4.8 of the Registrant s Quarterly Report on Form 10-Q filed November 8, 2012).
4.6	Registration Rights Agreement, dated August 22, 2012, between the Registrant and Redington, Inc. (incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K filed August 22, 2012).

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Exhibit Number	Description
4.7	Form of Warrant to Purchase Common Stock, dated May 14, 2013, issued to Samurai Investments San Diego LLC and Fountain Erika LLC (incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K filed May 10, 2013).
4.8	Amendment No. 1 to Warrant, dated May 29, 2013, entered into between the Registrant and Fountain Erika LLC.
10.1*	2000 General Stock Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 of the Registrant s Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).
10.2*	Amended and Restated 2004 Stock Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.2 of the Registrant s Annual Report on Form 10-K filed March 29, 2012).
10.3*	Form of Indemnity Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.3 of the Registrant s Annual Report on Form 10-K filed March 28, 2013).
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10.8	License Agreement, dated October 22, 2004, between the Registrant and Kyorin Pharmaceutical Co., Ltd., (incorporated by reference to Exhibit 10.18 of the Registrant s Registration Statement on Form S-1, as amended (File No. 333-119433), originally filed on October 1, 2004).
10.9	License Agreement, dated December 8, 2004, between the Registrant and Mitsubishi Tanabe Pharma Corporation (incorporated by reference to Exhibit 10.21 of the Registrant s Registration Statement on Form S-1, as amended (File No. 333-119433), originally filed on October 1, 2004).
10.10*	Employment Agreement, dated September 1, 2006, between the Registrant and Masatsune Okajima (incorporated by reference to Exhibit 10.12 of the Registrant s Annual Report on Form 10-K (File No. 001-33185) filed February 15, 2007).
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10.13*	

Executive Employment Agreement, dated April 1, 2007, between the Registrant and Yuichi Iwaki, M.D., Ph.D. (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 001-33185) filed April 4, 2007).

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Exhibit Number	Description
10.14*	2007 Employee Stock Purchase Plan of the Registrant (incorporated by reference to Appendix A of the Registrant s Definitive Proxy Statement on Schedule 14A (File No. 001-33185) filed March 13, 2007).
10.15	Development and Supply Agreement, dated as of March 26, 2009, between the Registrant and Hospira Worldwide, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed March 30, 2009).
10.16	Assignment Agreement, dated December 19, 2005, between Genzyme Corporation and Avigen, Inc. (incorporated by reference to Exhibit 10.58 of Avigen, Inc. s Annual Report on Form 10-K (File No. 000-28272) filed March 16, 2006).
10.17	Asset Purchase Agreement, dated December 17, 2008, between Baxter Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. and Avigen, Inc. (incorporated by reference to Exhibit 2.2 of Avigen, Inc. s Annual Report on Form 10-K filed March 16, 2009).
10.18*	Form of Amendment to Employment Agreement, dated December 31, 2011, between the Registrant and Yuichi Iwaki, M.D., Ph.D. (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed January 4, 2011).
10.19	Joint Venture Agreement, dated June 29, 2011, among the Registrant, Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. (incorporated by reference to Exhibit 10.44 of the Registrant s Current Report on Form 10-Q filed August 15, 2011).
10.20	Stock Purchase Agreement, dated September 26, 2011, between the Registrant and Kissei Pharmaceutical Co. Ltd., (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed September 27, 2011).
10.21	Sublease Agreement, dated February 27, 2013, between the Registrant and Denali Advisors LLC (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed March 1, 2013).
10.22	Securities Purchase Agreement, dated May 9, 2013, between the Registrant and Samurai Investments San Diego LLC and Fountain Erika LLC (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed May 10, 2013).
10.23*	2013 Equity Incentive Plan of the Registrant.
10.24	Equity Distribution Agreement, dated October 16, 2013, between the Registrant and Macquarie Capital (USA) Inc. (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed October 16, 2013).
10.25*	Form of Notice of Stock Option Grant and Stock Option Agreement for awards pursuant to the 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 of the Registrant s Quarterly Report on Form 10-Q filed November 7, 2013).
21.1	List of subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant s Annual Report on Form 10-K filed March 24, 2010).
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Powers of Attorney (see signature page).
31.1	

Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Act of 1933.

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Exhibit Number	Description
32.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial statements from MediciNova, Inc. on Form 10-K for year ended December 31, 2013 formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Stockholders Equity and Comprehensive Loss; (iv) Consolidated Statements of Cash Flows; and (v) the notes to the consolidated financial statements.

Portions of this Exhibit have been omitted pursuant to a grant of confidential treatment by the SEC.

* Indicates management contract or compensatory plan.

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SIGNATURES

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

MEDICINOVA, INC.
A Delaware Corporation

Date: March 27, 2014

By: /s/ Yuichi Iwaki
Yuichi Iwaki, M.D., Ph.D.
President & Chief Executive Officer

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Yuichi Iwaki Yuichi Iwaki, M.D., Ph.D.	Director, President, Chief Executive Officer and Acting Chief Financial Officer *(Principal executive officer, principal financial and accounting officer)*	March 27, 2014
/s/ Jeff Himawan Jeff Himawan, Ph.D.	Director	March 27, 2014
/s/ Yutaka Kobayashi Yutaka Kobayashi	Director	March 27, 2014
/s/ Kousuke Nakata Kousuke Nakata	Director	March 27, 2014
/s/ David O Toole David O Toole	Director	March 27, 2014

/s/ Hiroaki Shigeta	Director	March 27, 2014
Hiroaki Shigeta		

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INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 of the Registrant s Quarterly Report on Form 10-Q filed August 9, 2012).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 of the Registrant s Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).
3.3	Certificate of Designation, Preferences and Rights of the Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant s Current Report on Form 8-K filed September 27, 2011).
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant s Annual Report on Form 10-K (File No. 001-33185) filed February 15, 2007).
4.2	Amended and Restated Registration Rights Agreement, dated September 2, 2004, by and among the Registrant, its founders and the investors named therein (incorporated by reference to Exhibit 4.2 of the Registrant s Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).
4.3	Warrant, dated May 10, 2010, issued to Oxford Finance Corporation (incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K filed May 14, 2010).
4.4	Form of Warrant to Purchase Common Stock, dated March 29, 2011, issued to Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 4.1 of the Registrants Current Report 8-K filed March 24, 2011).
4.5	Warrant, dated August 22, 2012, issued to Redington, Inc., as amended (incorporated by reference to Exhibit 4.8 of the Registrant s Quarterly Report on Form 10-Q filed November 8, 2012).
4.6	Registration Rights Agreement, dated August 22, 2012, between the Registrant and Redington, Inc. (incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K filed August 22, 2012).
4.7	Form of Warrant to Purchase Common Stock, dated May 14, 2013, issued to Samurai Investments San Diego LLC and Fountain Erika LLC (incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K filed May 10, 2013).
4.8	Amendment No. 1 to Warrant, dated May 29, 2013, entered into between the Registrant and Fountain Erika LLC.
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