

MEDICINOVA INC  
Form 10-K  
March 31, 2011  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**Form 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2010**

**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**  
(State or Other Jurisdiction of Incorporation

**33-0927979**  
(I.R.S. Employer Identification No.)

or Organization)

**4350 La Jolla Village Drive, Suite 950, San Diego, CA**  
(Address of Principal Executive Offices)

**92122**  
(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**  
Common Stock, par value \$0.001 per share

**Name of Each Exchange on Which Registered**  
The NASDAQ Stock Market LLC

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

### Series A Participating Preferred Stock Purchase Rights

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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.

## Edgar Filing: MEDICINOVA INC - Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$50,126,446 based on the closing price of the registrant's common stock on the Nasdaq Global Market of \$4.75 per share on June 30, 2010. 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 30, 2011 was 15,247,104.

### **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 2010 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. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2010.

**Table of Contents**

**MEDICINOVA, INC.**

**FORM 10-K ANNUAL REPORT**

**For the Fiscal Year Ended December 31, 2010**

**Table of Contents**

	<b>Page</b>
<b>PART I</b>	
Item 1 <u>Business</u>	1
Item 1A <u>Risk Factors</u>	33
Item 1B <u>Unresolved Staff Comments</u>	57
Item 2 <u>Properties</u>	57
Item 3 <u>Legal Proceedings</u>	57
Item 4 <u>Reserved</u>	57
<b>PART II</b>	
Item 5 <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	58
Item 6 <u>Selected Financial Data</u>	62
Item 7 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	64
Item 7A <u>Quantitative and Qualitative Disclosures About Market Risk</u>	78
Item 8 <u>Financial Statements and Supplementary Data</u>	80
Item 9 <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	121
Item 9A(T) <u>Controls and Procedures</u>	121
Item 9B <u>Other Information</u>	123
<b>PART III</b>	
Item 10 <u>Directors, Executive Officers and Corporate Governance</u>	124
Item 11 <u>Executive Compensation</u>	124
Item 12 <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	124
Item 13 <u>Certain Relationships and Related Transactions, and Director Independence</u>	125
Item 14 <u>Principal Accounting Fees and Services</u>	125
<b>PART IV</b>	
Item 15 <u>Exhibits, Financial Statement Schedules</u>	126
<b><u>Signatures</u></b>	130

The MediciNova logo is a registered trademark of MediciNova, Inc. All other product and company names are registered trademarks or trademarks of their respective companies.

---

**Table of Contents****PART I****Forward-Looking Statements**

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

**Item 1. Business****Overview**

We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet medical need with a specific focus on the U.S. market. Through strategic alliances, primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope. In December 2009 we acquired Avigen Inc., or Avigen, a biopharmaceutical company that focused on identifying and developing differentiated products to treat patients with serious disorders, whose potential product candidate was AV411, a macrophage migration inhibitory factor and a glial attenuator for central nervous system, or CNS, disorders, such as neuropathic pain, opioid withdrawal and methamphetamine addiction.

**Table of Contents**

We believe that our ability to gain access to and acquire potentially high-value product candidates from Japanese and European pharmaceutical companies is largely attributable to the established relationships and broad industry experience of our management team. In particular, we believe our relationships with Japanese pharmaceutical companies and their executives provide us with a competitive advantage in opportunistically sourcing product candidates from Japanese pharmaceutical companies at attractive terms. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei Pharmaceutical Co., Ltd., or Kissei Pharmaceutical, Kyorin Pharmaceutical Co., Ltd., or Kyorin Pharmaceutical, Mitsubishi Tanabe Pharma Corporation and Meiji Seika Kaisha, Ltd., or Meiji Seika Kaisha, in Japan and Angiogene Pharmaceuticals, Ltd., or Angiogene Pharmaceuticals, in the United Kingdom, pursuant to which we have obtained rights to develop and commercialize our current product candidates.

Since our inception, we have acquired licenses to eight compounds for the development of ten product candidates in what we believe are large and underserved markets. Our development pipeline consists of eight product development programs which have been in clinical development for the treatment of asthma, acute exacerbations of asthma, diabetic neuropathic pain, opioid addiction, multiple sclerosis, or MS, other CNS disorders, interstitial cystitis, or IC, solid tumor cancers, Generalized Anxiety Disorder/insomnia, preterm labor and urinary incontinence. Our two earlier stage product development programs have been in preclinical development for the treatment of thrombotic disorders. In addition, we have expanded the development program for one of our prioritized product candidates, MN-221, to evaluate MN-221 for the treatment of Chronic Obstructive Pulmonary Disease, or COPD, exacerbations.

At present, we are focusing our resources on the following prioritized product development programs:

**Product**

<b>Candidate</b>	<b>Disease/Indication</b>	<b>Phase of Development</b>	<b>Licensors</b>	<b>Licensed Territory</b>
MN-221	Acute exacerbations of asthma and COPD exacerbations	Phase II clinical trial in emergency rooms at planned escalating doses in patients with severe, acute exacerbations of asthma completed in Q2, 2009	Kissei  Pharmaceutical	Worldwide, except Japan*
		Phase II clinical trial in emergency rooms to evaluate safety and efficacy in patients with severe, acute exacerbations of asthma initiated in Q1, 2009 and ongoing; expected to be completed in the second half of 2011		
		Phase Ib clinical trial to evaluate the safety and efficacy in patients with stable, moderate to severe COPD completed in Q1, 2010		

**Table of Contents**

<p>MN-166/ CNS disorders***</p> <p>AV411**</p>	<p>Phase II clinical trial completed in Q2, 2008.</p> <p>Prototype once-per-day oral formulation developed for future clinical trials</p> <p>Phase Ib/IIa clinical trial in diabetic neuropathic pain completed in Q4, 2007</p> <p>Phase Ib National Institute on Drug Abuse, or NIDA, funded-clinical trial in methamphetamine-dependent volunteers initiated in Q4, 2010</p> <p>Phase Ib/IIa NIDA-funded clinical trial to evaluate safety and efficacy in heroin-dependent volunteers completed in Q4, 2010</p>	<p>Kyorin Pharmaceutical (MN-166)</p>	<p>Worldwide, except Japan, China, Taiwan and South Korea (MN-166)</p>
--	--	---	--

\* Pursuant to our license agreement with Kissei Pharmaceutical, Kissei Pharmaceutical has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties. On March 3, 2011, we executed a joint venture agreement with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd., which provides for the establishment of a joint venture company to develop and commercialize MN-221 in China.

\*\* MN-166 and AV411 are both ibudilast, an orally available, small molecule therapeutic. With the acquisition of AV411, we are integrating the two ibudilast-based product development programs and pursuing discussions with potential partners to secure a strategic collaboration to advance clinical development of the combined development programs. Our rights to MN-166 licensed from Kyorin Pharmaceutical exclude ophthalmic solution formulations.

AV411 has advanced through multiple Phase I and IIa clinical trials in healthy volunteers and patients with neuropathic pain.

\*\*\* Other CNS disorders encompass MS, neuropathic pain, opioid addiction and withdrawal and methamphetamine addiction.

Upon completion of proof-of-concept Phase II clinical trials, we intend to enter into strategic alliances with leading pharmaceutical or biotech companies to support further clinical development, and plan to keep certain commercialization rights in select markets. In addition, we continue to limit development activities for the balance of our existing product candidates in order to focus on our prioritized programs. For each of these remaining product candidates, we plan to conduct development activities only to the extent deemed necessary to maintain our license rights or maximize its value while pursuing a variety of initiatives to monetize such product candidate on appropriate terms. We cannot assure you that we will be successful in monetizing these product candidates on attractive terms, or at all. See *Risk Factors*.





**Table of Contents**

Our remaining eight product development programs consist of:

<b>Product</b>				
<b>Candidate</b>	<b>Disease/Indication</b>	<b>Phase of Development</b>	<b>Licensor</b>	<b>Licensed Territory</b>
MN-001*	Bronchial asthma	Phase III clinical trial initiated in Q4, 2006 and terminated in Q2, 2007; Once-per-day oral dosing formulation prototypes developed	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan and South Korea
MN-001	Interstitial cystitis	Phase II clinical trial completed in Q1, 2007	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan and South Korea
MN-029	Solid tumors	Phase I clinical trial completed in Q2, 2006; Second Phase I clinical trial completed in Q4, 2007	Angiogene Pharmaceuticals	Worldwide
MN-305	Generalized Anxiety Disorder/ Insomnia	Phase II clinical trial completed in Generalized Anxiety Disorder in Q2, 2006 ; Phase II clinical trial in insomnia completed in Q4, 2007	Mitsubishi Tanabe Pharma Corporation	Worldwide, except Japan and certain other countries in Asia
MN-221	Preterm labor	Phase I clinical trial completed in Q2, 2007	Kissei Pharmaceutical	Worldwide, except Japan
MN-246	Urinary incontinence	Phase I clinical trial completed in Q4, 2006; Phase I food effects study completed in Q1, 2007	Mitsubishi Tanabe Pharma Corporation	Worldwide, except Japan and certain other countries in Asia
MN-447	Thrombotic disorders	Preclinical	Meiji Seika Kaisha	Worldwide, except Japan and certain other countries in Asia
MN-462	Thrombotic disorders	Preclinical	Meiji Seika Kaisha	Worldwide, except Japan and certain other countries in Asia

\* Our rights to MN-001 licensed from Kyorin Pharmaceutical exclude ophthalmic solution formulations. Although positive signs of efficacy were obtained in the clinical trials conducted on MN-001 in interstitial cystitis and MN-305 in Generalized Anxiety Disorder, the predefined primary statistical endpoints of the clinical trials were not achieved; therefore, we would not anticipate submitting either clinical trial as a pivotal trial supporting a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA. In the Phase II clinical trial conducted on MN-305 in insomnia, the predefined statistical endpoint of the clinical trial was not achieved; therefore, we terminated any further development of MN-305 for the treatment of insomnia.

## **Table of Contents**

### **Our Strategy**

Our goal is to build a sustainable biopharmaceutical business through the successful development and commercialization of differentiated products for the treatment of diseases with unmet medical need in high-value therapeutic areas. Key elements of our strategy are as follows:

*Concentrate our resources on our two prioritized product development programs, MN-221 and MN-166/AV411.* We intend to enter into strategic alliances with leading pharmaceutical or biotech companies to support further clinical development of both MN-221 and MN-166/AV411 in the United States. We may also decide to pursue potential partners and potential acquirers of license rights to our programs in markets outside the United States, with the goal of retaining significant commercial participation in these product opportunities.

*Pursue additional indications and commercial opportunities for our prioritized product candidates.* We will seek to maximize the value of MN-221 and MN-166/AV411 by pursuing other potential indications and commercial opportunities for such product candidates. For example, we have rights to develop and commercialize MN-221 for any disease or indication. In addition to the ongoing evaluation of MN-221 for the treatment of acute exacerbations of asthma, we expanded our development program for MN-221 to evaluate MN-221 for the treatment of COPD exacerbations utilizing our existing IND for MN-221.

*Maximize the value of the remainder of our diversified pipeline of existing product candidates.* We will conduct development activities strategically on the remainder of our existing product candidates, to the extent that we deem any further activities necessary to maintain our license rights or maximize their value, while aggressively pursuing a variety of initiatives to monetize these product candidates on appropriate terms.

*Opportunistically in-license additional product candidates through our global industry relationships.* Over the long term, we intend to expand our pipeline of in-licensed product candidates by continuing to cultivate and strengthen our business relationships with pharmaceutical companies in Japan and other markets. We believe our ability leverage industry relationships to acquire product candidates with high potential and existing preclinical or early clinical data from Japanese pharmaceutical companies provides us with a competitive advantage over other drug development companies in the U.S. market. We believe that additional diversification and expansion of our pipeline of product candidates will help maximize the commercial opportunity and mitigate the risks inherent in drug discovery and development.

*Strategically partner with pharmaceutical companies who are leaders in their fields to complete late stage product development and successfully commercialize our products.* We develop and maintain business development relationships with pharmaceutical therapeutic area leaders who seek late stage product candidates to complete development and commercialization. We intend to select partners with demonstrated ability to complete late stage development and successfully commercialize product candidates. To ensure our ability to build a sustainable business, we may selectively add commercial capabilities to our management team to support our evolution into a commercial entity as our product development programs mature.

### **Product Development Programs**

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

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 United States. We utilize the

---

## **Table of Contents**

existing data in preparing INDs or foreign equivalents and designing additional clinical trials to advance the regulatory approval process in the United States or abroad. Following are details of our product development programs:

### *Prioritized Product Candidates*

The current state of the development program for each of our two prioritized product candidates is described below.

#### *MN-221 for Acute Exacerbations of Asthma*

*Indication Overview and Market Opportunity.* An acute exacerbation of asthma is a long-lasting and severe asthma episode in which asthma symptoms are not responsive to initial bronchodilator or corticosteroid therapy. Acute exacerbations of asthma are an emergency situation that can lead to emergency department treatment and, in some cases, hospital admission or death. Beta-agonist agents are the mainstays of acute treatment for these types of asthma attacks and are included in the recommended standard of care according to the National Guideline Clearinghouse from the U.S. Department of Health and Human Services, or DHSS, for patients suffering from acute exacerbations of asthma.

Data from the National Center for Health Statistics show that visits to emergency departments for asthma increased from approximately 1.5 million in 1992 to approximately 1.7 million in 2006. There were approximately 456,000 hospital discharges and approximately 3,447 deaths due to asthma during 2007, according to the National Center for Health Statistics. Despite significant improvements in the treatment for asthma over the past 20 years, there has not been a corresponding decrease in hospitalizations due to asthma according to the National Center for Health Statistics (e.g. there were approximately 423,000 hospital discharges due to asthma in 1998). According to the National Heart, Lung and Blood Institute, the direct costs associated with hospital care due to asthma were estimated at \$5.5 billion in 2010. We believe that there remains an unmet medical need for a safe and effective treatment for acute exacerbations of asthma that could prevent some of these hospitalizations.

*Overview of MN-221 in Acute Exacerbations of Asthma.* MN-221 is a novel, highly selective  $\beta_2$ -adrenergic receptor agonist being developed for the treatment of acute exacerbations of asthma. We licensed MN-221 from Kissei Pharmaceutical in February 2004. Preclinical studies conducted *in vitro* and *in vivo* showed MN-221 to be highly selective for the  $\beta_2$ -adrenergic receptor. In these studies, the  $\beta_1$ -adrenergic receptor stimulating activity of MN-221 was less than that of other  $\beta_2$ -adrenergic receptor agonists in isolated rat atrium and *in vivo* cardiac function tests in rats, dogs and sheep, thereby suggesting that the stimulating action of older, less selective  $\beta_2$ -adrenergic receptor agonists on the heart via  $\beta_1$ -adrenergic receptors may be reduced with MN-221 due to its greater  $\beta_2$ -adrenergic receptor selectivity. *In vitro* studies also suggested that MN-221 may act as only a partial  $\beta_1$ -adrenergic receptor agonist in cardiac tissue, while acting as a full  $\beta_2$ -adrenergic receptor in lung tissue. In addition, a preclinical drug interaction study in dogs completed during 2008 demonstrated that, while each of albuterol and MN-221 induced an increase in heart rate independently, the addition of MN-221 by intravenous administration in combination with inhaled albuterol did not add to the heart rate increase associated with inhaled albuterol alone, which further suggests that MN-221 acts as a partial agonist at  $\beta_1$ -adrenergic receptors. We believe that this improved receptor binding and functional selectivity may result in fewer cardiovascular side effects than are commonly observed with other  $\beta_2$ -adrenergic receptor agonists used to treat this condition. We have developed and studied an intravenous formulation of MN-221 appropriate for hospital use.

*Clinical Results.* We completed a randomized, double-blind, placebo-controlled, dose escalation, multi-center Phase II clinical trial of MN-221 in 23 stable mild-to-moderate asthmatics, in August 2007. At each dose level in the escalation, patients were randomized to receive either a 15-minute intravenous infusion of MN-221 or placebo. This clinical trial achieved statistical significance in its primary endpoint of mean change

## Edgar Filing: MEDICINOVA INC - Form 10-K

in forced expiratory volume in one second, or FEV<sub>1</sub>, from baseline to measurement at 15 minutes (the end of the infusion) at doses of 10, 16, 30 and 60 micrograms per minute of MN-221 (p-value less than or equal to 0.0006) compared to placebo. MN-221 produced a significant linear, dose-related increase in mean change in post-infusion FEV<sub>1</sub>

**Table of Contents**

from baseline (p-value less than or equal to 0.0001) following a 15-minute intravenous infusion of MN-221. Significant improvements in mean change in post-infusion (15 minute) FEV<sub>1</sub> from baseline were observed at doses of 10, 16, 30 and 60 micrograms per minute (p-value less than or equal to 0.0006) and at the dose of 3.5<sup>1</sup> micrograms per minute (p-value=0.0106) compared to placebo. In the protocol correct population for this clinical trial, which consisted of 21 patients, the dose-related increases in FEV<sub>1</sub> were maintained for four hours (p-value=0.0393) and at eight hours (p-value=0.0424) following the 15-minute infusion of MN-221. MN-221 was well tolerated in this Phase II clinical trial, with only the expected  $\beta_2$ -adrenergic receptor pharmacology noted in some patients (*e.g.*, fall in serum potassium, elevation in plasma glucose, mild headache and mild tremors). There were no clinically significant cardiovascular, electrocardiogram, or ECG, or vital sign changes observed at any dose tested. In addition, no serious adverse effects were observed in this clinical trial.

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

We completed a randomized, modified single-blind, placebo-controlled, dose escalation Phase II clinical trial to evaluate MN-221 in patients with severe, acute exacerbations of asthma in emergency departments, which included 29 patients (13 treated with standard care only and 16 treated with MN-221 plus standard care) at planned escalating doses of 240 to 1,080 micrograms, in April 2009. All patients received standardized care consisting of inhaled albuterol, ipratropium and oral steroid treatment. No safety concerns with adding MN-221 to standardized care were identified following review of ECG laboratory and adverse experience data. The hospitalization rate among patients treated with standardized care only was 46 percent (six of 13), which was the anticipated rate, compared to a hospitalization rate of 25 percent (four of 16) among patients receiving MN-221 plus standardized care. Improvement in FEV<sub>1</sub> values generally appeared to be greater for patients receiving MN-221 in addition to standardized treatment. As specified in the protocol for this clinical trial, no inferential statistics (*e.g.*, p-values) were calculated for this study.

*Development Plans.* In January 2009, we initiated a randomized, double-blind, placebo-controlled Phase II clinical trial designed to evaluate the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma in emergency departments. We are utilizing clinical sites primarily in North America (including a majority of the clinical sites that participated in the smaller Phase II clinical trial concluded in April 2009) to enroll approximately 200 patients in this clinical trial, which is designed to compare standardized care to standardized care plus MN-221 at a dose of 1,200 micrograms administered over one hour. Once a patient has received the initial standardized care treatment regimen, the patient will be assessed for response to that treatment. If the patient's FEV<sub>1</sub> is less than or equal to 50 percent of predicted and the patient meets all other study entry criteria, the patient will be randomized to receive either MN-221 or placebo. Patients enrolled in the clinical trial will continue to receive standardized care as needed. The primary efficacy endpoint will be improvement in FEV<sub>1</sub>.

If we are successful in completing this Phase II clinical trial in the second half of 2011, we anticipate requesting an End-of-Phase II meeting with the FDA. If we are successful in entering into a strategic collaboration or raising additional capital, we would subsequently initiate our planned Phase III program.

**Table of Contents***MN-221 for Chronic Obstructive Pulmonary Disease Exacerbations*

*Indication Overview and Market Opportunity.* A COPD exacerbation is a sustained worsening of the patient's condition, from the stable state and beyond normal day-to-day variations, that is acute in onset and necessitates a change in regular medication in a patient with underlying COPD. Exacerbations are associated with a significant increase in mortality, hospitalization and healthcare utilization. According to data from the National Heart, Lung, and Blood Institute, an estimated 12.1 million adults had a diagnosis of COPD in the United States in the year 2001 and about 24 million adults have evidence of impaired lung function indicating that COPD is under diagnosed. According to data from the National Heart, Lung, and Blood Institute, in the year 2000, there were 119,000 deaths, 726,000 hospitalizations, and 1.5 million hospital emergency department visits due to COPD in the United States. The age-adjusted death rate for COPD increased more than 30 percent since 1980, according to a 2010 report on COPD from the American Lung Association, which used data from the Centers for Disease Control and Prevention. In 2002, according to the National Heart, Lung, and Blood Institute, direct costs for COPD were \$18.0 billion and indirect costs were \$14.1 billion in the United States. In 2010, according to the American Lung Association, the direct costs for COPD were approximately \$29.5 billion and indirect costs were approximately \$20.4 billion in the United States. We believe there remains an unmet medical need for a safe and effective treatment for COPD exacerbations that could prevent some of these hospitalizations.

*Overview of MN-221 in COPD Exacerbations.* In July 2009, we announced our plan to evaluate MN-221 for the treatment of COPD exacerbations. Inhaled  $\beta_2$ -adrenergic receptor agonists, which are the current standard of care, are often inadequate to control the symptoms of COPD exacerbations. We believe that MN-221 may offer an immediate intravenous delivery for this life-threatening condition for patients who cannot get the full benefit from treatment with inhaled  $\beta_2$ -adrenergic receptor agonists due to severe bronchoconstriction. In addition, we believe that MN-221 may offer the potential for fewer cardiovascular side effects than older  $\beta_2$ -adrenergic receptor agonists due to its greater selectivity for the  $\beta_2$ -adrenergic receptor. This could be very significant due to the relative older age population seen in COPD patients who tend to have more underlying heart disease.

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

*Development Plans.* We are now considering the next steps for the COPD development program.

*Ibutilast (MN-166/AV411): AV411 for Neuropathic Pain and Drug Addiction*

The AV411 portfolio, which includes the Phase II-staged lead drug compound and proprietary analogs, represents novel, first-in-class, non-opioid drugs for the treatment of several large pain and drug addiction indications. AV411 is a first-in-class, orally bioavailable small molecule, a glial attenuator that suppresses pro-inflammatory cytokines IL-1 $\beta$ , TNF- $\alpha$ , and IL-6, and may upregulate the anti-inflammatory cytokine IL-10. It has additionally been shown to be a toll-like receptor 4 (TLR4) functional antagonist that may contribute to its attenuation of neuroinflammation. While considered a New Molecular Entity, or NME, in the United States and Europe, it involves redirection of an approved drug, ibutilast, which was first approved in Japan more than 20 years ago. Ibutilast has been prescribed to over one million patients for a different indication and has a good post-marketing safety profile as reported in nearly 15,000 patients studied at the prescribed doses.





---

## **Table of Contents**

Based on our research, we have filed for patents protecting multiple uses of AV411 in neurological conditions, as well as for patents on AV411 analogs which we believe have the potential to be effective second generation molecules. As NMEs, AV411 and its analogs would be entitled to five years of marketing exclusivity from first approval in the U.S. and up to 10 years of exclusivity in the European Union.

*Neuropathic pain:* Glial activation in the brain and spinal cord contribute to the establishment and amplification of the chronic pain state. As part of Avigen's program investigating glial attenuation as a novel approach to the treatment of neuropathic pain, Avigen conceived and demonstrated that AV411 was efficacious in preclinical models of neuropathic pain and may be effective in a wide range of neuropathic pain syndromes including neuropathy, post-herpetic neuralgia, HIV neuropathy, radiculopathy, spinal cord injury and chemotherapy-induced neuropathy. While ibudilast was initially developed as a non-selective phosphodiesterase (PDE) inhibitor for the treatment of bronchial asthma, its efficacy in some neuropathic pain models appears to be independent of this activity and yet still linked to glial attenuation.

AV411 has advanced through multiple Phase I and IIa clinical trials in both healthy volunteers and patients for neuropathic pain, inclusive of a Phase Ib/IIa clinical trial in diabetic neuropathic pain. The program, under current FDA standards, is able to enter Phase II development for neuropathic pain in the United States based on completed Avigen preclinical and clinical development.

*Opioid withdrawal:* AV411 completed a Phase Ib/IIa clinical trial in opioid withdrawal and analgesia, or OWA, funded by NIDA and conducted at Columbia University by leading specialists in the study and treatment of substance abuse. AV411 and analogs have been shown in preclinical models of opioid (morphine or oxycodone) withdrawal to significantly reduce withdrawal symptoms. Moreover, AV411 attenuates both behavioral and neurochemical markers of opioid reward. AV411 and analogs are differentiated from other drug candidates in clinical trials that may demonstrate similar effects, in that AV411 and analogs are not narcotics and do not, themselves, provide reward or reinforcement in behavioral models of dependence. Thus, while current therapies involve substitution of one opioid for another (e.g. methadone for heroin), AV411 represents a novel, non-opioid, approach for the treatment of opioid withdrawal and dependence. Results from the recently-completed OWA trial indicated dose-related attenuation of the opioid withdrawal syndrome ( $p < 0.05$  for 80 mg/d treatment arm relative to placebo control on the Subjective Opioid Withdrawal Scale (SOWS) endpoint) and enhanced opioid analgesia ( $p < 0.05$  for the McGill Pain Questionnaire endpoint for the 80 mg/d treatment arm vs placebo control). Other measures of withdrawal (Clinicians Opioid Withdrawal Scale) or analgesia (quantitative time endpoints for cold pressor test) were not significantly attenuated.

*Methamphetamine addiction:* In collaborative studies with NIDA, AV411 has demonstrated utility in methamphetamine relapse in animals which translated into a NIDA-funded exploratory Phase Ib methamphetamine interaction clinical trial with investigators at the University of California Los Angeles.

*Development Plans.* We are not planning to undertake any further significant clinical development of AV411 until such time that we are successful in entering into a strategic collaboration to support further clinical development of our combined MN-166/AV411 ibudilast-based programs. We are actively pursuing potential partners for such purpose.

*Ibudilast (MN-166/AV411): MN-166 for Multiple Sclerosis*

*Indication Overview and Market Opportunity.* MS is an inflammatory disease of the CNS in which the body's immune system attacks the protective sheath surrounding nerve fibers. According to the National Multiple Sclerosis Society, MS affects approximately 400,000 people in the United States and approximately 2.5 million people worldwide. In addition, according to the National Multiple Sclerosis Society, approximately 200 people are diagnosed with MS in the United States each week. The most obvious effect of MS is its destruction of nerve fibers leading to the loss of muscle control. However, MS also affects multiple CNS functions. Currently, there is no known cure for the disease.

According to the National Multiple Sclerosis

---

## Table of Contents

Society, relapsing-remitting MS, or RRMS, is the most common type of the disease, and 85 percent of people with MS are initially diagnosed with RRMS. Secondary-Progressive MS (SPMS) follows an initial period of RRMS. According to sales data included in the most recent annual reports of the leading MS drug companies, including Biogen Idec Inc., Merck Serono S.A., Teva Pharmaceuticals Industries Ltd. and Bayer Schering Pharma AG, worldwide sales of drugs to treat MS exceeded \$11.0 billion in 2010.

The aim of treatment is to relieve symptoms of acute attacks by reducing the frequency of relapses and limiting the disabling effects of relapses and to minimize disability caused by disease progression. Steroids are used in treating MS to decrease the severity and shorten the duration of the attacks, but they do not change the course of the disease. Corticosteroid use is normally limited to the short-term treatment of MS, perhaps over a period of one to three weeks, as it generally is believed that the side effects and safety risks of long-term corticosteroid therapy outweigh clinical benefits in extended MS treatment. More recently, immunosuppressive agents and techniques have been introduced for the treatment of MS. However, these treatments are only partially effective and certain side effects may preclude their widespread use. These treatments may slow the course of disease progression and mitigate its effects temporarily, but additional drugs are often required to address the various CNS dysfunctions caused by the disease. We believe drugs for the treatment of MS that can be taken with less discomfort, particularly those that can be taken orally, with efficacy equal or better than the available treatments for MS would have widespread appeal.

*Overview of MN-166.* We licensed MN-166 from Kyorin Pharmaceutical in October 2004. MN-166 has been marketed in Japan and Korea since 1989 to treat cerebrovascular disorders and bronchial asthma. In preclinical *in vivo* and *in vitro* studies, MN-166 inhibited leukotriene activity, phosphodiesterases and nitric oxide synthase, all of which are inflammatory mechanisms known to be involved in MS. These studies also suggested that MN-166 may suppress the production of pro-inflammatory cytokines (IL-1 $\beta$ , TNF- $\alpha$ ) and enhance the production of the anti-inflammatory cytokines (IL-4, IL-10). Based on the potential mechanisms of action of MN-166, its clinical safety history in Japan, the results of pilot studies conducted by Kyorin Pharmaceutical in MS patients and the issuance of a U.S. patent covering the method of using MN-166 to treat the disease, we decided to pursue development of MN-166 as a novel, oral agent for the treatment of MS.

*Clinical Results.* Based on its anti-inflammatory activity and safety profile, MN-166 was evaluated for potential activity in MS in two pilot clinical trials sponsored by academic investigators in Japan. In one open-label pilot clinical trial, the investigators studied the effects of MN-166 on relapse rates in six MS patients who had a mean of four relapses per year. Following 12 to 20 months of treatment with MN-166, the average relapse rate was reduced. Over this time frame, there was no significant change in the mean Expanded Disability Status Score, or EDSS, a measure of MS drug efficacy and disease progression. No side effects of MN-166 were reported in this clinical trial. In a second pilot trial involving 12 MS patients receiving MN-166 for four weeks, MN-166 tended to normalize the levels of several chemical mediators of inflammation, including TNF- $\alpha$  and interferon gamma.

We completed a two-year Phase II multi-center, randomized, double-blind, placebo-controlled clinical trial of MN-166 for the treatment of patients with relapsing MS in April 2008. This clinical trial involved 297 patients with relapsing MS in several countries in Eastern Europe. Patients received either 30 mg of MN-166 per day, 60 mg of MN-166 per day or a placebo.

In the second year of the study, all patients received active drugs. Patients who received 30 or 60 mg of MN-166 per day during the first year of the study remained on the assigned dose for the second 12 months of the study; patients who received placebo during the first 12 months of the study were randomized to receive either 30 or 60 mg of MN-166 per day (double-blind maintained) during the second 12 months of the study. Clinical and radiological outcomes were evaluated. MN-166 treatment resulted in positive findings on three independent measures indicative of a potential disease-progression modifying effect. First, sustained disability progression was significantly less likely (by approximately 50 percent) in those patients receiving MN-166 at either 30 or 60 mg per day for 24 months than in those patients receiving the drug for 12 months ( $p=0.026$ ). Sustained disability

---

## Table of Contents

progression was measured as a greater than or equal to 1.0 point increase from baseline in the EDSS score for four consecutive months. Second, the significant reduction in brain volume loss ( $p=0.035$ ), as measured by cranial MRI scans, observed after 12 months in patients treated with 60 mg per day of MN-166 compared to placebo was again demonstrated in year two of the study. Brain volume loss was significantly less ( $p=0.030$ ) in patients receiving 60 mg per day of MN-166 for 24 months compared to the other treatment groups. Third, MN-166 treatment at 60 mg per day significantly reduced the relative risk for conversion of new inflammatory lesions identified at month two to PBHs eight months later at month ten by 37 percent ( $p=0.011$ ); such lesions that remain unchanged for eight months are considered PBHs as compared to transient inflammatory lesions that are more closely associated with relapses. MN-166 treatment at 30 mg per day resulted in a trend toward reducing evolution to PBH ( $p=0.074$ ). MN-166 was well tolerated at all doses over the two years of this clinical trial, with the most common adverse events possibly related to MN-166 involving mild, transient gastrointestinal disturbances and depression. Of the 297 patients enrolled in this clinical trial, 245 patients completed the full two years of treatment. In September 2008, data from this completed two-year clinical trial was presented at the World Congress for Treatment and Research in MS.

*Development Plans.* At present, with the acquisition of AV411 in December 2009, we are not planning to undertake any further significant clinical development of MN-166 until such time that we are successful in entering into a strategic collaboration to support further clinical development of our combined MN-166/AV411 ibudilast-based programs. We are actively pursuing potential partners for such purpose.

### *Other Product Candidates*

We intend to limit development activities on the balance of our ten product candidates. For each of these product candidates, we plan to conduct development activities only to the extent that we deem any further activities necessary to maintain our license rights or maximize its value, while pursuing a variety of initiatives to monetize such product candidate on appropriate terms. The status of the development program for each of these non-prioritized product candidates is described below.

### *MN-001 for Asthma*

*Indication Overview and Market Opportunity.* Asthma is a chronic inflammatory disease of the airways in which symptom control is the key to effective disease management. Alleviation of acute asthmatic symptoms and blocking of late phase inflammation are both important to asthma therapy. According to the CDC and the Global Initiative for Asthma, there are approximately 24.6 million asthma patients in the United States and over 300 million asthma patients worldwide.

According to the most recent annual reports of the leading asthma drug companies, GlaxoSmithKline plc, Merck & Co., Inc., AstraZeneca plc and Roche Holding Ltd., worldwide sales of asthma therapeutics increased to over \$22 billion in 2010. Leading treatments currently include inhaled corticosteroids, bronchodilators and leukotriene antagonists. Worldwide sales of the Flovent<sup>®</sup> and Pulmicort<sup>®</sup> inhaled corticosteroids were over \$2.1 billion in 2010 according to the annual reports of GlaxoSmithKline plc and AstraZeneca plc. Inhaled steroids, such as Flovent<sup>®</sup> (fluticasone) and Vanceril<sup>®</sup> (beclomethasone), are more broadly effective in blocking late phase inflammation, but their general side effects require careful monitoring. Leukotriene antagonists, such as Singulair<sup>®</sup> (montelukast) or Accolate<sup>®</sup> (zafirlukast), became available as a new asthma therapy in the late 1990s. These drugs block the actions of leukotrienes, which are pro-inflammatory chemical mediators, and the subsequent inflammation caused by eosinophil migration to the lungs. According to Merck & Co., Inc.'s 2010 Annual Report, worldwide sales of Singulair<sup>®</sup>, a leading leukotriene antagonist, were \$5.0 billion in 2010.

*Overview of MN-001 in Asthma.* MN-001 is a novel, orally bioavailable compound being developed for the treatment of bronchial asthma. We licensed MN-001 from Kyorin Pharmaceutical in March 2002. In *in vivo* preclinical studies conducted by Kyorin Pharmaceutical and us,

Edgar Filing: MEDICINOVA INC - Form 10-K

MN-001 combined the positive attributes of the leukotriene antagonists and inhaled steroids, while maintaining an acceptable safety profile.

---

## Table of Contents

In preclinical pharmacology studies, MN-001 inhibited airway hyper-reactivity through a reduction of airway inflammation. *In vitro* studies and animal studies also suggested that MN-001 may affect many of the downstream mechanisms activated by mast cell degranulation, which is the release of chemicals that cause inflammation. MN-001 also demonstrated that it is a potent inhibitor of pro-inflammatory enzymes *in vitro* (e.g., 5-lipoxygenase and phosphodiesterase 4), as it prevented migration of inflammatory cells to the lungs of rodents in these studies. In addition, in guinea pig asthma models, MN-001 was more selective than steroids in affecting cells involved in the inflammatory process and not those involved in cellular immunity.

*Clinical Results.* MN-001 has proven to be well tolerated in early clinical testing. Treatment-related adverse effects, primarily consisting of gastrointestinal discomfort such as diarrhea, loose stools, nausea and upper abdominal pain, were mild, transient and reversible. These adverse effects were consistent with findings in preclinical studies.

We conducted a randomized, double-blind, placebo-controlled, multi-center Phase II clinical trial in patients with mild-to-moderate asthma, which was completed in the fourth quarter of 2005. In this clinical trial, 147 patients were randomly assigned to receive placebo or MN-001 tablets in one of three oral dosing regimens for four weeks. The primary endpoint of the trial was achieved with a statistically significant improvement in FEV<sub>1</sub> after four weeks of treatment with 500 mg of MN-001 at three times daily dosage, or TID, compared to placebo (p-value=0.021; intent-to-treat, observed cases). A similar trend was observed for the 750 mg two times daily dosage, or BID, of MN-001 (p-value=0.058). Positive trends in secondary outcome measures were also observed in the 500 mg TID treatment group, including serial spirometry, morning and evening peak flow rates, and provocative concentration causing a 20 percent fall in FEV<sub>1</sub>, or PC20, values in a methacholine challenge test, each of which is a common measure of respiratory function. MN-001 was well tolerated in this clinical trial with 89 percent of patients completing four weeks of treatment. There was no apparent difference between placebo and any of the active treatment groups in adverse events leading to discontinuation or in adverse events attributable to treatment.

### *MN-001 for Interstitial Cystitis*

*Indication Overview and Market Opportunity.* IC is a chronic disease of the bladder characterized by urinary frequency and urgency, nighttime urination and pelvic and bladder pain. It is widely believed that IC is due to an altered or defective bladder lining and an increased number of activated bladder mast cells, which are specialized cells that release biochemicals and cause inflammation. According to the National Kidney and Urologic Diseases Information Clearinghouse, which is a division of the National Institutes of Health, an estimated 1.3 million patients suffer from IC in the United States, and more than one million of them are women. We believe that IC is currently underdiagnosed and that the market for drugs that treat IC will likely expand with the introduction of effective new treatments.

*Overview of MN-001 in Interstitial Cystitis.* MN-001 is a novel, orally bioavailable, anti-inflammatory compound being developed for the treatment of IC. Data that we collected in connection with the development of MN-001 for bronchial asthma and data collected by Kyorin Pharmaceutical provided us with a strong scientific rationale for evaluating MN-001 as an oral treatment for IC. MN-001 has been shown to block a number of the inflammatory mechanisms activated by mast cell degranulation that are important in the pathogenesis of inflammatory disorders, including IC and asthma (e.g., leukotriene receptor antagonism and inhibition of phosphodiesterases III and IV, 5-lipoxygenase, phospholipase C and thromboxane A2). In addition, MN-001 produced anti-inflammatory effects in a variety of rodent models of IC and asthma; in these models, MN-001 reduced bladder hyper-reactivity much in the same way that it reduced airway hyper-reactivity in the lung.

*Clinical Results.* We conducted a randomized, double-blind, placebo-controlled multi-center Phase II clinical trial in patients with moderate-to-severe IC, which was completed in the first quarter of 2007. This clinical trial involved 305 patients at 37 clinical sites in the United States. Results from this clinical trial indicated that, while well-tolerated, MN-001 did not show a statistically significant clinical benefit compared to



---

## Table of Contents

placebo on the primary endpoint (to be much or very much improved overall on a patient-rated global response assessment) at the doses tested in this clinical trial (500 mg once or twice a day for eight weeks). Results from this clinical trial also indicated that IC patients were more than twice as likely to respond on 500 mg of MN-001 administered twice a day compared to placebo (25 percent compared to 12 percent, p-value=0.04) after four weeks of treatment. This difference, however, was not observed at eight weeks due to continued improvement among placebo-treated patients. The response rate of patients treated with 500 mg of MN-001 once a day did not significantly differ from placebo at either four or eight weeks.

### *MN-029 for Solid Tumors*

*Indication Overview and Market Opportunity.* The American Cancer Society estimates that more than 1.5 million Americans were diagnosed with cancer in 2010, of which more than 750,000 patients were diagnosed with lung, prostate, colon, rectum or breast solid tumor cancers. The American Cancer Society also estimates that approximately 569,000 patients were ultimately to die from cancer in 2010. According to IMS Health, the global market for oncology products exceeded \$48.0 billion in 2008.

Tumor blood vessels are a promising target for cancer therapy. Compounds that act to deprive tumors of their blood supply fall into two classes: angiogenesis inhibitors and vascular disrupting agents, or VDAs. Angiogenesis inhibitors block the formation of new blood vessels formed in response to tumor growth, whereas VDAs disrupt blood flow through existing tumor blood vessels. We believe that VDAs have a potential advantage over angiogenesis inhibitors because VDAs work on existing tumor blood vessels and can kill hundreds of cancer cells that depend on that blood supply with even a brief interruption in blood flow, rather than simply slowing tumor growth by blocking new blood vessel formation.

*Overview of MN-029.* MN-029 is a novel, small molecule VDA being developed for the treatment of solid tumors. We licensed MN-029 from Angiogene Pharmaceuticals in June 2002. Several preclinical pharmacology studies conducted by Angiogene Pharmaceuticals and us 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. 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, or DCE-MRI.

*Clinical Results.* To date, we have conducted two Phase I clinical trials of MN-029 for the treatment of solid tumors, which completed in 2006 and 2007, respectively.

In the first Phase I clinical trial, MN-029 was administered as an intravenous infusion once every three weeks. Results from this clinical trial showed that MN-029 was well tolerated at doses that reduced tumor blood flow. A maximum tolerated dose of 180 mg/m<sup>2</sup> per dose was established in this clinical trial. The most common side effects of MN-029 were characteristic of other VDAs and included nausea, vomiting, fatigue and diarrhea. Nine of 34 patients with advanced solid tumors for whom no standard therapy was available had stable disease after three cycles of treatment. Six patients had prolonged (greater than six months) stable disease. Although no patients showed objective responses based on Response Evaluation Criteria in Solid Tumors, or RECIST criteria, which is tumor length on computed tomography, or CT, or MRI scans, semi-automated measurements of tumor volumes from CT scans showed a measureable reduction in tumor burden in the subject with the largest reduction in tumor blood flow (Ktrans -40 percent). Tumor blood flow reduction assessed by dynamic contrast-enhanced magnetic resonance imaging, or DCE-MRI, was recorded at doses greater than or equal to 120 mg/m<sup>2</sup>.



## Edgar Filing: MEDICINOVA INC - Form 10-K

In the second Phase I clinical trial, MN-029 was administered as an intravenous infusion every seven days (days 1, 8, 15) followed by a 13-day recovery period (one cycle). Results from this clinical trial showed that MN-029 was well tolerated. The maximum dose was limited to 180 mg/m<sup>2</sup> per dose based on the results of the

---

**Table of Contents**

other Phase I trial that employed a less aggressive dosing schedule. The most common side effects of MN-029 in this clinical trial included nausea, vomiting, arthralgia and headache. Eleven of 20 patients with advanced solid tumors for whom no standard therapy was available had stable disease after two cycles of treatment. Four subjects continued on extended cycles of MN-029 treatment. Based on RECIST criteria, one patient with metastatic pancreatic cancer had an overall partial response with a duration of 74 days. Seven patients had stable disease with a median duration of 83 days.

*MN-305 for Generalized Anxiety Disorder/Insomnia*

*Indication Overview and Market Opportunity.* The essential characteristic of Generalized Anxiety Disorder is excessive, uncontrollable worry about everyday events. This constant worry affects daily functioning and can cause severe physical symptoms. Generalized Anxiety Disorder can occur with other anxiety disorders, depressive disorders or substance abuse. Generalized Anxiety Disorder is often difficult to diagnose because it is not triggered by a specific object or situation. The intensity, duration and frequency of the worry are disproportionate to the issue. As a result, Generalized Anxiety Disorder tends to interfere with the patient's performance of tasks and ability to concentrate. According to the National Institute of Mental Health, anxiety disorders affect approximately 40 million American adults, of whom approximately 6.8 million suffer from Generalized Anxiety Disorder. Anxiety disorders are the most prevalent of neuropsychiatric conditions, yet are generally considered to be under-diagnosed and therefore undertreated. Therefore, we believe that there is a significant opportunity for the introduction of new anxiety reducing drugs.

A variety of pharmacologic agents are used to manage patients with anxiety disorders. Benzodiazepines have been the mainstay of the treatment of acute anxiety since the late 1960s. However, their efficacy as a treatment has been limited by problems faced in chronic use due to their sedative effects. In the late 1980s, buspirone was introduced and widely used even though it takes effect slowly. Buspirone was well tolerated and relatively safe. During the late 1990s, newer anti-depressants, notably the specific serotonin reuptake inhibitors, or SSRIs, were increasingly used to treat anxiety as well. While effective, the use of SSRIs may result in a variety of undesirable side effects, including agitation and sexual dysfunction. Also, SSRIs may take weeks to exert their beneficial effects.

*Overview of MN-305 in Generalized Anxiety Disorder/Insomnia.* MN-305 is a serotonin receptor agonist with high affinity and selectivity for the serotonin 5-HT<sub>1A</sub> receptor subtype. Drugs that act through this mechanism, such as buspirone, have been proven to be clinically effective in treating Generalized Anxiety Disorder. We licensed MN-305 from Mitsubishi Pharma Corporation, now Mitsubishi Tanabe Pharma Corporation, in April 2004. MN-305 has been shown to be more potent than buspirone and to exhibit anti-anxiety efficacy in a wide range of preclinical rodent models. For example, in a social interaction test, MN-305 prolonged the duration of social interaction in rats. Preclinical and clinical studies conducted by Mitsubishi Tanabe Pharma Corporation and us also suggest that MN-305 may have a more rapid onset of action than buspirone.

*Clinical Results.* Preliminary evidence of anti-anxiety efficacy was provided by a six-week, open-label, fixed-flexible dose Phase II clinical trial conducted by Mitsubishi Tanabe Pharma Corporation in Japan in 61 patients with neurotic disorders. The neurotic disorders included Generalized Anxiety Disorder, panic disorder, agoraphobia, mixed anxiety and depressive disorder and dysthymia. MN-305 was well tolerated, with headaches being the most common side effect in this clinical trial. At the end of the clinical trial, the mean Hamilton Rating Scale for Anxiety score, or HAM-A score, which is a scale used to measure the intensity of anxiety symptoms, was reduced compared to the pre-treatment value. Similarly, a majority of the patients were rated Moderately Improved or better following treatment with MN-305. In addition, MN-305 was well tolerated in several clinical trials conducted by Mitsubishi Tanabe Pharma Corporation in healthy volunteers and patients with anxiety disorders and Major Depressive Disorder. These studies did not evaluate the reduction of anxiety symptoms in patients that were not treated with MN-305.

## Table of Contents

The IND for MN-305 was transferred to us from Mitsubishi Tanabe Pharma Corporation, which enabled us to conduct a Phase II randomized, double-blind, placebo-controlled clinical trial in 416 patients with Generalized Anxiety Disorder, which was completed in the second quarter of 2006. The results revealed trends for improvement in all efficacy outcome measures. Statistically significant improvements in the total HAM-A score and in anxious mood, which is item 1 of the HAM-A score and was a secondary endpoint in this clinical trial, were observed through eight weeks of treatment. However, statistical significance on change from baseline of the total HAM-A score after ten weeks of treatment, which was the primary outcome measure of this clinical trial, was not achieved. MN-305 was well tolerated at all doses in this clinical trial, and we believe the findings were sufficiently positive to warrant further clinical evaluation of this product candidate.

We analyzed the results from our Phase II clinical trial of MN-305 in Generalized Anxiety Disorder and performed in-depth analyses of subgroups that showed statistically significant improvement in certain aspects of the HAM-A score (*e.g.*, insomnia). Based on these analyses, we initiated a Phase II proof-of-concept clinical trial of MN-305 for the treatment of insomnia in the first quarter of 2007 to assess the effects of three dosages of MN-305 (1 mg, 3 mg and 6 mg) and placebo, all administered orally approximately 60 minutes before bedtime. This clinical trial, which involved 74 subjects at ten study centers in the United States, was completed in the fourth quarter of 2007. This clinical trial failed to achieve statistical significance in its primary endpoint of reducing Wake (time) After Sleep Onset, or WASO. MN-305 was well tolerated in this clinical trial with no clinically significant adverse events observed at any dose tested, and there was no evidence of any decrements in psychomotor performance, as assessed in digit symbol substitution and symbol copying tests, in patients treated with MN-305. Based upon the results of this clinical trial, we decided to terminate the evaluation of MN-305 for the treatment of insomnia.

### *MN-221 for Preterm Labor*

*Indication Overview and Market Opportunity.* Preterm labor is caused by the onset of uterine contractions before term. According to a November 2002 publication in *Obstetrics & Gynecology*, preterm labor is the leading cause of neonatal mortality and a substantial portion of all birth-related short and long-term morbidity. Successful inhibition of premature birth is known to reduce the risk of complications. Despite extensive research into preterm labor during the past several decades, the rate of premature births has not decreased. According to the National Vital Statistics Reports issued by the U.S. Department of Health and Human Services, or DHHS, there were 4.3 million births in the United States in 2007. The 2007 preterm birth rate was 12.7 percent. The DHHS estimates that the costs associated with preterm births are over \$26 billion annually. According to the World Health Organization, six percent to seven percent of all births in Europe occur before term.

Currently, therapy for preterm labor remains targeted at uterine contractions.  $\beta_2$ -adrenergic receptor agonists are generally used as first-line treatments for premature labor. The only FDA-approved treatment for preterm labor is ritodrine, a  $\beta_2$  agonist. However, ritodrine has not been available for sale in the U.S. market since 1999. The more widely used treatment for preterm labor is another  $\beta_2$  agonist, terbutaline; however, this drug is not approved by the FDA for preterm labor. Atosiban, an oxytocin antagonist, is available in Europe, but was denied regulatory approval in the United States. The usefulness of these  $\beta_2$ -adrenergic receptor agonists is often limited by the adverse reactions they produce, which include cardiovascular side effects such as heart palpitations. As a result, we believe that there is a need for treatments with better safety and tolerability profiles that are effective in reducing the premature birth rate and/or providing for longer gestation.

On March 3, 2011, we executed a joint venture agreement with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd., which provides for the establishment of a joint venture company to develop and commercialize MN-221 in China. See *Recent Developments*.

*Overview of MN-221 in Preterm Labor.* MN-221 is highly-selective  $\beta_2$ -adrenergic receptor agonist being developed for the treatment of preterm labor. We licensed MN-221 from Kissei Pharmaceutical in February 2004. Preclinical testing *in vitro* and *in vivo* showed MN-221 to be more selective for the  $\beta_2$ -adrenergic receptor



---

## Table of Contents

than other  $\beta_2$ -adrenergic receptor agonists currently used to treat preterm labor. Moreover, *in vitro* studies also suggested that MN-221 may act as only a partial  $\beta_1$ -adrenergic receptor agonist in cardiac tissue, while acting as a full  $\beta_2$ -adrenergic receptor in the uterus. This improved receptor binding and functional selectivity may result in fewer cardiovascular side effects than are commonly observed with other  $\beta_2$ -adrenergic receptor agonists used to treat this condition. In preclinical pharmacology studies in pregnant rats and sheep conducted by Kissei Pharmaceutical, MN-221 reduced the number of spontaneous or drug-induced uterine contractions. Furthermore, in these studies, MN-221 delayed both normal and preterm labor in rats and caused a marked increase in the bodyweight of rat pups as a result of prevention of premature birth. In rat and sheep studies which compared MN-221 to ritodrine and/or terbutaline, the potency of MN-221 was greater than those  $\beta_2$ -adrenergic receptor agonists.

*Clinical Results.* To date, pharmacokinetic and safety data has been generated from human experience with MN-221 through Phase I clinical studies in healthy male and non-pregnant female volunteers conducted by Kissei Pharmaceutical in Japan and the United Kingdom and a Phase I clinical trial in the United States conducted by us. A total of 244 healthy subjects received intravenous infusions of either MN-221 or a placebo. MN-221 was generally well tolerated. A pilot double-blind, placebo-controlled Phase II clinical trial of MN-221 was completed in 2004 by Kissei Pharmaceutical in seven women in preterm labor in the United Kingdom. A trend towards a reduction in the number of uterine contractions was observed in MN-221-treated women and, as a result, only limited conclusions could be drawn from this clinical trial. No serious adverse events related to MN-221 were observed in this clinical trial.

We initiated a Phase I clinical trial in healthy pregnant women in the third quarter of 2006. Ten healthy, pregnant volunteers who were not in labor participated in this clinical trial, which was completed in the second quarter of 2007. The volunteers received a single-dose intravenous infusion regimen of MN-221, consisting of two consecutive rounds of a 15-minute priming and a 105-minute maintenance infusion to deliver 294 micrograms of MN-221 over four hours. The primary objectives of this clinical trial were to determine the pharmacokinetics, safety and tolerability of this infusion regimen of MN-221 in pregnant women. No significant safety concerns with MN-221 were identified in this clinical trial.

### *MN-246 for Urinary Incontinence*

*Indication Overview and Market Opportunity.* Urinary incontinence occurs when normal regulation of bladder function is lost. According to the DHHS, there are over 13 million adults in the United States suffering from urinary incontinence.

The market for drugs to treat urinary incontinence is expected to grow substantially as more patients seek treatment and as newer drugs are introduced to the market. According to GlobalData, the global market for urinary incontinence was \$2.5 billion in 2009 and is projected to grow to \$3.4 billion by 2017. The current marketplace is dominated by anti-cholinergic drugs that are modestly effective and produce treatment-limiting side effects such as dry mouth. According to Pfizer Inc.'s 2009 annual report, sales of its Detrol were approximately \$1.2 billion in 2009.

*Overview of MN-246 in Urinary Incontinence.* MN-246 is a novel  $\beta_3$ -adrenergic receptor agonist being developed for the treatment of urinary incontinence. We licensed MN-246 from Mitsubishi Pharma Corporation, now Mitsubishi Tanabe Pharma Corporation, in December 2004. We believe that MN-246 represents a new approach to treating urinary incontinence and may have advantages over existing therapies, including potential improvements in efficacy through increases in bladder volume with decreases in involuntary bladder contractions and the absence of anti-cholinergic side effects, such as dry mouth. In preclinical studies in rats conducted by Mitsubishi Tanabe Pharma Corporation, MN-246 was more potent and active than oxybutynin and propiverine in increasing bladder volume. In addition, the studies showed that MN-246 produced little or no increase in residual urine volume and no anti-cholinergic side effects in rats. MN-246 also increased bladder volume in preclinical studies conducted on dogs and monkeys.



---

## **Table of Contents**

*Clinical Results.* We completed a double-blind, randomized, placebo-controlled, single escalating dose Phase I clinical trial of MN-246 for the treatment of urinary incontinence in healthy volunteers to evaluate the safety, tolerability and pharmacokinetics of MN-246 in the fourth quarter of 2006. We also conducted a Phase I food effects study in healthy volunteers, which was completed in the first quarter of 2007. MN-246 was tolerated in both clinical trials.

### *MN-447 and MN-462 for Thrombotic Disorders*

*Indication Overview and Market Opportunity.* Despite advances in the treatment of cardiovascular disease, or CVD, more than 616,000 people died of heart disease in 2007, according to the CDC's National Vital Statistics Reports. Heart disease causes approximately 25% of deaths in the United States. According to the American Heart Association, there are 80 million individuals in the United States that currently live with some form of CVD, which can include high blood pressure, coronary heart disease, stroke, angina (chest pain), myocardial infarction (heart attack) and congenital heart defects. According to Datamonitor, worldwide sales of antithrombotic drugs are forecasted to reach approximately \$22 billion in 2017. We believe that there remains an unmet medical need for safe and effective treatments for thrombotic conditions, including acute coronary syndrome, myocardial infarction, peripheral arterial disease and percutaneous coronary interventions.

According to the CDC, CVD remains the leading cause of death in the United States for both men and women. Given the high mortality and morbidity rates associated with CVD. We believe there is an urgent need for more targeted therapies that can intervene in known molecular pathways and minimize damage to the heart and related tissues.

*Overview of MN-447 and MN-462 in Thrombotic Disorders.* MN-447 and MN-462 are novel, small molecule antithrombotic agents being developed for the treatment of various thrombotic disorders. We licensed MN-447 and MN-462 from Meiji Seika Kaisha in November 2006.

MN-447 is a cardioprotective, anti-platelet agent that acts as a dual antagonist of glycoprotein, or GP, IIb/IIIa and integrin  $\alpha_v\beta_3$ , receptors that play key roles in blood clot formation and various cell behaviors and functions such as leukocyte adhesion. Preclinical studies have demonstrated that MN-447 acts downstream by inhibiting the final common pathway of platelet aggregation—the cross-linking of platelets via fibrinogen bridges to GP IIb/IIIa receptors. Inhibition of integrin  $\alpha_v\beta_3$  receptors has been linked to an inhibition of leukocyte adhesion to endothelium (the layer of cells lining blood vessels), reduction of hyperplasia (abnormal cellular proliferation) and lumen stenosis (blood vessel constriction) in response to vascular injury. In animal models of myocardial infarction and unstable angina, the dual inhibitory activity of MN-447 produced superior cardioprotective efficacy, such as reduction in infarct size after reperfusion (restoration of blood flow) compared to inhibition of the GP IIb/IIIa receptor alone, and showed a low risk of bleeding.

MN-462 is a selective inhibitor of a key enzyme in the intrinsic antifibrinolytic mechanism, plasma carboxypeptidase B, or CPB, and also called activated thrombin-activatable fibrinolysis inhibitor, or TAFI, which inhibits physiological fibrinolysis, or the lysis or dissolving of blood clots. By enhancing intrinsic fibrinolysis through plasma CPB inhibition, MN-462 has the potential to reduce and prevent thrombus or blood clot formation, as well as dissolve formed thrombus. In preclinical studies, MN-462 demonstrated significant fibrinolytic-enhancing and anti-thrombotic activities as monotherapy in several thrombosis models, as well as activities when used as an adjunct to fibrinolytics such as tissue plasminogen activator, or t-PA. The effect of MN-462 in enhancing the intrinsic fibrinolytic process was also observed to result in a low risk of bleeding.

### **Sales and Marketing**

## Edgar Filing: MEDICINOVA INC - Form 10-K

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



## **Table of Contents**

### **Manufacturing**

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

Pursuant to the terms of our license agreement with Kissei Pharmaceutical for MN-221, Kissei Pharmaceutical has the exclusive right to manufacture the commercial supply of the API for MN-221. We continue to negotiate with Kissei Pharmaceutical for the commercial supply of the API for MN-221. If we enter into a supply agreement with Kissei Pharmaceutical, we will purchase from Kissei Pharmaceutical all API that we require for the commercial supply of MN-221, if such product candidate is approved for commercial sale by the FDA or other regulatory authorities.

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

### **Intellectual Property and License Agreements**

Since our inception in September 2000, we have entered into eight license agreements which cover our current product candidates. In general, we seek to procure patent protection for our anticipated products, or obtain such protection from the relevant patents owned by our licensors. To date, we have obtained licensed rights under 14 issued U.S. patents and 10 pending U.S. patent applications. We also have obtained licensed rights to over 185 issued and pending foreign patents and applications corresponding to these U.S. patents and patent applications. In addition to these licensed rights, we hold seven issued U.S. patents and one U.S. patent application relating to MN-001 and its metabolite, MN-002. These patents and pending patent applications contain claims directed to compositions, polymorphs, methods of use and/or methods of manufacture. 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-221*

On February 25, 2004, we entered into an exclusive license agreement with Kissei Pharmaceutical for the development and commercialization of MN-221. Kissei Pharmaceutical is a fully integrated Japanese pharmaceutical company and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan), sublicensable 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

## Edgar Filing: MEDICINOVA INC - Form 10-K

license under one U.S. patent and one U.S. patent application and certain corresponding patents and patent applications in foreign countries and is sublicensable upon receipt of the written consent of Kissei Pharmaceutical. The U.S. patent for MN-221 has composition of matter and method of use claims.

## Table of Contents

The U.S. composition of matter patent underlying the license issued on October 17, 2000 and is set to expire no earlier than February 18, 2017. Corresponding composition of matter patents in various other countries are set to expire no earlier than February 18, 2017. Under the terms of the agreement, we granted to Kissei Pharmaceutical a royalty-free, non-exclusive right and license to use our know-how and patents relating to MN-221 to develop products incorporating the MN-221 compound outside of our territory. Kissei Pharmaceutical also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties and the exclusive right to manufacture and supply us with the API that we require for clinical development of MN-221 and commercial sale of any approved product.

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 Pharmaceutical during the development phase and 180 days' prior written notice to Kissei Pharmaceutical 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 Pharmaceutical 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 Pharmaceutical \$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.

### *MN-166*

On October 22, 2004, we entered into an exclusive license agreement with Kyorin Pharmaceutical for the development and commercialization of MN-166. Kyorin Pharmaceutical is a fully integrated Japanese pharmaceutical company and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan), sublicensable 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 several other countries are set to expire no earlier than August 10, 2018. Under the terms of the agreement, we granted to Kyorin Pharmaceutical an exclusive, royalty-free, sublicensable license to use the preclinical, clinical and regulatory databases to develop ophthalmic products incorporating the MN-166 compound anywhere in the world and non-ophthalmic products incorporating the MN-166 compound outside of our territory.

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

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



---

## **Table of Contents**

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

We have also filed a patent application directed to the use of MN-166 for the treatment of progressive neurodegenerative diseases in the United States and are pursuing counterparts of this patent application in certain foreign jurisdictions.

With the acquisition of Avigen, we own, co-own or hold licenses to three issued U.S. patents and eight pending U.S. patent applications, one of which was granted on March 29, 2011, as well as corresponding pending non-U.S. patent applications. The three patents were issued in 2009 in the United States (7,534,806- Use of Ibudilast for the Treatment of Neuropathic Pain Syndromes; 7,585,875-Substituted pyrazolo-pyridine compounds and their methods of use; and 7,622,256- Method for selecting compounds that modulate macrophage migration inhibitory factor-induced expression of ICAM-1 and/or VCAM-1) and will expire in 2025, 2027, and 2027, respectively. The patent applications are primarily related to Avigen's development portfolio of small molecule-based products and are currently directed to methods of treating various indications using AV411 and analogs.

### *MN-001*

On March 14, 2002, we entered into an exclusive license agreement with Kyorin Pharmaceutical for the development and commercialization of MN-001. We obtained an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan) sublicenseable 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, sublicenseable license under one U.S. patent and certain corresponding patents and patent applications 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 is set to expire on December 30, 2011. Certain annuities were not paid in a timely manner with respect to certain foreign patents licensed under MN-002, resulting in the lapse of patents in certain countries. In such jurisdictions, we intend to rely upon the applicable period of post-approval exclusivity, in addition to any patents that may issue from our own patent applications. Under the terms of the agreement, we granted to Kyorin Pharmaceutical an exclusive, royalty-free, sublicenseable license to use the preclinical, clinical and regulatory databases to develop ophthalmic products incorporating the MN-001 compound anywhere in the world and non-ophthalmic products incorporating the MN-001 compound outside of our territory.

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

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

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

products.

## **Table of Contents**

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

### *MN-029*

On June 19, 2002, we entered into an exclusive license agreement with Angiogene Pharmaceuticals for the development and commercialization of the ANG-600 series of compounds. Angiogene Pharmaceuticals is a privately held, British drug discovery company. We obtained an exclusive, worldwide, sublicenseable 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, sublicenseable license under three U.S. patents, two U.S. patent applications 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. 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 on January 14, 2020.

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

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

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

### *MN-305*

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

Under the terms of the agreement, we granted to Mitsubishi Tanabe Pharma Corporation a license to use our know-how and patents relating to MN-305 to develop products incorporating the MN-305 compound outside of our territory. Mitsubishi Tanabe Pharma Corporation also has the

## Edgar Filing: MEDICINOVA INC - Form 10-K

right to co-promote licensed products in our territory on terms to be agreed upon by the parties.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party. We may terminate the agreement if, in our reasonable opinion, the



## Table of Contents

safety, patient tolerability, efficacy, profile or commercial viability of MN-305 does not justify continued development with 90 days written notice to Mitsubishi Tanabe Pharma Corporation or, in the event that a third party claims that the licensed intellectual property related to MN-305 infringes such third party's intellectual property rights, with 30 days written notice.

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

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

### *MN-246*

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

The issued U.S. patent covers generic phenylethanolamines encompassed by a given chemical formula, including MN-246, processes for the production of such phenylethanolamines, a pharmaceutical composition of such phenylethanolamines and methods of use for such phenylethanolamines for the treatment of a variety of human or animal ailments, including accelerated or spasmodic gastrointestinal motility, dysuria, pollakisuria, urinary incontinence, obesity and diabetes. This U.S. patent is set to expire on October 24, 2016. Foreign counterparts have been filed or patented in other countries and are also set to expire no earlier than October 24, 2016. Under the terms of the agreement, we granted to Mitsubishi Tanabe Pharma Corporation a license to use our know-how and patents relating to MN-246 to develop products incorporating the MN-246 compound outside of our territory. Mitsubishi Tanabe Pharma Corporation also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties.

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

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



## **Table of Contents**

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

### *MN-447*

On November 1, 2006, we entered into an exclusive license agreement with Meiji Seika Kaisha for the development and commercialization of MN-447. Meiji Seika Kaisha is a fully integrated Japanese pharmaceutical company and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People's Republic of China, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sublicensable license from Meiji Seika Kaisha for MN-447 (and any other compound claimed or covered by U.S. patent 6,420,558) for any human use. This license includes an exclusive sublicensable license under one U.S. patent and certain corresponding patents and patent applications in foreign countries. The U.S. patent covering MN-447 and methods of treating an integrin  $\alpha\text{v}\beta\text{3}$ -mediated disease, platelet thrombosis, aggregation and related disorders, which issued on July 16, 2002, is set to expire on April 9, 2019. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. Under the terms of the license, we granted a license to Meiji Seika Kaisha to use our know-how and patents relating to MN-447 to develop products incorporating the MN-447 compound outside of our territory.

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

The term of the agreement is determined on a country-by-country basis and extends until the expiration of the last Meiji Seika Kaisha 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 15 years from the date of first commercial sale, 15 years from the date of first commercial sale.

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

### *MN-462*

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

to MN-462 to develop products incorporating the MN-462 compound outside of our territory.

This license agreement may be terminated by either party following an uncured breach of any material provision of the agreement by the other party upon 90 days written notice or the inability or delay in performing

---

## **Table of Contents**

under the agreement due to a force majeure event which lasts longer than 12 months. We also have the right to terminate the agreement in the event of third party intellectual property claims which are not timely remedied by us and Meiji Seika Kaisha or if, in our reasonable opinion, the safety, patient tolerability, efficacy, profile or commercial viability of MN-462 does not justify continued development. Meiji Seika Kaisha also has the right to terminate the agreement in the event that we cease development of MN-462 for a period of one year or longer.

The term of the agreement is determined on a country-by-country basis and extends until the expiration of the last Meiji Seika Kaisha 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 15 years from the date of first commercial sale, 15 years from the date of first commercial sale.

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

### *General*

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

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being issued or that, if issued, any of such patents will afford protection against competitors with similar technology or products or could not be circumvented or challenged. For example, we have U.S. patents covering the method of using MN-166 to treat MS and the method of using AV411 to treat neuropathic pain, but we do not have any composition of matter patent claims for MN-166 or AV411. 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 patent, other patents we have exclusive rights to through our licensor or any patents we may obtain for MN-166 or AV411.

In addition, if we develop certain products that are not covered by any patents, we will be dependent on obtaining market exclusivity under the data exclusivity provisions of Hatch-Waxman Act for such products. If we are unable to obtain strong proprietary rights 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.



---

**Table of Contents****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 United States 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-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  $\beta_2$ -adrenergic receptor agonist), inhaled ipratropium (an anticholinergic) and oral or injected corticosteroids. In addition, subcutaneously administered terbutaline (a  $\beta_2$ -adrenergic receptor agonist) is sometimes used to treat this condition, particularly in pediatric patients. Certain oral anti-inflammatory asthma drugs are being investigated in an intravenous form for the treatment of acute exacerbations of asthma. On March 3, 2011, Palatin Technologies, Inc. announced that the FDA has cleared Palatin's request to begin a Phase IIA proof-of-concept human trial under an IND using a subcutaneously administered formulation of PL-3994, an NPR-A agonist compound, in development for treatment of acute exacerbations of asthma. The press release states that Palatin does not intend to initiate either the proof-of-concept human trial or preclinical inhalation toxicity studies unless and until an agreement is reached with a development and marketing partner or Palatin receives funding to support the proof-of-concept Phase IIA human trial or preclinical inhalation toxicity studies from a third party, such as grant funding from an agency of the federal government.

*MN-221 for Chronic Obstructive Pulmonary Disease Exacerbations*

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

*MN-166 for Multiple Sclerosis*

## Edgar Filing: MEDICINOVA INC - Form 10-K

Our MN-166 product candidate has been in development for the treatment of MS. Current treatments for MS include the beta interferons, such as Biogen Idec Inc.'s Avonex® (beta interferon), Teva Pharmaceutical Industries Ltd.'s and Sanofi-Aventis Copaxone® (glatiramer acetate), Merck Serono's and Pfizer Inc.'s Rebif.



---

## **Table of Contents**

(beta interferon), Bayer Schering Pharma AG's Betaseron/Betaferon® and Biogen Idec Inc.'s Tysabri® (natalizumab), all of which are administered by injection. Of the many new agents in development for MS, only a few, such as Sanofi-Aventis' teriflunomide, Novartis AG's fingolimod/FTY720, Teva Pharmaceutical Industries Ltd.'s laquinimod and Biogen Idec Inc.'s BG-12, are intended for oral administration like MN-166.

### *AV411 for Other Central Nervous System Disorders*

Our AV411 product candidate has been in development for treatment of neuropathic pain and opioid withdrawal and methamphetamine addiction. Current treatments for neuropathic pain include anti-epileptics such as Pfizer Inc.'s Neurontin® (gabapentin) and Lyrica® (pregabalin), and antidepressants, including Eli Lilly & Co.'s Cymbalta® (duloxetine). We are aware of additional compounds for chronic neuropathic pain that are currently in development at numerous companies including Bayer Schering Pharma AG, GlaxoSmithKline plc, Merck & Co., Inc., Novartis AG, Pfizer Inc., Cognetix, Inc., GW Pharmaceuticals plc, Indevus Pharmaceuticals, Inc., Nastech Pharmaceutical Company Inc., Avanir Pharmaceuticals, Solace Pharmaceuticals, Pain Therapeutics, Inc., and XenoPort, Inc.

Current treatments for withdrawal symptoms include narcotics such as generic methadone and Reckitt Benckiser Pharmaceuticals, Inc.'s Suboxone® (buprenorphine) and Subutex® (buprenorphine + the narcotic antagonist naloxone). Limited non-narcotic drug candidates for withdrawal symptoms exist. Britannia Pharmaceuticals Limited's BritLofex® (Lofexidine), licensed for development in U.S. clinical trials to US WorldMeds LLC, is an alpha adrenoceptor agonist like clonidine which may have somewhat less orthostatic hypotension limitations.

### *MN-001 for Bronchial Asthma*

Our MN-001 product candidate has been in development for the treatment of bronchial asthma. There are two currently marketed leukotriene inhibitors, Merck & Co. Inc.'s Singulair® (montelukast) and AstraZeneca PLC's Accolate® (zafirlukast). There are also several products in clinical development to treat bronchial asthma, including Mitsubishi Tanabe Pharma Corporation's MCC 847 (masilukast), which is another leukotriene inhibitor currently in Phase III clinical testing in Japan.

### *MN-001 for Interstitial Cystitis*

Our MN-001 product candidate has been in development for the treatment of IC. There are two currently marketed products, Teva Pharmaceutical Industries Ltd.'s Elmiron® and Bioniche Pharma Group Limited's RIMSO-5®. There is also a product in clinical development to treat IC, Taiho Pharmaceutical Co., Ltd.'s IPD-1151 (suplatast tosilate), which is currently in Phase III clinical testing in Japan. In addition, Urigen Pharmaceuticals, Inc.'s URG-101 for the treatment of painful bladder syndrome/interstitial cystitis is in Phase II clinical testing.

### *MN-029 for Solid Tumors*

Our MN-029 product candidate has been in development for the treatment of solid tumors. There are a number of compounds in clinical development with a mechanism similar to MN-029, including Oxigene Inc.'s ZBRESTAT (fosbretabulin) and Sanofi-Aventis' AVE 8062, which

are in Phase III clinical testing.

*MN-305 for General Anxiety Disorder*

Our MN-305 product candidate has been in development for the treatment of General Anxiety Disorder. There are a number of approved products to treat Generalized Anxiety Disorder, including Eli Lilly and Company's Cymbalta® (duloxetine).

## **Table of Contents**

### *MN-221 for Preterm Labor*

Our MN-221 product candidate has been in development for the treatment of preterm labor. There are a number of oxytocin antagonists undergoing clinical evaluation, including GlaxoSmithKline plc's GSK221149, which is currently in Phase II clinical testing.

### *MN-246 for Urinary Incontinence*

Our MN-246 product candidate has been in development for the treatment of urinary incontinence. There are a number of compounds in various stages of clinical development to treat urinary incontinence. Pfizer Inc.'s Detrol (tolterodine tartrate) is a market leader, and other marketed drugs were introduced in the first quarter of 2005, including Astellas Pharma Inc.'s VESicare (solifenacin succinate) and Novartis AG's Enablex (darifenacin), both of which are anti-cholinergic agents. Ono Pharmaceutical Co., Ltd. and Kyorin Pharmaceutical have received approval for Staybla (muscarinic antagonist). Schwarz Pharma AG's Toviz (fesoterodine fumarate), another anti-cholinergic, has also recently been approved. Kissei Pharmaceutical, Astellas Pharma Inc. and GlaxoSmithKline plc also have  $\beta_3$ -adrenergic receptor agonists for the treatment of this indication.

### *MN-447 and MN-462 for Thrombotic Disorders*

Our MN-447 and MN-462 product candidates have been in development for the treatment of thrombotic disorders. Both product candidates are currently in preclinical development; therefore, we have not identified the particular thrombotic disorders that we intend to target upon reaching the clinical development stage for these product candidates. Consequently, we cannot accurately evaluate the competition we will face. Currently, the market leaders for anti-thrombotic drugs are Bristol-Myers Squibb Company's and Sanofi-Aventis' Plavix (clopidogrel) and Sanofi-Aventis' Lovenox (enoxaparin).

## **Government Regulation**

Government authorities in the United States 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 United States, 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 United States, drugs and drug testing are regulated by the FDA under the Federal Food, Drug and Cosmetic Act, as well as state and local government authorities. All of our product candidates in development will require regulatory approval by government agencies prior to

## Edgar Filing: MEDICINOVA INC - Form 10-K

commercialization. To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy, as well as detailed information on the manufacture and composition of the product and proposed labeling. Our product candidates are in the early stages of testing and none has been approved. The steps required before a drug can be approved generally involve the following:

completion of preclinical laboratory and animal tests;

submission of an IND, which must become effective before human clinical trials may begin in the United States;

## **Table of Contents**

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 an NDA accompanied by a substantial user fee;

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

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

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

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

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

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

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

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

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

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

We cannot be certain that we will successfully complete Phase I, II or III testing of our drug candidates within any specific time period, if at all. Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in

## **Table of Contents**

accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

*The NDA Process.* If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of a NDA. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical product for marketing and sale in the United States. The NDA must contain a description of the manufacturing process and quality control methods, as well as results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the submission of the NDA, unless an exemption applies.

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

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

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

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

The NDA holders and manufacturers of approved products will be subject to continual review and periodic inspections by the FDA and other authorities, where applicable, and must comply with ongoing requirements,





## **Table of Contents**

including the FDA's cGMP requirements. Manufacturers must provide certain safety and efficacy information and make certain other required reports. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, record-keeping and other requirements. The FDA periodically inspects drug manufacturing facilities to evaluate compliance with cGMP requirements. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

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

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

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research.

### *Foreign Regulatory Approval*

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

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



## **Table of Contents**

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

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

## **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. As of March 29, 2011, we had 18 full-time employees, following a reduction in force, or RIF, to down-size the company to save costs. We believe even after the RIF that our relations with our employees are good, and we have no history of work stoppages.

## **Recent Developments**

### *Joint Venture Letter of Intent*

On March 3, 2011, we executed a joint venture agreement with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd., which provides for the establishment of a joint venture company to develop and commercialize MN-221 in China. The agreement provides that the business scope of the joint venture company will be to in-license authorized drug candidates from us, manage and operate a facility to manufacture such drug candidates for the Chinese market and promote, distribute and sell such drug candidates in the Chinese market. The joint venture company will also be responsible for conducting all clinical trials necessary to gain regulatory approval in China. The joint venture company will initially conduct the activities described above with respect to MN-221; however other drug candidates may be brought within the scope if the parties to the agreement unanimously agree. We will contribute 4,290,000 RMB in cash for a 30% interest in the joint venture. Our responsibilities relate to granting rights to MN-221 in China to the joint venture, while the other parties are responsible for providing funding for the joint venture's activities. We will receive a license fee payment equal to our capital contribution for the license to MN-221. Any amendment requires the written agreement of all three parties thereto.

### *Avigen Management Transition Plan*

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

immediately prior to the effective time of the merger.

## **Table of Contents**

### *Firm Commitment Underwritten Public Offering*

On March 23, 2011, we announced a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of \$3.00 per unit for gross proceeds of \$8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of \$3.56 per share. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallocation. On March 29, 2011, we received net proceeds of approximately \$7.9 million, after underwriter discount and underwriter expenses and no warrants exercised.

### *Oxford Loan Update*

In anticipation of not achieving either of the affirmative covenants required under our loan agreement with Oxford Finance Corporation, or Oxford, by March 31, 2011, we negotiated with Oxford the repayment of the loan in full on April 1, 2011, wherein Oxford agreed to waive the early payment penalty of approximately \$437,000.

## **Company Information**

We were originally incorporated in the State of Delaware in September 2000. Our principal executive offices are located at 4350 La Jolla Village Drive, Suite 950, San Diego, CA 92122. Our telephone number is (858) 373 1500. Our website is [www.medicinova.com](http://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 of Form 10K.

## **Table of Contents**

### **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 are a development stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the year ended December 31, 2010, we had a net loss of \$20.2 million and our accumulated deficit was approximately \$267.5 million. If we are successful in securing a strategic collaboration or in raising additional capital to support the expansion of our business, our annual net losses may increase over the next several years as we expand our infrastructure and incur significant costs related to the development of our product candidates.

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

We believe our existing cash and cash equivalents at December 31, 2010, together with the \$7.9 million of net proceeds from our public offering which closed on March 29, 2011, will be sufficient to fund our operating requirements and debt repayment obligations for at least the next 12 months. We have based our cash estimates on our anticipated repayment of the Oxford loan on April 1, 2011, pursuant to an executed pay-off letter between us and Oxford dated March 31, 2011, and our assumptions related to when our ongoing clinical trial for MN-221 will be completed.

These assumptions may prove to be wrong, and we could spend our available financial resources before we complete the clinical trial. Our future capital 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;

## Edgar Filing: MEDICINOVA INC - Form 10-K

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;

---

**Table of Contents**

the costs associated with the operations or wind-down of any business it 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 increase in connection with ongoing and planned clinical trials primarily related to MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, and any other development activities that it may initiate. In addition, our general and administrative expenses may increase in future periods as a result of several factors, including our research and development activities, our business development activities and any expansions in our infrastructure related to such activities. Consequently, we expect to continue to incur significant and increasing 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 fail to obtain the capital necessary to fund our operations, we will be unable to develop and commercialize our product candidates.***

We have consumed substantial amounts of capital since our inception. From our inception to December 31, 2010, we had an accumulated deficit of \$267.5 million. Our cash and cash equivalents were approximately \$28.3 million at December 31, 2010.

Our business will continue to require us to incur substantial research and development expenses and we do not expect to be able to fund these expenses solely from upfront cash or milestones from collaborations or strategic alliances. As such we may be required to raise capital from one or more sources in the near term to continue our operations at or close to the levels currently conducted. We believe that without raising additional capital soon from accessible sources of financings, we will not otherwise have adequate funding to complete the development of MN-221 including pivotal clinical trials or the commercialization of any products we successfully develop. Our business plan assumes that we will use approximately \$15.2 million of our existing cash resources to fund repayment of our loan from Oxford on April 1, 2011 pursuant to an executed pay-off letter dated March 31, 2011. We also have assumed that all of our restricted cash will be used to pay our convertible notes that mature on June 18, 2011, although one or more holders may elect to convert some or all of the convertible notes to common stock at a conversion rate of \$6.80 per share prior to the maturity date. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, arrangements with partners, or from other sources, or 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, further reduce general and administrative expenses and have a substantial negative effect on our results of operations and financial condition.

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

To date, we have funded our operations primarily from sales of our securities and, to a lesser extent, debt financing. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argenes, Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. We completed our agreement with Asahi Kasei Pharma Corporation and terminated our agreement with Argenes, Inc.; therefore, we will not generate any further revenues from these agreements. We





---

## **Table of Contents**

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 two prioritized product candidates, MN-221 and MN-166/AV411, and we cannot be certain that either of these product candidates 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, selling, 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 United States 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. We currently have two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations and MN-166/AV411, a combined ibudilast product development program covering MS and other CNS disorders, and the success of our business currently depends on their successful development and commercialization. Neither of these product candidates has completed the clinical development process; therefore, we have not submitted an NDA or foreign equivalent or received marketing approval for either of these two prioritized product candidates. In addition, we are not currently planning to fund any further significant clinical development of MN-166/AV411 until such time that we are able to secure a strategic collaboration to advance the combined development programs, which may delay or impede the process of completing clinical trials and seeking regulatory approval for this product candidate. We also cannot assure you that we will be able to secure such a strategic collaboration on attractive financial and other terms, or at all.

The clinical development programs for MN-221 and MN-166/AV411 may not lead to commercial products for a number of reasons, including our clinical trials' failure to demonstrate to the FDA's satisfaction that these product candidates are 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 either MN-221 or MN-166/AV411 in a timely manner would have a material and adverse impact on our business and our stock price.

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

Our product candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. The process of obtaining FDA and other regulatory approvals is costly, time-consuming, uncertain and subject to unanticipated delays. To receive regulatory approval for the commercial sale of any of our product candidates, we must conduct, at our own expense, adequate and well-controlled clinical trials in human patients to demonstrate the efficacy and safety of the product candidate. Clinical testing is expensive, takes many years and has an uncertain outcome. To date, we have obtained regulatory authorization to conduct clinical trials for eight of our product development programs. Investigational New Drug Applications, or INDs, were approved by the FDA and are active for seven of our product candidates. We also have obtained Clinical Trial Authorizations, or CTAs, for the ongoing Phase II clinical trial for MN-221 in Canada, Australia and New Zealand. Through the acquisition of Avigen, we have assumed responsibility for AV411 clinical trials including one active IND for neuropathic pain and cross-reference and drug product support

---

## **Table of Contents**

of the NIDA-funded opioid withdrawal investigator-initiated IND with Columbia University drug addiction clinical researchers. In the third quarter of 2010, a NIDA-funded investigator-initiated IND with University of California Los Angeles was given approval by the FDA to proceed with an initial trial of our neurological drug candidate, ibudilast (MN-166/AV411), as a potential new pharmacotherapy for methamphetamine addiction. The study will be led by established clinical research investigators in the treatment of drug addiction.

It may take years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell any products derived from any of our product candidates that are ultimately approved by the FDA or foreign regulatory authorities. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, in October 2007, we announced that our Phase II clinical trial of MN-305 for the treatment of insomnia failed to achieve statistical significance in its primary endpoint, and, as a result, we terminated development of MN-305 for the treatment of insomnia. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after 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;

patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;

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

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

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

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

*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

**Table of Contents**

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 ongoing and planned 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. For example, through the third quarter of 2010 we continued to experience an overall slower than anticipated enrollment of patients for our ongoing Phase II clinical trial evaluating the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma for various reasons such as the length of time required to stay in the emergency room, or ER, during the treatment period. Our enrollment rates have improved since September 30, 2010, we believe, due in part to changes to the protocol that shortened the length of time the patient needed to stay in the ER and that gave the ER physician control over the standard-of-care that was given to the patient during the treatment period. However, there is no assurance that we will complete enrollment in the second half of 2011.

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.

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;

## Edgar Filing: MEDICINOVA INC - Form 10-K

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

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

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

## **Table of Contents**

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

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

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

With the exception of AV411, we license the rights to develop and market our product candidates. Currently, we have licensed rights relating to eight compounds for the development of ten product candidates.

We are obligated to develop and commercialize these 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.

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

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

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

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



## Table of Contents

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. Following completion of the Phase II clinical trial for MN-166 for the treatment of MS in the second quarter of 2008 and the acquisition of AV411 in December 2009, we do not plan to undertake any further significant clinical development activities for any of our product candidates other than MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, other than those activities deemed necessary to maximize each product candidate's value, until such time that we are successful in entering into a partnership or collaboration to further development of such 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;

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.

---

**Table of Contents**

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

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

***Our loan and security agreement with Oxford requires principal repayment on March 31, 2011 if we do not achieve certain affirmative covenants, and the agreement requires us to pledge substantial assets and also contains various covenants that may restrict our business and financing activities.***

On May 10, 2010, we entered into the Loan Agreement with Oxford governing the terms of our \$15 million senior secured credit facility. We were required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan, we are required to make payments of outstanding principal and interest in 30 equal monthly installments. The Loan Agreement also requires that on or before March 31, 2011 we must have either (i) entered into a collaboration, joint venture or partnership with a non-affiliate providing for up-front cash proceeds to us (with such proceeds received on or before March 31, 2011) of not less than \$15 million from either or a combination of an upfront payment(s) or proceeds from the sale or conversion of our securities issued in connection therewith or (ii) received positive Phase IIb data on MN-221, as defined in a completed partnership or joint venture agreement relating to MN-221, or had a positive-end of Phase II meeting with the FDA and obtained the approval of the board of directors to proceed to Phase III with MN-221. We do not anticipate achieving either of these affirmative covenants by March 31, 2011. However, Oxford has agreed to waive early payment penalties of approximately \$437,000 if we repay the loan in full on April 1, 2011.

The Loan Agreement is secured by a first priority security interest in substantially all of our assets, other than intellectual property. If we fail to repay the loan when it matures, the lender could initiate foreclosure proceedings against our pledged assets. Any foreclosure proceedings would have a material adverse effect on our business, financial condition and results of operations.

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

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

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,

---

## **Table of Contents**

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 United States or abroad.

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

If we fail to comply with applicable regulatory requirements in the United States 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.

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

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

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



## **Table of Contents**

the CROs, clinical investigators and other service providers may have relationships with other commercial entities, some of which may have competitive products under development or currently marketed, and our competitive position could be harmed if they assist our competitors. If any of these third parties does not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates. In addition, while we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

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

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

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

To date, we have entered into an agreement with Hospira Worldwide, Inc. for the development and supply of finished product of MN-221 for the treatment of acute exacerbations of asthma utilizing Hospira's proprietary ADD-Vantage drug delivery system that we intend to use in clinical trials and the commercial market if MN-221 receives regulatory approval. In addition to Hospira's proprietary drug delivery system, we anticipate entering into a commercial supply agreement for finished product of MN-221 in standard vials. However, other than Hospira, we do not have agreements established regarding commercial supply of finished product of MN-221 in standard vials or for the active pharmaceutical ingredient, or API, or finished product for any of our product candidates. In particular, pursuant to our license agreement with Kissei Pharmaceutical Co. Ltd., Kissei Pharmaceutical has the exclusive right to manufacture the commercial supply of the API for MN-221. Therefore, we will need to successfully negotiate a commercial supply agreement with Kissei Pharmaceutical on commercially reasonable terms, or another third-party manufacturer in the event that we are unable to reach agreement with Kissei Pharmaceutical, in order to manufacture the API for MN-221 on a commercial scale if MN-221 is approved by the FDA or other regulatory authorities for commercial sale. We will also need to successfully negotiate a supply agreement with a third-party manufacturer on commercially reasonable terms in order to manufacture the finished product of MN-221 in standard vials. 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

## **Table of Contents**

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 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





## **Table of Contents**

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.

*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-221 or MN-166/AV411, our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the terms of its use, or it may not include one or more of our intended indications.

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

issue warning letters or untitled letters;

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

impose other civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing clinical trials;

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

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

seize or detain products or require a product recall.

*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 payors and our profitability and growth will depend on a number of factors, including:

demonstration of efficacy;

changes in the standard of care for the targeted indication;

relative convenience and ease of administration;

**Table of Contents**

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 payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

***If our 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 payors, 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 payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors 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 payors may conclude that our products are less safe, less clinically effective or less cost-effective than existing products, and third-party payors 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 payors, 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 payors make reimbursement available, payment levels may not be sufficient to make the sale of our products profitable.

Also, 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 payors 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 payors provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies

## Edgar Filing: MEDICINOVA INC - Form 10-K

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 payors, including government payors, are instituting could have a material adverse effect on our ability to operate profitably.

---

**Table of Contents**

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

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

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

difficulties in integrating the development program for the acquired product candidate into our existing operations;

diversion of financial and management resources from existing operations;

risks of entering new markets or technologies and of receiving regulatory approval;

inability to generate sufficient revenues to offset acquisition costs; and

delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

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

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

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued services with us, whether through employment, service on our board of directors or a consulting agreement. We are also substantially dependent on the continued services of clinical development personnel because of the highly technical nature of our product development programs. We are not presently aware of any plans of our executive officers or key personnel to retire or leave employment with the company. Each of our executive officers is party to an employment agreement that continues in effect until the earliest of termination of employment upon (i) consent of the parties, (ii) cause or other material breach of the agreement, (iii) death or permanent disability and (iv) three months' written notice. Following termination of employment, these individuals may engage in other businesses that may compete with us.

If we acquire or license new product candidates, our success will depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our product development programs depend on our ability to attract and retain highly experienced clinical development and regulatory personnel. However, we face competition for experienced

## **Table of Contents**

scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our corporate headquarters is located. Our short operating history and the uncertainties attendant to being a development-stage biopharmaceutical company could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives. In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These third parties are not our employees and may have commitments to, or contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with our product candidates.

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

*If we are unable to establish our sales and distribution capabilities, we will be unable to successfully commercialize our product candidates.*

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in obtaining regulatory approvals for any of our product candidates or acquiring other approved products, we will need to establish sales, marketing and distribution capabilities on our own or with partners in order to commercialize an approved product. The acquisition or development of an effective sales and marketing infrastructure will require a significant amount of our financial resources and time and could negatively impact our commercialization efforts, including delay of a product launch. We may be unable to establish and manage a sufficient or effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore hindering our ability to generate revenues and achieve or sustain profitability. In addition, if we are unable to develop internal sales capabilities, we will need to contract with third parties or establish a partnership to market and sell the product. If we are unable to establish adequate sales and marketing 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 United States, we may be required to market our product candidates outside of the United States 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 United States 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 proposals to implement similar controls in the United States to continue. Another example of proposed reform that could affect our business is drug reimportation into the United States. 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 President signed into law the Patient Protection and Affordable Care Act, which imposes numerous provisions over a four-year period. We have begun to assess the impact of this Act, but, at this early stage the likely impact cannot be ascertained with any degree of certainty.



## **Table of Contents**

***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.

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

As of March 29, 2011, we had 18 full-time employees, following a reduction in force which took place in January 2011, wherein we down-sized the company to save costs. If we are successful in securing a strategic collaboration or raising additional capital, our management, personnel,

## Edgar Filing: MEDICINOVA INC - Form 10-K

systems and facilities currently in place may not be adequate to support the company's needs. For example, we may hire additional personnel in clinical development, regulatory affairs and business development to further strengthen our core competencies or choose to develop sales, marketing and distribution capabilities for certain of our product candidates. Our need to effectively manage our operations, growth and product development programs requires that we:

manage our clinical trials effectively;

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

ensure that our consultants, CROs and other service providers successfully carry out their contractual obligations, provide high quality results and meet expected deadlines; and

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

**Table of Contents**

We may be unable to successfully implement these tasks on a larger scale, which may impact our ability to timely achieve our development and commercialization goals, if at all.

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

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

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

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

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

the unpredictable effects of collaborations during these periods;

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

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

the costs of any litigation;

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

general and industry-specific economic conditions.

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

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

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

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

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

## Table of Contents

Market until its closure in 2010) of the Osaka Securities Exchange, or OSE, also require that we comply either with Section 404 of the Sarbanes-Oxley Act or equivalent regulations in Japan and we elected to comply with Section 404. As a result, we are required to perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404. We are subject to attestation by our registered public accounting firm on our report regarding internal control over financial reporting for the year ended December 31, 2010 under Japanese securities laws. Our efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. We cannot be certain that a material weakness will not be identified when we test the effectiveness of our controls in the future. If a material weakness is identified, we could be subject to sanctions or investigations by Nasdaq, the SEC, the OSE or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

***We identified a material weakness in our internal control over financial reporting, and any failure to effectively remediate the material weakness identified as of September 30, 2010 could result in material misstatements in our financial statements.***

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that creates a reasonable possibility that a material misstatement of our interim or annual financial statements will not be prevented or detected on a timely basis. In the course of carrying out the required quarterly evaluation and preparing the financial statements as of September 30, 2010, management identified control overrides and policy deviations by one of our senior executive officers. The following deficiencies in internal control over financial reporting, which collectively represented a material weakness in our internal control over financial reporting, were reported by management to our Audit Committee:

A senior executive officer lacked a sufficient control awareness related to compliance with our Code of Conduct, contract review and approval policies, and certain human resources policies and procedures for employee terminations.

We did not design adequate human resources policies and procedures related to ensuring compliance with our Code of Conduct.

Our management team is committed to achieving and maintaining a strong control environment and an overall tone within the organization that empowers all employees to act with the highest standards of ethical conduct. In addition, management remains committed to the process of developing and implementing improved corporate governance and compliance initiatives. Our Board and management team implemented the following remediation plan to address the material weakness and enhance our internal controls:

The Board revised our contract review and approval policy to require the signature of two executive officers, one of whom must be the Chief Financial Officer or his designee;

The Board assigned additional responsibility to the Compensation Committee, including requirements that the Compensation Committee approve (1) any salary increases/adjustments greater than 10%, (2) any promotion or hiring into any position at the level of Vice President or above, (3) the salary of any individual promoted or hired for any position at the level of Vice President or above and (4) the granting to any employee of benefits or other perquisites not generally available to all employees;

The Board changed the reporting lines of our Vice President of Clinical Development and our Manager of Human Resources and Administration; and

## Edgar Filing: MEDICINOVA INC - Form 10-K

Due to the appearance of a possible conflict of interest, the Board granted a waiver under our Code of Conduct to a senior executive officer and one of our other employees with respect to any joint real estate and banking transactions to which they are party as of November 13, 2010.

## **Table of Contents**

In addition, subsequent to September 30, 2010, our Board formed a Strategic and Operational Review Committee comprised of certain members of our Board and our senior management team that has been tasked with reviewing all key strategic and operational matters. Our Board and our senior management team may engage additional third-party specialists to further review and identify any other enhancements to our internal controls that may help prevent future significant deficiencies and/or material weaknesses.

We have tested our remediation plan with the assistance of a third party and we have conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010. The framework on which such evaluation was based is contained in the report entitled *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the *COSO Report* ). Based on our evaluation under the criteria set forth in the *COSO Report*, our management concluded our internal control over financial reporting was effective as of December 31, 2010. Our registered public accounting firm has issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2010 wherein they opine on the effectiveness of our internal control over financial reporting as of December 31, 2010. 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.

If significant deficiencies or additional material weaknesses in our internal control are discovered or occur in the future, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation and, our common stock could be delisted from Nasdaq and the Jasdak Market of the OSE.

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

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

### ***We may not realize all of the anticipated benefits of the combined clinical development programs based on ibudilast.***

We may not be able to successfully secure a strategic collaboration to advance the combined ibudilast development programs. Following completion of the Phase II clinical trial of MN-166 for the treatment of MS in the second quarter of 2008 and the acquisition of AV411 in December 2009, we have not undertaken, nor do we plan to undertake, any further significant clinical development of MN-166/AV411 until such time that we secure a strategic collaboration to advance the combined clinical development of MN-166/AV411 ibudilast-based development program. We cannot assure you that we will be able to secure such a strategic collaboration or otherwise further advance, or recognize value from, a combined MN-166/AV411 clinical development program.

---

## **Table of Contents**

### **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/AV411 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/AV411 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 a method of use patent for MN-166, which covers the use of the API found in our MN-166 product candidate for the treatment of MS. We also have a method of use patent for AV411 for the treatment of neuropathic pain syndromes.

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

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

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

obtain and maintain patents to protect our product candidates;





**Table of Contents**

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States 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

---

**Table of Contents**

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 United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates and which could have a material effect in developing and commercializing one or more of our product candidates. The owner of a patent that is arguably infringed can bring a civil action seeking to enjoin an accused infringer from importing, making, marketing, distributing, using or selling an infringing product. We may need to resort to litigation to enforce our intellectual property rights or to seek a declaratory judgment concerning the scope, validity or enforceability of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

payment of actual damages, royalties, lost profits, potential enhanced damages and attorneys' fees, if any infringement for which we are found liable is deemed willful, or a case against us is determined by a judge to be exceptional;

injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;

having to enter into license arrangements that may not be available on reasonable or commercially acceptable terms; or

significant cost and expense, as well as distraction of our management from our business.

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

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

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

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

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

## Edgar Filing: MEDICINOVA INC - Form 10-K

Despite the listing of our common stock on the Nasdaq Global Market and the Jasdaq Market of the Osaka Securities Exchange in Japan, trading volume in our securities has been light and an active trading market may not develop for our common stock. In December 2010, our average trading volume was approximately 1,700 shares per day on the Nasdaq Global Market and approximately 25,000 shares per day on the Jasdaq Market.

**Table of Contents**

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 4, 2005 through December 31, 2010, our common stock has traded as high as approximately \$42.00 and as low as approximately \$1.40. 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, and particularly our prioritized product candidates;

the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;

FDA or foreign regulatory actions, including failure to receive regulatory approval for any of our product candidates;

announcements of technological innovations, new commercial products or other material events by us or our competitors;

disputes or other developments concerning our intellectual property rights;

market conditions in the pharmaceutical and biotechnology sectors;

actual and anticipated fluctuations in our quarterly or annual operating results;

price and volume fluctuations in the overall stock markets;

any potential delisting of our securities;

changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;

additions or departures of key personnel;

discussions of our business, management, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;

litigation or public concern about the safety of our potential products;

public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques; or

## Edgar Filing: MEDICINOVA INC - Form 10-K

regulatory developments in the United States and in foreign countries.

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

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These

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

## **Table of Contents**

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

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

We have also registered all common stock that we may issue under our current employee benefits plans and upon exercise of warrants. As a result, these shares can be freely sold in the public market upon issuance, subject to the terms of the underlying agreements governing the grants and the restrictions of the securities laws. In addition, our directors and officers may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

*Anti-takeover provisions in our charter documents and under Delaware law and the existence of our stockholder rights plan 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 <sup>2</sup>/<sub>3</sub> percent stockholder approval; and

provide for a classified board of directors with staggered terms.

In addition, we adopted a stockholder rights plan in November 2006, pursuant to which each share of our common stock includes an attached preferred stock purchase right, that is designed to impede takeover transactions that are not supported by our board of directors.



## Edgar Filing: MEDICINOVA INC - Form 10-K

We also may be subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In any event, these provisions may delay or prevent a third party from acquiring us. Any such delay or prevention could cause the market price of our common stock to decline.

## **Table of Contents**

*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 lease approximately 12,699 square feet of office space at our headquarters in San Diego, California under a lease that expires in August 2011. We have no laboratory, research or manufacturing facilities, and we currently do not plan to purchase or lease any such facilities, as such services are provided to us by third-party service providers. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms. In addition to our headquarters, we also lease approximately 1,726 square feet of office space in Tokyo, Japan under a lease that expires in May 2011. Currently, we do not have plans to renew our San Diego lease agreement. We are considering month-to-month lease options, as well as reducing the size of our facility space and/or utilizing virtual offices.

### **Item 3. Legal Proceedings**

On March 3, 2011, we received a legal letter from a former employee who had been terminated in January 2011 pursuant to our planned reduction-in-force to save costs. The legal letter did not assert a claim outright; however, there were allegations made in the legal letter that could threaten litigation against us. We have engaged legal counsel in connection with the possibility of a lawsuit given this legal letter and the fact that this former employee's separation agreement has expired. No accrual has been made for this threatened lawsuit in our financial statement as of December 31, 2010. In the event of a lawsuit, we intend to defend ourselves.

We may be a party to lawsuits in the normal course of business. Litigation and governmental investigations can be expensive and disruptive to normal business operations. Moreover, the results of legal proceedings are difficult to predict. Significant judgments or settlements in connection with legal proceedings may have a material adverse effect on our business, financial condition and results of operations. We are not a party to any material legal proceedings.

### **Item 4. Reserved**



**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

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

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

	<b>Common Stock Price</b>	
	<b>High</b>	<b>Low</b>
<b>Fiscal year ended December 31, 2009</b>		
First quarter	\$ 3.20	\$ 1.43
Second quarter	\$ 4.25	\$ 1.93
Third quarter	\$ 7.76	\$ 4.00
Fourth quarter	\$ 8.44	\$ 5.60
<b>Fiscal year ended December 31, 2010</b>		
First quarter	\$ 9.00	\$ 6.09
Second quarter	\$ 7.51	\$ 4.75
Third quarter	\$ 6.40	\$ 4.44
Fourth quarter	\$ 5.95	\$ 4.51

**Holder of Common Stock**

As of March 29, 2011, there were approximately 7,000 holders of record of our common stock.

**Dividend Policy**

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

**Use of Proceeds**

On March 23, 2011, we announced a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of \$3.00 per unit for gross proceeds of \$8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of \$3.56 per share. Net proceeds received, after estimated underwriting discount and underwriter expenses, and assuming the warrants are not exercised, was approximately \$7.9 million. The offering closed on March 29, 2011. We intend to use \$4.5 million of such net proceeds to fund development work for MN-221 and \$500,000 of such net proceeds for other research and development on MN-166/AV411. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, technologies, product candidates or other intellectual property, although we have no present commitments or agreements to do so.

**Table of Contents****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.

**Performance Graph**

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

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

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

**Table of Contents**

**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 January 1, 2010, to the Jasdaq Market (total index). The graph assumes an initial investment of \$100 on January 1, 2010, and that all dividends were reinvested.

	<b>3/31/2010</b>	<b>6/30/2010</b>	<b>9/30/2010</b>	<b>12/30/2010</b>
MediciNova, Inc.	\$ 100	\$ 67	\$ 64	\$ 60
Jasdaq Total Index	\$ 100	\$ 96	\$ 90	\$ 98

\* 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.

**Table of Contents**

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

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

	<b>12/7/2006</b>	<b>12/31/2007</b>	<b>12/31/2008</b>	<b>12/31/2009</b>	<b>12/31/2010</b>
MediciNova, Inc.	\$ 100	\$ 38	\$ 13	\$ 58	\$ 39
NASDAQ Biotechnologies Index	\$ 100	\$ 101	\$ 88	\$ 102	\$ 117
NASDAQ Composite Index	\$ 100	\$ 109	\$ 65	\$ 93	\$ 109



**Table of Contents****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,					September 26, 2000 (inception) to December 31, 2010
	2010	2009	2008	2007	2006	
<b>Statements of Operations Data:</b>						
Revenues	\$	\$	\$	\$	\$	264 \$ 1,558
Operating expenses:						
Cost of revenues					147	1,258
Research and development	9,711	10,873	13,828	42,121	32,171	154,257
General and administrative	8,172	10,366	8,773	11,373	9,624	97,199
Total operating expenses	17,883	21,239	22,601	53,494	41,942	252,714
Operating loss	(17,883)	(21,239)	(22,601)	(53,494)	(41,678)	(251,156)
(Impairment charge)/gain, net on investment securities and ARS put	(785)	310	(1,260)			(1,735)
Foreign exchange gain/(loss)	4	(14)	(88)			(98)
Other expense	(181)					(181)
Interest expense	(1,768)	(242)				(2,010)
Other income, net	439	823	2,038	4,611	5,988	19,059
Income Taxes	(13)	(7)	(14)	(20)		(54)
Net loss	(20,187)	(20,369)	(21,925)	(48,903)	(35,690)	(236,175)
Accretion to redemption value of redeemable convertible preferred stock						(99)
Deemed dividend resulting from beneficial conversion on Series C redeemable convertible preferred stock						(31,264)
Net loss applicable to common stockholders	\$ (20,187)	\$ (20,369)	\$ (21,925)	\$ (48,903)	\$ (35,690)	\$ (267,538)
Basic and diluted net loss per share	\$ (1.63)	\$ (1.68)	\$ (1.82)	\$ (4.16)	\$ (3.52)	
Shares used to compute basic and diluted net loss per share	12,410,576	12,105,835	12,072,027	11,752,139	10,130,920	

**Table of Contents**

	2010	2009	As of December 31,		2006
			2008	2007	
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and current investment securities	\$ 28,252	\$ 43,497	\$ 19,297	\$ 70,635	\$ 104,051
ARS put current		2,557			
Restricted cash, investment and letter of credit- current	29,313				
Working capital	21,554	24,500	17,836	65,938	100,102
Restricted cash, investment and letter of credit- long-term		31,223			
Investment-long-term		2,085	24,047		
ARS put long-term			5,793		
Total assets	72,934	94,327	50,224	73,752	111,591
Current portion of long-term debt	4,952				
Long-term debt, less current portion	9,484				
ARS loan payable		17,605			
Convertible notes	28,626	29,258			
Deficit accumulated during the development stage	(267,538)	(247,351)	(226,982)	(205,057)	(156,154)
Total stockholders equity	24,704	40,013	48,045	66,608	100,981

## **Table of Contents**

### **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion and analysis together with Item 6. Selected Financial Data and the 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 diseases with unmet medical need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope.

We are a development stage company. We have incurred significant net losses since our inception. At December 31, 2010, from inception, our accumulated deficit was approximately \$267.5 million, including \$48.3 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders' warrants. We expect to incur substantial net losses for the next several years as we continue to develop certain of our existing product development programs, primarily MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, and over the long-term if we are successful in expanding our research and development programs and acquiring or in-licensing products, technologies or businesses that are complementary to our own.

We have acquired licenses to eight compounds for the development of ten product candidates. Our development pipeline consists of eight product development programs which have been in clinical development for the treatment of acute exacerbations of asthma, diabetic neuropathic pain, opioid addiction, MS, bronchial asthma, IC, solid tumor cancers, Generalized Anxiety Disorders/insomnia, preterm labor and urinary incontinence, and two product development programs which have been in preclinical development for the treatment of thrombotic disorders. In addition, we have expanded our development program for MN-221 for the treatment of COPD exacerbations.

In December 2009 we acquired Avigen, a biopharmaceutical company that focused on identifying and developing differentiated products to treat patients with serious disorders, whose potential product candidate is AV411, a microphage migration inhibitor and a glial attenuator, for CNS disorders, such as neuropathic pain, and opioid addiction and withdrawal and methamphetamine addiction. Avigen's AV411 and our MN-166 are both ibudilast, an orally available, small molecule therapeutic. To date, we continue to integrate the two ibudilast-based product development programs and pursue discussions with potential partners to secure a strategic collaboration to advance clinical development of the combined development programs.

#### ***Avigen Transaction***

## Edgar Filing: MEDICINOVA INC - Form 10-K

On December 18, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of ours, merged with and into Avigen, with Avigen continuing as the surviving entity and wholly-owned subsidiary of ours. Under the terms of the merger, we issued \$29.4 million in secured convertible notes that mature on June 18, 2011, the 18-month anniversary of the closing of the merger. Holders of these convertible notes may convert their notes into our common stock at an initial conversion price of \$6.80 per share. At the maturity of the convertible notes, the remaining holders would be paid out the same per share amount as the Avigen shareholders that elected to

---

**Table of Contents**

receive cash at the merger closing, plus accrued interest. As part of the merger consideration, the former Avigen shareholders were also entitled to receive approximately \$0.04 per share, which was paid in two increments in 2010, and rights under contingent payment rights issued as part of the merger consideration. The amount to be paid in the two installments was net of a reconciliation of Avigen expenses and a letter of credit after expiry. Under the first and second installments paid out, we paid \$140,119 and \$73,449, respectively, to Avigen shareholders who elected payment in cash and we issued an additional principal amount of \$685,917 and \$359,551, respectively, in convertible notes to Avigen shareholders who elected payment in convertible notes in lieu of a cash payment.

As a result of the Avigen transaction, our consolidated financial statements include Avigen's operations after the completion of the acquisition. We accounted for the Avigen merger using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that most assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and that the fair value of acquired in-process research and development, or IPR&D, be recorded on the balance sheet. Also, transaction costs are expensed as incurred. As a result of the Avigen transaction we recorded \$4.8 million of IPR&D related to Avigen's AV411 asset and we originally recorded \$9.1 million of goodwill related to the excess purchase price over the assigned values of the net assets acquired. With the reconciliation of expenses performed and the remaining amount of the letter of credit known upon expiry, goodwill was adjusted by approximately \$0.5 million to \$9.6 million to reflect the increase in liabilities assumed. The goodwill was primarily a result of the conversion feature related to the convertible notes issued pursuant to the merger agreement. Our annual test date for IPR&D and goodwill impairment is December 31. We operate as one reporting segment and, during the year ended December 31, 2010 through the date of this report, there were no triggering events, market conditions (such as a drop in our stock price by more than 50%) or other factors (such as adverse clinical trial results) that would indicate possible or actual impairment of IPR&D or goodwill.

***Convertible Notes***

At the closing of the Avigen merger, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into an indenture. Under the terms of a separate trust agreement, or Trust Agreement, \$29.4 million, which represents the First Payment Consideration less \$6.0 million paid out to Avigen shareholders who elected cash payment and the initial principal amount of the convertible notes, or Convertible Notes, was deposited with a trust agent for the benefit of the holders and us (the amount of such deposit together with interest accrued and capitalized thereon, the Property). Provided no event of default has occurred and is continuing, we will be able to direct the investment and reinvestment of the Property in certain approved investment options, including certain money market funds. At the maturity of the Convertible Notes on June 18, 2011, the 18-month anniversary of the closing of the merger, we plan to use the Property to pay the principal amount of, and accrued interest on, the Convertible Notes.

The Convertible Notes are our secured obligations, and the indenture does not limit other indebtedness of ours, secured or unsecured. The indenture contains limited covenants, including a requirement that we deliver to holders of the Convertible Notes quarterly statements setting forth the principal amount of the Convertible Notes at the close of the fiscal quarter as well as information regarding the amount of interest capitalized to such Convertible Notes during the fiscal quarter.

Holders of the Convertible Notes may submit conversion notices, which are irrevocable, instructing the trustee to convert such Convertible Notes into shares of our common stock at an initial conversion price of \$6.80 per share. Following each conversion date, which date generally is the final business day of each calendar month, we will issue the number of whole shares of common stock issuable upon conversion as promptly as practicable (and in any event within 10 business days). Any fractional shares (after aggregating all Convertible Notes being converted by a holder on such date) will be rounded down and we will deliver cash out of the separate trust for the current market value of the fractional share. The indenture includes customary anti-dilution adjustments and events of default.

## **Table of Contents**

### ***Contingent Payment Rights***

At the closing of the Avigen merger, we, Avigen and American Stock Transfer & Trust Company, LLC, as rights agent, entered into a Contingent Payment Rights Agreement, or CPR Agreement. The CPR Agreement sets forth the rights that former Avigen stockholders have with respect to each CPR held after the closing of the merger. The CPR Agreement provides for the payment of the following amounts on a pro rata basis:

if the first milestone payment under Avigen's agreement with Genzyme, or the Genzyme Agreement, is received before August 18, 2011, \$6,000,000 or such lesser cash amount paid by Genzyme;

if the first milestone payment has not occurred and the Parkinson's Product, as defined in the Genzyme Agreement, is sold or otherwise disposed of by us before August 18, 2011, 50 percent of the net proceeds of such sale or disposition received before August 18, 2011; and

if the trust established pursuant to the Avigen MTP is terminated, the amount remaining in such trust upon termination (less any payments required to be made under Avigen's Management Transition Plan Trust Agreement), such amount currently estimated at \$624,000. As of December 31, 2010, the Avigen MTP has not been terminated.

All payments will be made on a pro rata basis. In each case, the payments will be net of any related taxes and out-of-pocket costs, damages, fines, penalties and expenses incurred by us. The contingent payment rights are not transferable, except in limited circumstances.

### ***Revenues and Cost of Revenues***

We recognized no revenues for each of the years in the three-year period ended December 31, 2010.

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

Our research and development expenses consist primarily of the license fees related to our product candidates, salaries and related employee benefits, costs associated with the preclinical and clinical development of our product candidates, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. We use external service providers to manufacture our product candidates 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; therefore, these research and development expenses consist substantially of external costs, such as 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 consist of costs of compensation and other expenses for research and development personnel, supplies, materials, facility costs and depreciation. Research and development costs are expensed as incurred or accrued based on certain contractual factors such as for estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, accruals are adjusted. To date, our yearly budget estimates have not differed significantly from the actual costs incurred.



**Table of Contents**

The following table summarizes our research and development expenses for the periods indicated for each of our product candidates. 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	Disease/Indication	Year ended December 31,		
		2010	2009	2008
MN-221	Acute exacerbations of asthma and COPD	\$ 7,304	\$ 8,419	\$ 6,542
MN-166/AV411	Multiple sclerosis/other CNS disorders	885	635	3,363
MN-001	Bronchial asthma	49	64	73
MN-001	Interstitial cystitis	49	27	11
MN-029	Solid tumors	106	86	796
MN-305	Generalized Anxiety Disorder/Insomnia	9	(1)	18
MN-221	Preterm labor	7	1	99
MN-246	Urinary incontinence	(16)	15	(17)
MN-447	Thrombotic disorders	18		123
MN-462	Thrombotic disorders			5
Unallocated		1,300	1,627	2,815
Total research and development		\$ 9,711	\$ 10,873	\$ 13,828

As of the end of the second quarter of 2007, we determined to focus our resources on the development of our two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS. In the third quarter of 2009, we determined to expand the product development program for MN-221 to evaluate MN-221 for the treatment of COPD exacerbations. In the second quarter of 2008, we completed the Phase II clinical trial of MN-166 ibudilast for the treatment of MS and in December 2009, through the Avigen acquisition, we acquired AV411 ibudilast for the treatment of other CNS disorders (neuropathic pain, opioid addiction and withdrawal and methamphetamine addiction). To date, we continue to work on combining the two ibudilast-based development programs and we are pursuing discussions with potential partners to secure a strategic collaboration. As such, we do not plan to undertake any further significant clinical development of MN-166/AV411 until such time that we secure a strategic collaboration to advance the combined ibudilast-based development program. We anticipate that our research and development expenses will increase with respect to MN-221 over the next few quarters as we strive to complete the current clinical trial, MN-221 CL-007 in the second half of 2011. In addition, with respect to MN-166/AV411, in future periods, we will limit expenditures on this product candidate to those development activities deemed necessary, if any, to maximize its value for purposes of securing a partner for clinical development.

We intend to limit our expenditures on the remainder of our existing product candidates to only those activities deemed necessary to maintain our license rights or maximize the value of such product candidates, if any, while pursuing a variety of initiatives to monetize such product candidates on appropriate terms. As a result, we expect that research and development expenses will decrease or otherwise remain low for the remainder of our existing product candidates in future periods. These eight non-prioritized product development programs consist of the following:

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

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



## Edgar Filing: MEDICINOVA INC - Form 10-K

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

## **Table of Contents**

MN-305 for the treatment of Generalized Anxiety Disorder/insomnia, for which we completed a Phase II clinical trial for the treatment of Generalized Anxiety Disorder in the second quarter of 2006 and a Phase II clinical trial for the treatment of insomnia in the fourth quarter of 2007;

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

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

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

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

## ***General and Administrative***

Our general and administrative expenses primarily consist of salaries, benefits and consulting and professional fees related to our administrative, finance, human resources, business development, legal and information systems support functions. In addition, general and administrative expenses include facilities and insurance costs. General and administrative costs are expensed as incurred or accrued based on monitoring the status of the specified project, contractual factors such as milestones or retainer fees, services provided and invoices received. As actual costs become known to us, we adjust our accruals. To date, general and administrative accruals have not differed significantly from the actual costs incurred.

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

## ***Long-term Debt***

On May 10, 2010, we entered into a loan and security agreement, or the Loan Agreement, with Oxford, under which we borrowed \$15.0 million. The financing is used to satisfy working capital needs, including the continued clinical development of MN-221.

We are required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan on August 1, 2013, we will be required to make payments of outstanding principal and interest in 30 equal monthly installments. The stated interest rate on the loan is 12.87 percent. The effective interest rate on the loan was 18.14 percent when taking into consideration the deferred interest payment, the relative fair value of the warrants issued in connection with the loan and the fees associated with procuring the loan. Pursuant to the Loan Agreement, we also issued to Oxford a warrant to acquire up to 198,020 shares of our common stock, par value \$0.001 per share, at an exercise price of \$6.06 per share. Based on a Black Scholes model, the relative fair value of the warrant was approximately \$859,000. In addition, the warrant and debt instrument are immediately separable and were issued separately; thus, we accounted for the warrant as a component of stockholders' equity as the agreement requires settlement in shares and under no provision of the agreement are

we required to settle the warrant in cash.

We paid Oxford a facility fee of \$150,000 and we paid outside third parties fees of approximately \$180,000. We will also pay Oxford a deferred interest payment equal to \$450,000, payable on September 30, 2011, provided that a pro rata portion of such deferred interest payment shall be paid upon any prepayment of the loan. In addition, if we prepay all or a portion of the loan prior to maturity, we will pay Oxford a prepayment penalty of three percent of the total amount prepaid if the prepayment occurs prior to May 10, 2011, two percent of the total amount prepaid if the prepayment occurs between May 11, 2011 and May 10, 2012 and one percent of the total amount prepaid if the prepayment occurs on or after May 10, 2012.

## **Table of Contents**

We accounted for the interest on the long-term debt under the effective interest method wherein we treated the debt issuance costs paid directly to Oxford and the fair value of the warrants issued to Oxford as a discount on the debt (or a contra liability) and we treated the debt issuance costs paid to third parties as an asset. The related amortization of the debt discount is recorded as interest expense and the amortization of the debt issuance costs paid to third parties is recorded as other expense in our consolidated statement of operations.

In addition, the Loan Agreement contains covenants that restrict our ability to:

incur additional indebtedness;

create liens;

enter into certain merger and licensing transactions;

dispose of certain of our assets;

enter into certain fundamental corporate changes;

make certain types of investments; and

make certain payments and distributions.

The Loan Agreement requires that, on or before March 31, 2011, we must have either (i) entered into a collaboration, joint venture or partnership with a non-affiliate providing for up-front cash proceeds to us (with such proceeds received on or before March 31, 2011) of not less than \$15.0 million from either or a combination of an upfront payment(s) or proceeds from the sale or conversion of our securities issued in connection therewith or (ii) received positive Phase IIb data on MN-221, as defined in a completed partnership or joint venture agreement relating to MN-221, or had a positive end-of-Phase II meeting with the FDA and obtained the approval of the board of directors to proceed to Phase III with MN-221.

We do not anticipate achieving either of these affirmative covenants by March 31, 2011 and Oxford has agreed to waive early payment penalties of approximately \$437,000 if we repay the loan in full on April 1, 2011. See Notes to Consolidated Financial Statements Note 12, Subsequent Events, for further information on the Oxford loan.

### ***Investment Securities and ARS Put***

Our investment securities had consisted of auction rate securities, or ARS, all of which had AAA ratings at the time of original purchase. ARS are generally long-term debt instruments that historically have provided liquidity through a Dutch auction process that resets the applicable interest rate at predetermined calendar intervals, typically seven, 28, 35 or 49 days. All of our ARS principally represent insurance notes and

portfolios of securities (primarily commercial paper).

In August 2008, UBS, the brokerage firm through which we purchased the majority of our investment securities, all of which were ARS entered into a settlement with the SEC, the New York Attorney General and other state agencies. Under the settlement, we received the right to sell to UBS the ARS held in accounts with UBS at par value at any time during the period beginning June 30, 2010 and ending July 2, 2012. The right to sell the ARS back to UBS is considered an ARS Put. As part of the settlement, UBS also offered to us a no net cost loan program, or ARS Loan, whereby we would be able to borrow up to 75 percent of the market value, as determined by UBS at its sole discretion, of our ARS that have been pledged as collateral at an interest cost that would not exceed the interest being paid on the underlying ARS investments. We measured the UBS ARS on a Level 3 basis, as defined by ASC 820, using a discounted cash flow valuation model, employing liquidity discounts and assumptions made regarding interest rate and maturity.

## **Table of Contents**

We elected to measure the ARS Put under the fair value option of ASC 825, authoritative guidance on financial instruments (formerly SFAS No. 159), to mitigate the volatility in reported earnings due to the linkage of certain of our ARS and the ARS Put. Under ASC 825, any subsequent increase or decrease in the fair value of the ARS Put would be recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations. The fair value of the ARS Put was also determined by a discounted cash flow valuation model with assumptions being made related to interest rate, maturity and liquidity.

On December 31, 2008, we designated our investment securities portfolio as trading investment securities; therefore, any additional increase or decrease in the fair value of our investment securities is recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations.

We exercised our ARS Put on June 30, 2010. Upon settlement of the ARS Put in July 2010, the UBS ARS were redeemed at par value by UBS and the associated ARS Loan was repaid, which resulted in a net gain of approximately \$138,000 being recorded in our consolidated statement of operations related to the redemption of the UBS ARS and ARS Put. Therefore, as of December 31, 2010, we no longer held any investment securities originally purchased by UBS and we no longer held the ARS Put.

In the third quarter of 2010, we reclassified our long-term investment securities to current investment securities because we no longer had the intent to hold these securities for more than a year. In addition, the fair market value of these investment securities were no longer determined on a Level 3 basis based on a discounted cash flow model employing liquidity discounts, but rather on a Level 2 basis, as defined by ASC 820, based on indicative liquidation quotes in an inactive market. During the twelve months ended December 31, 2010, we recorded impairment charges of \$923,000 on these investment securities to write them down to fair market value based on the indicative quotes received from third party brokers. All impairment charges were recorded in our consolidated statement of operations in the current year.

As of December 31, 2010, we no longer held any investment securities.

### ***Foreign Exchange Loss/(Gain)***

To date, we have conducted most of our clinical trials in the United States. However, the Phase II clinical trial for MN-166 for the treatment of MS that was completed in 2008 was conducted in Eastern Europe and the ongoing Phase II clinical trial in MN-221 for the treatment of acute exacerbations of asthma has a small number of clinical sites located in Canada, Australia and New Zealand in which certain of the invoices are denominated in the Canadian dollar, the Australian dollar and the New Zealand dollar, respectively. In addition, we have certain investor relation invoices denominated in Japanese Yen and we have certain manufacturing invoices denominated in British Pounds. At this time, we have not established a hedging program to mitigate our foreign exchange exposure. Foreign exchange gain/loss is based on the difference between the exchange rate at the settlement date and the exchange rate at the balance sheet date.

### ***Other Expense***

Other expense consists of accretion related to the convertible notes and the amortization of debt issuance costs paid to third parties.

***Interest Expense***

Interest expense consists of interest charged on our ARS Loan, interest charged on our long-term debt based on the effective interest method and amortization of debt discount.

***Other Income***

Other income consists of interest earned on our cash, cash equivalents and ARS.

## **Table of Contents**

### **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 United States. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities at the date of the consolidated financial statements, as well as the revenues and expenses during the reporting periods. We evaluate our estimates and judgments 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 that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our most critical accounting estimates include our recognition of research and development expenses, which impacts operating expenses and accrued liabilities, and stock-based compensation, which impacts operating expenses. We review our estimates, judgments 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 and Development Expenses***

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

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

We grant options to purchase our common stock to our employees and directors under our Amended and Restated 2004 Stock Incentive Plan. Additionally, we have outstanding stock options that were granted under our 2000 General Stock Incentive Plan. The benefits provided under both of these plans requires stock-based compensation for an award of equity instruments, including stock options and employee stock purchase rights, issued to employees to be recognized as a cost in the consolidated financial statements. The cost of these awards is measured according to the grant date fair value of the stock award and is recognized over the period during which an employee is required to provide service in exchange for the award, which is usually the vesting period. 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.



## Edgar Filing: MEDICINOVA INC - Form 10-K

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

## **Table of Contents**

Stock option compensation expense is recognized on a straight-line basis over the vesting period of the underlying option, generally four years.

### ***Business Combinations***

Our consolidated financial statements include an acquired business' operations after the completion of the acquisition. We account for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that most assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and that the fair value of acquired in-process research and development, or IPR&D, be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the purchase price over the assigned values of the net assets acquired is recorded as goodwill. See Notes to Consolidated Financial Statements' Note 2. Avigen Transaction for further information on IPR&D and goodwill.

### ***Fair Value Measurements***

We are required to measure certain assets and liabilities at fair value, either upon initial measurement or for subsequent accounting or reporting. We use fair value extensively in the initial measurement of net assets acquired in a business combination and when accounting for and reporting on investment securities and certain financial instruments or assets. We estimate fair value using an exit price approach, which requires, among other things, that we determine the price that would be received to sell an asset or paid to transfer a liability in an orderly market of market participants, considering the highest and best use of assets and, for liabilities, assuming the risk of non-performance will be the same before and after the transfer. Many, but not all, of our financial instruments are carried at fair value. In addition, as required under accounting rules for business combinations, the assets acquired and liabilities assumed from Avigen on December 18, 2009 have been recorded at their estimated fair values as of the acquisition date. For additional information on the valuation approach to determine fair value, including a description of the inputs used, see Long Lived Assets below and Notes to Consolidated Financial Statements' Note 2. Avigen Transaction. Also, for information on fair value for our financial instruments, see Notes to Consolidated Financial Statements' Note 3. Fair Value Measurements' Other Than Intangibles and Goodwill.

### ***Long-Lived Assets and Impairment of Long-Lived Assets***

We review long-lived assets, including property and equipment, and other intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable and we perform impairment testing for goodwill and IPR&D annually. When it is determined that impairment has occurred, a charge to operations will be recorded. Impairment on property and equipment or other intangible assets, if any, is assessed using discounted cash flows. Impairment on goodwill is assessed on our overall market capitalization, as we operate under one reporting segment. Impairment on IPR&D is assessed on a fair value cost approach.

### ***New Accounting Standards Adopted***

In October 2009, the Financial Accounting Standards Board, or FASB, ratified Accounting Standards Update, or ASU, No. 2010-13, which eliminates the residual method of allocation and the requirement to use the relative selling price method when allocating revenue in a multiple deliverable arrangement. When applying the relative selling price method, the selling price for each deliverable shall be determined using vendor specific objective evidence of selling price, if it exists, otherwise third-party evidence of selling price. If neither vendor specific objective evidence nor third-party evidence of selling price exists for a deliverable, companies shall use its best estimate of the selling price for that

## Edgar Filing: MEDICINOVA INC - Form 10-K

deliverable when applying the relative selling price method. ASU 2010-13 shall be effective in fiscal years beginning on or after June 15, 2010, with earlier application permitted. Companies may elect to adopt this guidance prospectively for all revenue arrangements entered into or materially

---

## **Table of Contents**

modified after the date of adoption, or retrospectively for all periods presented. The adoption of this accounting standard did not have a material effect on our consolidated results of operations or financial condition.

In March 2010, the FASB issued ASU No. 2010-11, *Derivatives and Hedging (Topic 815): Scope Exception Related to Embedded Credit Derivatives*. The FASB believes this ASU clarifies the type of embedded credit derivative that is exempt from embedded derivative bifurcation requirements. Specifically, only one form of embedded credit derivative qualifies for the exemption—one that is related only to the subordination of one financial instrument to another. As a result, entities that have contracts containing an embedded credit derivative feature in a form other than such subordination may need to separately account for the embedded credit derivative feature. The amendments in the ASU are effective for each reporting entity at the beginning of its first fiscal quarter beginning after June 15, 2010. The adoption of this accounting standard did not have a material effect on our consolidated results of operations or financial condition.

In April 2010, FASB issued ASU No. 2010-12, which indicates that the SEC staff would not object to incorporating the effects of the Health Care and Education Reconciliation Act of 2010 (which was enacted on March 30, 2010) when accounting for the Patient Protection and Affordable Care Act (which was enacted on March 23, 2010). This view is based partly on the SEC's understanding that the two aforementioned acts, when taken together, represent the current health care reforms as passed by Congress and signed by the President. We have performed an initial review of the two acts and do not believe that either will have a material impact on our consolidated results of operations or financial condition. Our belief is based on the fact that: (i) we are a development stage biopharmaceutical whose lead drug candidates are in Phase II of development and we have no other revenue generating products; therefore the pharmaceutical industry fee should not be applicable to us, nor would we be impacted by the drug subsidy changes; (ii) we have less than 25 employees so the fee for health plans will have minimal impact to our operating expenses; (iii) we do not have high-cost coverage health plans, nor do we offer retiree medical benefits; thus, the fees and the changes related to these would not impact our operating expenses; and (iv) with regard to the limit on tax-deductible employee compensation, this should not impact our tax position as we are currently a net loss company and will continue to be a net loss company in the foreseeable future. The health care reforms also provide for a new investment tax credit for qualified therapeutic discovery, for which we submitted an application on July 16, 2010. In October 2010, we were notified that our application for a grant payment under the investment tax credit for qualified therapeutic discovery was not approved by the Department of Health and Human Services.

In April 2010, the FASB issued ASU No. 2010-17, which codifies the consensus reached in EITF No. 08-9, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and nonsubstantive milestones, and each milestone should be evaluated individually to determine if it is substantive. The amendments in this ASU are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this standard will not have a material effect on our consolidated results of operations or financial condition.

### ***Recently Issued Accounting Standards***

In December 2010, the FASB issued ASU No. 2010-027, *Fees Paid to the Federal Government by Pharmaceutical Manufacturers* which provides guidance concerning the recognition and classification of the new annual fee payable by branded prescription drug manufacturers and importers on branded prescription drugs which was mandated under the health care reform legislation enacted in the U.S. in March 2010. Under this new accounting standard, the annual fee would be presented as a component of operating expenses and recognized over the calendar year such fees are payable using a straight-line method of allocation unless another method

## **Table of Contents**

better allocates the fee over the calendar year. This ASU is effective for calendar years beginning on or after December 31, 2010, when the fee initially becomes effective. The adoption of this accounting standard will not have an impact on our financial position or results of operations.

### ***Internal Controls Material Weakness Remediation***

As of December 31, 2010, management believes that the material weakness in our internal control over financial reporting that was included in Item 4 of our Form 10-Q for the quarter ended September 30, 2010 has been effectively remediated. Prior to the quarter ended December 31, 2010, the remediation measures as described below were implemented.

We have taken appropriate actions to remediate the material weakness related to the identified control overrides and policy deviations by one of our senior executive officers, which, collectively, represented a material weakness in our internal control over financial reporting. Our remediation plan included disclosing the granting of a waiver under our code of conduct to a senior executive and another employee due to the appearance of a possible conflict of interest, re-aligning certain reporting structures, updating our contract review and approval policy to require one signatory to be our Chief Financial Officer, strengthening certain human resource policies by amending our compensation committee charter and creating a strategic and oversight committee comprised of certain board members and the senior management team to review key issues.

## **Results of Operations**

### ***Comparison of the Years ended December 31, 2010 and 2009***

#### ***Revenues***

There were no revenues for the years ended December 31, 2010 or December 31, 2009.

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

Research and development expenses for the year ended December 31, 2010 were \$9.7 million, a decrease of \$1.2 million compared to \$10.9 million for the year ended December 31, 2009. This decrease in research and development expenses was due to a decrease of \$1.1 million in spending on our prioritized asset MN-221 for the treatment of acute exacerbations of asthma, primarily due to the completion of the clinical trial evaluating MN-221 at planned escalating doses in patients with severe acute exacerbations of asthma treated in emergency departments in 2009, a decrease of \$0.3 million primarily in unallocated R&D expenses due to a reduction in personnel costs and a reduction in intellectual property legal costs related to the overall review of our patent portfolio, offset by an increase in spending of \$0.2 million primarily to complete the clinical trial, principally funded by the National Institute in Drug Addiction, in our other prioritized asset MN-166/AV411 ibudilast for the treatment of opioid withdrawal.

*General and Administrative*

General and administrative expenses were \$8.2 million for the year ended December 31, 2010, a decrease of \$2.2 million compared to \$10.4 million for the year ended December 31, 2009. This decrease in general and administrative expenses was the result of a \$1.6 million decrease in professional fees incurred due to the completion of the Avigen transaction in 2009, a decrease of \$0.7 million due to the absence of bonus accruals in 2010 for company management, offset by an increase of \$0.1 million in other expenses.

## **Table of Contents**

### *Impairment Charge/Gain, net, on Investment Securities and ARS Put*

Net impairment charge on investment securities for the year ended December 31, 2010 was \$785,000, as compared to a net gain on investment securities of \$310,000 for year ended December 31, 2009. The net impairment charge in 2010 was a result of writing down the fair market value of our investment securities still held to liquidation value as we planned to sell investment securities in fourth quarter of 2010, offset by the gain recorded on the redemption of the UBS ARS and ARS Put. In 2009, all investment securities had been valued based on a discounted cash flow model employing liquidity discounts, which resulted in a net gain.

### *Foreign Exchange Loss/Gain*

Foreign exchange gain for the year ended December 31, 2010 was \$4,000, as compared to a foreign exchange loss of \$14,000 for the year ended December 31, 2009. The foreign exchange gain in was a result of the revaluation of Japanese yen-denominated liabilities, whereas in 2009 the revaluation of the euro-denominated liability resulted in a foreign exchange loss.

### *Other Expense*

Other expense for the year ended December 31, 2010 was \$181,000, as compared to \$0 for the year ended December 31, 2009. Other expense relates to accretion on the convertible notes and amortization of debt issuance costs paid to third parties. We did not have long-term debt in 2009.

### *Interest Expense*

Interest expense for the year ended December 31, 2010 was \$1.8 million, as compared to \$242,000 for the year ended December 31, 2009. The increase in interest expense was due to the interest charged on the long-term debt using the effective interest method, offset by a decrease in the amount of interest charged on the ARS Loan as the ARS Loan was repaid in July 2010. In 2009 interest expense was only comprised of interest charged on the ARS Loan.

### *Other Income*

Other income for the year ended December 31, 2010 was \$439,000, as compared to \$823,000 for the year ended December 31, 2009. The decrease is due to a decrease in interest income due to a lower yield earned on invested balances as we converted higher yielding investment securities into cash, which were invested in money market funds to preserve liquidity and principal.

### *Comparison of the Years ended December 31, 2009 and 2008*

*Revenues*

There were no revenues for the year ended December 31, 2009 or December 31, 2008.

*Research and Development*

Research and development expenses for the year ended December 31, 2009 were \$10.9 million, a decrease of \$2.9 million compared to \$13.8 million for the year ended December 31, 2008. This decrease in research and development expenses primarily resulted from the following:

a decrease of \$2.7 million due to the completion of the two year Phase II clinical trial for MN-166 for the treatment of MS;



**Table of Contents**

a decrease of \$0.9 million related primarily to the completion of clinical trials for MN-029 for the treatment of solid tumors and other non-prioritized assets; and

a decrease of \$1.2 million in research and development personnel costs not tracked to a specific development program,

which decrease was offset primarily by a net increase of \$1.9 million related to the conduct of Phase II clinical trials for MN-221 for the treatment of acute exacerbations of asthma and COPD.

*General and Administrative*

General and administrative expenses were \$10.4 million for the year ended December 31, 2009, an increase of \$1.6 million compared to \$8.8 million for the year ended December 31, 2008. The \$1.6 million increase was primarily related to expenses in connection with the Avigen transaction, including expenses related to legal fees to review and draft the merger agreement and related registration statement, accounting fees related to review of and consent for the registration statement, the cost of the fairness opinion, and printing and mailing costs related to the special shareholders meeting needed to approve the Avigen transaction.

*Gain/Impairment Charge on Investment Securities and ARS Put*

For the year-ended December 31, 2009, we recorded a net gain of \$0.3 million on our investment securities and ARS Put, as compared to a net impairment charge of \$1.3 million for the year-ended December 31, 2008. The net gain in 2009 on our investment securities and ARS Put is primarily due to a change in assumed maturity in our discounted cash flow valuation analysis. In 2009 we utilized a five year assumed maturity on our ARS subject to UBS settlement, as opposed to a seven year assumed maturity in 2008. The change in assumed maturity was based on the outlook for the ARS market.

*Foreign Exchange Loss*

Foreign exchange loss was \$14,000 for the year ended December 31, 2009, a decrease of \$74,000 compared \$88,000 for the year ended December 31, 2008. The decrease in foreign exchange loss was due to less weakening of the U.S. dollar against the euro and the settlement of the foreign currency denominated contract.

*Other Income, net*

Other income, net consisted of interest income earned on our cash and investment balances and totaled \$581,000 for the year ended December 31, 2009, a decrease of \$1.4 million compared to \$2.0 million for the year ended December 31, 2008. The decrease was primarily due to a decrease in interest earned on most of our cash and investment balances due to lower interest rates as a result of the continued economic downturn. In addition, during the year ended December 31, 2009, \$235,000 of interest expense was recorded on the ARS Loan.

**Liquidity and Capital Resources**

We incurred losses of \$20,187,308, \$20,368,890 and \$21,924,929 for the years ended December 31, 2010, 2009, and 2008 respectively. We have an accumulated deficit of \$267,538,407 as of December 31, 2010. Additionally, we have used net cash of \$17,698,079, \$17,014,162 and \$21,118,380 to fund our operating activities for the years ended December 31, 2010, 2009, and 2008, respectively. To date these operating losses have been funded primarily through the private placement of our equity securities, the public sale of our common stock, long-term debt, the conversion of convertible notes to our common stock and the exercise of founders' warrants, net of treasury stock repurchases.

During 2010, we expanded our Phase II clinical trial (MN-221-CL-007) activities while simultaneously pursuing available financing sources to support operations. We have had, and continue to have, an ongoing need

**Table of Contents**

to raise additional cash from outside sources to fund our operations. If we are to be successful, we must raise outside capital in the future. If we cannot do so, we will be required to further reduce our research, development, and administrative operations, including reductions of our employee base, in order to offset the lack of available funding.

As a development stage company, we have consumed substantial amounts of capital since our inception. We do not have any material commitments for capital expenditures, however, we have an ongoing 200 patient Phase II clinical trial (MN-221-CL-007) for which we expect to complete enrollment in the third quarter of 2011. Our clinical studies are administered by third-party CROs and there is a significant degree of estimation involved in quantifying the expense associated with clinical trial activity. We accrue costs for work performed by CROs based on the achievement of contracted milestone activities and on internal estimates of activities using patient enrollment and contractual or estimated rates during the period. If we do not receive complete and accurate information from the CRO or third parties on a timely basis or correctly estimate the outcome of contract negotiations, activity levels and the enrollment rate, this could potentially impact R&D expense and cash payments in subsequent periods.

We have had, and continue to have, an ongoing need to raise additional cash from outside sources to fund our operations. We are pursuing financing opportunities in both the private and public debt and equity markets as well as through strategic corporate partnerships. We have an established history of raising capital through equity and debt, and we are currently involved in discussions with multiple parties. In March 2011, we raised approximately \$8.3 million in gross proceeds (approximately \$7.9 million, net of underwriting discount and underwriter expenses) from a firm underwritten public offering in which we offered 2,750,000 units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. The purchase price for each unit was \$3.00 and each warrant has an exercise price of \$3.56 per share. In addition, in March 2011, the underwriter exercised 50,666 units of its 412,500 unit over-allotment. As of March 31, 2011, our cash and cash equivalents, along with the proceeds from our recent offering, are our principal sources of liquidity. Our business will continue to require us to incur substantial research and development expenses and our business plan assumes that we will use approximately \$15.2 million of our cash resources to fund repayment of our loan from Oxford on April 1, 2011, as agreed upon by Oxford and us in an executed pay-off letter dated March 31, 2011. We also have assumed that all of our restricted cash will be used to pay our convertible notes that mature on June 18, 2011, although one or more holders may elect to convert some or all of the convertible notes to common stock at a conversion rate of \$6.80 per share prior to the maturity date.

We believe our current liquidity position will be sufficient to fund our operations for at least the next 12 months. We expect to utilize our cash and cash equivalents to fund our operations, including research and development of our product development candidates and for clinical trials. Additionally, we believe that without additional sources of financing, we do not currently have adequate funding to complete the research and development and clinical trials required to bring our future products to market; therefore, we will require significant additional funding. If we are unsuccessful in our efforts to raise additional funds, we will be required to significantly reduce or curtail our future research and development activities and other operations.

**Table of Contents***Other Significant Cash and Contractual Obligations*

The following summarizes our scheduled long-term contractual obligations that may affect our future liquidity as of December 31, 2010 (in thousands):

Contractual Obligations	Total	Payment Due By Period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	\$ 480	\$ 458	\$ 22	\$	\$
License obligations(1)					
Convertible Notes due 2011(2)	\$ 28,626	28,626	\$		
Notes Payable due 2013(3)	\$ 18,394	6,646	\$ 11,748		
Escrow Agreement(2)	\$ 47	\$ 47			
Total(4)	\$ 47,547	\$ 35,777	\$ 11,770	\$	\$

- (1) Under the license agreements for our product candidates, we may be required to make future payments based upon the occurrence of certain milestones related to clinical development, regulatory or commercial events. We will also be required to pay royalties on any net sales of the licensed products, if any are approved by the FDA or foreign regulatory authorities for commercial sale. These milestone payments and royalty payments under our license agreements are not included in the table above because we cannot determine when, or if, the related milestones will be achieved or the events triggering the commencement of payment obligations will occur at present.
- (2) These were initially recorded at fair value which is less than face value due to a lack of marketability discount employed in the binomial option pricing model we used to value these contractual obligations. The carrying values of these contractual obligations have been adjusted to reflect payments, interest, conversions into common stock and accretion, accordingly.
- (3) The contractual obligations are based on the stated amortization schedule, assuming no event of default.
- (4) We also enter into agreements with third parties to conduct our clinical trials, manufacture our product candidates, perform data collection and analysis and other services in connection with our product development programs. Our payment obligations under these agreements depend upon the progress of our product development programs. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements.

**Off-Balance Sheet Arrangements**

At December 31, 2010, we did not have any relationship with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance variable interest, or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we did not engage in trading activities involving non-exchange traded contracts. As a result, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We do not have relationships and transactions with persons and entities that derive benefits from their non-independent relationship with us or our related parties except as disclosed herein.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

## Edgar Filing: MEDICINOVA INC - Form 10-K

Our primary exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on investment securities. As of December 31, 2010, we had no investment securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments (if any).

**Table of Contents**

Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We mitigate default risk by investing in investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments due to their relatively short term nature. Declines in interest rates over time will, however, reduce our interest income, while increases in interest rates over time will increase our interest income.

Cash and cash equivalents as of December 31, 2010 were \$28.3 million and were primarily invested in money market interest bearing accounts and money market funds. A hypothetical 10% adverse change in the average interest rate on our money market cash investments and short-term investments would have had no material effect on net income for the year ended December 31, 2010.

**Table of Contents**

**Item 8. Financial Statements and Supplementary Data**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

MediciNova, Inc.:

We have audited the accompanying consolidated balance sheets of MediciNova, Inc. and subsidiaries (a development stage company) (the Company) as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the two-year period ended December 31, 2010 and for the period from September 26, 2000 (inception) through December 31, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. The cumulative statements of operations and cash flows for the period from September 26, 2000 (inception) through December 31, 2008 and the statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and for each of the years in the eight-year period ended December 31, 2008 were audited by other auditors whose report has been furnished to us, and our opinion insofar as it relates to the amounts included for the period September 26, 2000 through December 31, 2008 is based solely on the report of the other auditors.

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 the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of MediciNova, Inc. and subsidiaries (a development stage company) as of December 31, 2010 and 2009, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2010 and for the period from September 26, 2000 (inception) through December 31, 2010, 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), the Company's internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 31, 2011 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

San Diego, California

March 31, 2011



**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders

MediciNova, Inc.

We have audited the accompanying consolidated statements of operations, and cash flows of MediciNova, Inc. (a development stage company) for the year ended December 31, 2008 and for the period from September 26, 2000 (inception) through December 31, 2008 (not included herein), and the statements of stockholders' equity for the period from September 26, 2000 (inception to December 31, 2000 and for each of the eight years in the period ended December 31, 2008). 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 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 the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of MediciNova, Inc.'s (a development stage company) consolidated operations and its cash flows for the year ended December 31, 2008, and the period from September 26, 2000 (inception) through December 31, 2008 (not included herein), and the consolidated statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and each of the eight years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

March 27, 2009

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,252,204	\$ 19,241,581
Investment securities-current (Note 3)		24,254,987
ARS put current (Note 3)		2,557,007
Restricted cash (Notes 1 and 2)	28,688,892	
Restricted investment (Notes 1 and 2)	623,751	
Restricted letter of credit (Notes 1 and 2)	47	
Prepaid expenses and other current assets	779,103	869,649
<b>Total current assets</b>	<b>58,343,997</b>	<b>46,923,224</b>
Restricted cash (Notes 1 and 2)		30,045,965
Goodwill (Notes 1 and 2)	9,600,241	9,142,205
In-process research and development (Notes 1 and 2)	4,800,000	4,800,000
Restricted investment (Notes 1 and 2)		676,499
Restricted letter of credit (Notes 1 and 2)		500,042
Property and equipment, net	65,209	153,547
Long-term investments (Note 3)		2,085,425
Other assets (Note 4)	124,722	
<b>Total assets</b>	<b>\$ 72,934,169</b>	<b>\$ 94,326,907</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,099,625	\$ 1,300,271
ARS loan payable (Note 3)		17,605,485
Management transition plan liability (Note 2)	623,751	
Current portion of long-term debt	4,951,610	
Convertible notes (Notes 1, 2 and 8)	28,626,296	
Escrow holdback (Notes 1 and 2)	47	1,094,045
Accrued expenses	1,133,273	1,276,036
Income taxes payable	6,847	
Accrued compensation and related expenses	348,755	1,146,960
<b>Total current liabilities</b>	<b>36,790,204</b>	<b>22,422,797</b>
Management transition plan liability (Note 2)		676,499
Deferred tax liability (Note 9)	1,956,000	1,956,000
Long-term debt, less current portion (Notes 3 and 4)	9,483,605	
Convertible notes (Notes 1, 2 and 8)		29,258,137
<b>Total liabilities</b>	<b>48,229,809</b>	<b>54,313,433</b>
Commitments and contingencies (Note 7)		
Stockholders equity:		

Edgar Filing: MEDICINOVA INC - Form 10-K

Preferred stock, \$0.01 par value; 500,000 shares authorized at December 31, 2010 and December 31, 2009; no shares outstanding at December 31, 2010 and December 31, 2009		
Common stock, \$0.001 par value; 30,000,000 shares authorized at December 31, 2010 and December 31, 2009; 12,482,867 and 12,172,510 shares issued at December 31, 2010 and December 31, 2009, respectively, and 12,439,132 and 12,122,217 shares outstanding at December 31, 2010 and December 31, 2009, respectively	12,484	12,170
Additional paid-in capital	293,483,920	288,652,712
Accumulated other comprehensive loss	(55,702)	(64,914)
Treasury stock, at cost; 43,735 shares at December 31, 2010 and 50,293 shares at December 31, 2009	(1,197,935)	(1,235,395)
Deficit accumulated during the development stage	(267,538,407)	(247,351,099)
<b>Total stockholders' equity</b>	<b>24,704,360</b>	<b>40,013,474</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 72,934,169</b>	<b>\$ 94,326,907</b>

*See accompanying notes to consolidated financial statements.*

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years ended December 31,			Period from
	2010	2009	2008	September 26, 2000 (inception) to December 31, 2010
Revenues	\$	\$	\$	\$ 1,558,227
Operating expenses:				
Cost of revenues				1,258,421
Research and development	9,710,977	10,873,169	13,827,651	154,256,844
General and administrative	8,171,811	10,366,291	8,773,695	97,198,809
Total operating expenses	17,882,788	21,239,460	22,601,346	252,714,074
Operating loss	(17,882,788)	(21,239,460)	(22,601,346)	(251,155,847)
(Impairment charge)/gain, net on investment securities and ARS put	(785,478)	310,250	(1,259,984)	(1,735,212)
Foreign exchange gain/(loss)	3,955	(13,622)	(88,159)	(97,826)
Other expense	(180,507)			(180,507)
Interest expense	(1,768,354)	(242,371)		(2,010,725)
Other income	438,542	823,320	2,038,219	19,058,076
Income taxes	(12,678)	(7,007)	(13,559)	(53,244)
Net loss	(20,187,308)	(20,368,890)	(21,924,829)	(236,175,285)
Accretion to redemption value of redeemable convertible preferred stock				(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock				(31,264,677)
Net loss applicable to common stockholders	\$ (20,187,308)	\$ (20,368,890)	\$ (21,924,829)	\$ (267,538,407)
Basic and diluted net loss per common share	\$ (1.63)	\$ (1.68)	\$ (1.82)	
Shares used to compute basic and diluted net loss per share	12,410,576	12,105,835	12,072,027	

*See accompanying notes to consolidated financial statements.*

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS**

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

Edgar Filing: MEDICINOVA INC - Form 10-K

Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock					31,264,677		(31,264,677)	
Accretion to redemption value of redeemable convertible preferred stock							(78,756)	(78,756)
Net loss and comprehensive loss							(48,272,603)	(48,272,603)
Balance at December 31, 2004	1,291,150	12,912	50,000	50	103,603,582	(1,194,721)	(94,752,701)	7,669,122

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS (Continued)**

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

Edgar Filing: MEDICINOVA INC - Form 10-K

Accretion to redemption value of redeemable convertible preferred stock									
Purchase of treasury stock at \$11.10 per share in December					(55,445)				(55,445)
Comprehensive loss:									
Net loss						(25,692,135)			(25,692,135)
Accumulated other comprehensive loss					(15,188)				(15,188)
Total comprehensive loss									(25,707,323)
Balance at December 31, 2005	9,885,585	9,885	257,032,491	(799,439)	(15,188)	(55,445)	(120,464,525)		135,707,779



**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS (Continued)**

	Convertible preferred stock	Common stock		Additional paid-in capital	Deferred Compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
	Share Amount	Shares	Amount						
Cashless warrant exercises of 260,000 in February, April and August		260,000	260	(260)					
Warrant exercises of 275,000 shares at \$1.00 per share in March and August		275,000	275	274,725					275,000
Write off balance of deferred employee stock-based compensation as of 12/31/05				(799,439)	799,439				
Option exercises of 1,400 shares at \$10.00 per share in May and August		1,400	2	13,998					14,000
Amortization of deferred employee stock-based compensation				2,090,182					2,090,182
Purchase of treasury stock from \$10.30 - \$13.10 per share in February, March, May, June, July, September and October							(1,382,425)		(1,382,425)
Comprehensive loss:									
Net loss								(35,689,611)	(35,689,611)
Accumulated other comprehensive loss						(34,017)			(34,017)
Total Comprehensive loss									(35,723,628)
Balance at December 31, 2006		10,421,985	10,422	258,611,697		(49,205)	(1,437,870)	(156,154,136)	100,980,908
Cashless warrant exercises of 650,047 in January and September		650,047	650	(650)					
Issuance of common stock in a public offering at \$12.00 per share in February		1,000,000	1,000	10,638,600					10,639,600
Employee stock-based compensation				3,939,416					3,939,416
Issuance of shares under an employee stock purchase plan at \$6.72							33,782		33,782
Comprehensive loss:									
Net loss		(5)						(48,903,244)	(48,903,244)
Accumulated other comprehensive loss						(82,261)			(82,261)

Edgar Filing: MEDICINOVA INC - Form 10-K

Total comprehensive loss							(48,985,505)
Balance at December 31, 2007	12,072,027	12,072	273,189,063	(131,466)	(1,404,088)	(205,057,380)	66,608,201

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS (Continued)**

	Convertible preferred stock		Common stock		Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
	Shares	Amount	Shares	Amount						
Employee stock-based compensation					3,172,712					3,172,712
Issuance of shares under an employee stock purchase plan at \$2.33 average								86,726		86,726
Comprehensive loss:										
Net loss									(21,924,829)	(21,924,829)
Accumulated other comprehensive income							101,722			101,722
Total comprehensive loss										(21,823,107)
Balance at December 31, 2008		12,072,027	12,072	12,072	276,361,775		(29,744)	(1,317,362)	(226,982,209)	48,044,532
Employee stock-based compensation					2,371,636					2,371,636
Option exercises		100,483	98	98	406,259					406,357
Fair value of redemption feature of Avigen purchase (Note 2)					9,513,042					9,513,042
Issuance of shares under an employee stock purchase plan at \$2.21 average								81,967		81,967
Comprehensive loss:										
Net loss									(20,368,890)	(20,368,890)
Accumulated other comprehensive loss							(35,170)			(35,170)
Total comprehensive loss										(20,404,060)
Balance at December 31, 2009		12,172,510	12,170	12,170	288,652,712		(64,914)	(1,235,395)	(247,351,099)	40,013,474
Employee stock-based compensation					2,000,935					2,000,935
Option exercises		44,948	49	49	166,550					166,599
Issuance of shares for Convertible Notes (Notes 2 and 9)		265,409	265	265	1,804,515					1,804,780
Fair value of warrant issued in conjunction with Loan Agreement (Note 4)					859,208					859,208
Issuance of shares under an employee stock purchase plan at \$6.56 average								37,460		37,460

Edgar Filing: MEDICINOVA INC - Form 10-K

Comprehensive loss:									
Net loss							(20,187,308)	(20,187,308)	
Accumulated other comprehensive income					9,212			9,212	
Total comprehensive loss								(20,178,096)	
Balance at December 31, 2010									
	\$	12,482,867	\$ 12,484	\$ 293,483,920	\$	\$ (55,702)	\$ (1,197,935)	\$ (267,538,407)	\$ 24,704,360

*See accompanying notes to consolidated financial statements.*

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years ended December 31,			Period from
	2010	2009	2008	September 26, 2000 (inception) to December 31, 2010
<b>Operating activities:</b>				
Net loss	\$ (20,187,308)	\$ (20,368,890)	\$ (21,924,829)	\$ (236,175,285)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash stock-based compensation	2,000,935	2,371,636	3,172,712	48,308,533
Depreciation and amortization	108,257	219,202	305,018	1,903,555
Amortization of premium/discount on investment securities, convertible debt, debt discount and issuance costs	624,931		(691,706)	(1,851,489)
Impairment charge/(gain), net on investment securities and ARS Put	785,478	(310,250)	1,259,984	1,735,212
(Gain)/loss on disposal of assets	(1,360)	11,997		10,637
Impairment of sublease				35,259
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	90,546	(114,383)	1,725,295	(742,154)
Accounts payable, income tax payable, accrued expenses and deferred rent	(327,352)	890,854	(5,109,397)	1,977,738
Accrued compensation and related expenses	(798,205)	285,672	144,543	252,614
Restricted assets	5,999			5,999
<b>Net cash used in operating activities</b>	<b>(17,698,079)</b>	<b>(17,014,162)</b>	<b>(21,118,380)</b>	<b>(184,539,381)</b>
<b>Investing activities:</b>				
Cash paid for acquired business, net of acquired cash	(458,036)	(2,371,749)		(2,829,785)
Purchases of investment securities			(2,000,000)	(377,205,766)
Maturities or sales of investment securities	28,111,943	1,252,846	23,550,000	377,918,240
Acquisition of property and equipment	(18,559)	(16,447)		(2,271,505)
Proceeds from sales of property and equipment				256,845
<b>Net cash provided by / (used in) investing activities</b>	<b>27,635,348</b>	<b>(1,135,350)</b>	<b>21,550,000</b>	<b>(4,131,971)</b>
<b>Financing activities:</b>				
Net proceeds from the sale of common stock	166,599	406,357		121,463,522
Sale of preferred stock, net of issuance costs				80,216,971
Proceeds from ARS loan		17,605,485		17,605,485
Repayment of ARS loan	(17,605,485)			(17,605,485)
Net proceeds from debt	14,670,000			14,670,000
Proceeds from conversion of convertible notes	1,804,780			1,804,780
Purchase of treasury stock, net of employee stock purchases	37,460	81,967	86,726	(1,231,717)
<b>Net cash (used in) / provided by financing activities</b>	<b>(926,646)</b>	<b>18,093,809</b>	<b>86,726</b>	<b>216,923,556</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>	<b>9,010,623</b>	<b>(55,703)</b>	<b>518,346</b>	<b>28,252,204</b>
Cash and cash equivalents, beginning of period	19,241,581	19,297,284	18,778,938	
<b>Cash and cash equivalents, end of period</b>	<b>\$ 28,252,204</b>	<b>\$ 19,241,581</b>	<b>\$ 19,297,284</b>	<b>\$ 28,252,204</b>

Supplemental disclosure of non-cash operating and financing activities:

## Edgar Filing: MEDICINOVA INC - Form 10-K

Conversion of convertible preferred stock into common stock upon initial public offering	\$	\$	\$	\$ 43,515,677
Restricted assets, cash unrestricted upon conversion of convertible notes	\$ 1,805,342	\$	\$	\$ 1,805,342
Supplemental disclosures of cash flow information:				
Income taxes paid	\$ 12,678	\$ 9,434	\$ 24,528	\$ 46,640
Interest paid	\$ 1,163,053	\$ 235,364	\$	\$ 1,398,417
Supplemental disclosure of investing activities related to business acquisition:				
Fair value of assets acquired	\$ (458,036)	\$ 36,687,706	\$	\$ 36,229,670
Liabilities assumed	\$	\$ (1,008,687)	\$	\$ (1,008,687)
Deferred tax liability	\$	\$ (1,956,000)	\$	\$ (1,956,000)
Fair value of total merger consideration (Note 2)	\$	\$ (42,865,224)	\$	\$ (42,865,224)

*See accompanying notes to consolidated financial statements.*

**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**Notes to Consolidated Financial Statements**

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

*The Company*

We were incorporated in the state of Delaware in September 2000. We are a development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet medical need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope.

We incurred losses of \$20,187,308, \$20,368,890 and \$21,924,929 for the years ended December 31, 2010, 2009, and 2008 respectively. We have an accumulated deficit of \$267,538,407 as of December 31, 2010. Additionally, we have used net cash of \$17,698,079, \$17,014,162 and \$21,118,380 to fund our operating activities for the years ended December 31, 2010, 2009, and 2008, respectively. To date these operating losses have been funded primarily through the private placement of our equity securities, the public sale of our common stock, long-term debt, the conversion of convertible notes to our common stock and the exercise of founders' warrants, net of treasury stock repurchases.

During 2010, we expanded our Phase II clinical trial (MN-221-CL-007) activities while simultaneously pursuing available financing sources to support operations. We have had, and continue to have, an ongoing need to raise additional cash from outside sources to fund our operations. If we are to be successful, we must raise outside capital in the future. If we cannot do so, we will be required to further reduce our research, development, and administrative operations, including reductions of our employee base, in order to offset the lack of available funding.

As a development stage company, we have consumed substantial amounts of capital since our inception. We do not have any material commitments for capital expenditures, however, we have an ongoing 200 patient Phase II clinical trial (MN-221-CL-007) for which we expect to complete enrollment in the third quarter of 2011. Our clinical studies are administered by third-party CROs and there is a significant degree of estimation involved in quantifying the expense associated with clinical trial activity. We accrue costs for work performed by CROs based on the achievement of contracted milestone activities and on internal estimates of activities using patient enrollment and contractual or estimated rates during the period. If we do not receive complete and accurate information from the CRO or third parties on a timely basis or correctly estimate the outcome of contract negotiations, activity levels and the enrollment rate, this could potentially impact R&D expense and cash payments in subsequent periods.

We have had, and continue to have, an ongoing need to raise additional cash from outside sources to fund our operations. We are pursuing financing opportunities in both the private and public debt and equity markets as well as through strategic corporate partnerships. We have an established history of raising capital through equity and debt, and we are currently involved in discussions with multiple parties. In March 2011, we raised approximately \$8.3 million in gross proceeds (approximately \$7.9 million, net of underwriting discount and underwriter expenses and

## Edgar Filing: MEDICINOVA INC - Form 10-K

no exercise of warrants) from a firm underwritten public offering in which we offered 2,750,000 units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. The purchase price for each unit was \$3.00 and each warrant has an exercise price of \$3.56 per share. In addition, in March 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. As of March 31, 2011, our cash and cash equivalents, along with the proceeds from our recent offering, are our



## **Table of Contents**

principal sources of liquidity. Our business will continue to require us to incur substantial research and development expenses and our business plan assumes that we will use approximately \$15.2 million of our cash resources to fund repayment of our loan from Oxford on April 1, 2011, as agreed upon by Oxford and us in an executed pay-off letter dated March 31, 2011. We also have assumed that all of our restricted cash will be used to pay our convertible notes that mature on June 18, 2011, although one or more holders may elect to convert some or all of the convertible notes to common stock at a conversion rate of \$6.80 per share prior to the maturity date.

We believe our current liquidity position will be sufficient to fund our operations for at least the next 12 months. We expect to utilize our cash and cash equivalents to fund our operations, including research and development of our product development candidates and for clinical trials. Additionally, we believe that without additional sources of financing, we do not currently have adequate funding to complete the research and development and clinical trials required to bring our future products to market; therefore, we will require significant additional funding. If we are unsuccessful in our efforts to raise additional funds, we will be required to significantly reduce or curtail our future research and development activities and other operations.

## ***Basis of Presentation***

Our primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, conducting research and development, performing business and financial planning and raising capital. Accordingly, in connection with preparation of the consolidated financial statements we operate under one reporting segment and are considered to be in the development stage, under the authoritative guidance for development stage entities, Accounting Standards Codification, or ASC, 915.

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

*Avigen Transaction.* On December 18, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of ours, merged with and into Avigen, Inc., or Avigen, with Avigen continuing as the surviving entity and wholly-owned subsidiary of ours, or the Merger. Under the terms of the merger agreement, Avigen shareholders, at their election, received an amount per share either in cash, convertible notes issued by us or a combination thereof, upon closing. Of the 29,852,115 shares of Avigen common stock outstanding, approximately 17% of Avigen shareholders elected to receive cash at closing in the amount of approximately \$1.19 per share with an additional \$0.04 per share paid in two increments during fiscal year 2010, while the remaining 83% received the corresponding value of additional convertible notes issued by us. See Notes to Consolidated Financial Statements Note 2, Avigen Transaction, for additional information on the merger.

## ***Principles of Consolidation***

The consolidated financial statements include the accounts of MediciNova, Inc. and its wholly-owned subsidiaries. MediciNova, Inc. and its subsidiaries are collectively referred to herein as we, our or us. We do not have any interests in any variable interest entities.

On December 13, 2006, MediciNova (Europe) Limited, a wholly-owned subsidiary of MediciNova, Inc., was incorporated under the laws of England and Wales and established for the purpose of facilitating the clinical development of our compounds for the European marketplace.

Edgar Filing: MEDICINOVA INC - Form 10-K

MediciNova (Europe) Limited's functional currency is the U.S. dollar, the reporting currency of its parent.

## **Table of Contents**

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

On August 17, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of MediciNova, Inc. was incorporated under the General Corporation Law of the State of Delaware for the purpose of facilitating the Merger (the "Merger") with Avigen, Inc., or Avigen. See Notes to Consolidated Financial Statements Note 2. Avigen Transaction, for more information regarding the merger.

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

### ***Reclassifications***

Certain amounts in the consolidated statements of operations for the year ended December 31, 2009 and the consolidated statement of cash flows for the year ended December 31, 2009 and the period from September 26, 2000 (inception) to December 31, 2010 have been reclassified to conform the presentation of interest expense, other expense and other income.

### ***Use of Estimates***

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

### ***Cash and Cash Equivalents***

Cash and cash equivalents consist of cash and other highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents at December 31, 2010 consisted of money market funds.

### ***Investment Securities and ARS Put***

Our investment securities consisted of ARS, all of which had AAA ratings at the time of original purchase. ARS are generally long-term debt instruments that historically have provided liquidity through a "Dutch" auction process that resets the applicable interest rate at predetermined calendar intervals, typically seven, 28, 35 or 49 days. All of our ARS principally represent insurance notes and portfolios of securities (primarily commercial paper).

## Edgar Filing: MEDICINOVA INC - Form 10-K

In August 2008, UBS, the brokerage firm through which we purchased the majority of our investment securities, all of which were auction rate securities, or ARS, entered into a settlement with the SEC, the New York Attorney General and other state agencies. Under the settlement, we received the right to sell to UBS the ARS held in accounts with UBS at par value at any time during the period beginning June 30, 2010 and ending July 2, 2012. The right to sell the ARS back to UBS is considered an ARS Put. As part of the settlement, UBS also offered to us a no net cost loan program, or ARS Loan, whereby we would be able to borrow up to 75 percent of the market value, as determined by UBS at its sole discretion, of our ARS that have been pledged as collateral at an interest cost that would not exceed the interest being paid on the underlying ARS investments. We measured the UBS ARS on a Level 3 basis, as defined by ASC 820, using a discounted cash flow valuation model, employing liquidity discounts and assumptions made regarding interest rate and maturity.

## **Table of Contents**

We elected to measure the ARS Put under the fair value option of ASC 825, authoritative guidance on financial instruments, to mitigate the volatility in reported earnings due to the linkage of certain of our ARS and the ARS Put. Under ASC 825, any subsequent increase or decrease in the fair value of the ARS Put would be recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations. The fair value of the ARS Put was also determined by a discounted cash flow valuation model with assumptions being made related to interest rate, maturity and liquidity.

At December 31, 2008, we designated our investment securities portfolio as trading investment securities; therefore, any additional increase or decrease in the fair value of our investment securities is recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations.

We exercised our ARS Put on June 30, 2010. Upon settlement of the ARS Put in July 2010, the UBS ARS were redeemed at par value by UBS and the associated ARS Loan was repaid, which resulted in a net gain of approximately \$138,000, being recorded in our consolidated statement of operations related to the redemption of the UBS ARS and ARS Put.

In the third quarter of 2010, we reclassified our long-term investment securities to current investment securities because we no longer had the intent to hold these securities for more than a year. In addition, the fair market value of these investment securities were no longer determined on a Level 3 basis based on a discounted cash flow model employing liquidity discounts, but rather on a Level 2 basis, as defined by ASC 820, based on indicative liquidation quotes in an inactive market. During the twelve months ended December 31, 2010, we recorded impairment charges of \$923,000 on these investment securities to write them down to fair market value based on the indicative quotes received from third party brokers. All impairment charges were recorded in our consolidated statement of operations in the current year.

As of December 31, 2010, we no longer held any investment securities other than those held in the money market funds classified as cash equivalents.

### ***Restricted Cash***

Restricted cash consists of cash held in a separate trust account, managed by a third-party, in connection with the Avigen transaction. Restricted cash is released to us upon conversion of convertible notes into shares of our common stock. (See Convertible Notes discussion below.)

### ***Restricted Investment***

Restricted investment consists of cash held in an irrevocable grantor trust, or rabbi trust, which is intended to fund benefit obligations under the Avigen Management Transition Plan, or the Avigen MTP. These funds represent reserves for benefits eligible to terminated employees as defined by the MTP. Upon termination of the trust, the merger agreement provides that these funds be paid to the former Avigen stockholders on a pro rata basis see Notes to Consolidated Financial Statements Note 2. Avigen Transaction for further information.

### ***Restricted Letter of Credit***

Restricted letter of credit consisted of cash provided as a credit guarantee and security for an irrevocable letter of credit related to the original lease of office space which expired November 30, 2010. The funds remaining after the letter of credit expired reverted to the escrow holdback account described below.

*Convertible Notes*

At the closing of the Merger, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into an indenture. Under the terms of a separate trust agreement, \$29.4 million, which represents the initial

---

## **Table of Contents**

principal amount of the convertible notes, or Convertible Notes, or 83% of the First Payment Consideration, was deposited with a trust agent for the benefit of the holders and us (the amount of such deposit together with interest accrued and capitalized thereon, the Property). Provided no event of default has occurred and is continuing, we will be able to direct the investment and reinvestment of the Property in certain approved investment options, including certain money market funds. At the maturity of the Convertible Notes on June 18, 2011, the 18-month anniversary of the closing of the Merger, we plan to use the Property to pay the principal amount of, and accrued interest on, the remaining Convertible Notes. At acquisition date, we recorded the Convertible Notes in our consolidated balance sheet at fair value see Notes to Consolidated Financial Statements Note 2. Avigen Transaction for further information on the valuation of the Convertible Notes.

Holders of the Convertible Notes may submit conversion notices, which are irrevocable, instructing the trustee to convert such Convertible Notes into shares of our common stock at an initial conversion price of \$6.80 per share. Following each conversion date, which date generally is the final business day of each calendar month, we will issue the number of whole shares of common stock issuable upon conversion as promptly as practicable (and in any event within 10 business days). Any fractional shares (after aggregating all Convertible Notes being converted by a holder on such date) will be rounded down and we will deliver cash out of the separate trust for the current market value of the fractional share. The indenture includes customary anti-dilution adjustments and events of default.

### ***Escrow Holdback***

At the closing of the Merger, we and Avigen funded in cash and letter of credit \$1,500,000 in a separate escrow account, or Second Payment Consideration, pursuant to an escrow agreement. The Second Payment Consideration is considered the Escrow Holdback . We (Avigen and us) had identified certain additional liabilities of approximately \$400,000 prior to closing of the Merger. As such, in accordance with the procedures set forth in the escrow agreement, \$400,000 was released from the escrow account in satisfaction of these additional liabilities. A reconciliation of expenses was performed around June 30, 2010 and the letter of credit expired in November 2010. As a result, the Second Payment Consideration of \$0.04 per share was paid in two installments. At acquisition date, we recorded the Escrow Holdback in our consolidated balance sheet at fair value see Notes to Consolidated Financial Statements Note 2. Avigen Transaction for further information on the valuation of the Escrow Holdback.

### ***Concentrations and Uncertainties***

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

On May 10, 2010, we entered into a loan and security agreement, or Loan Agreement, with Oxford Finance Corporation, or Oxford, under which we borrowed \$15.0 million. We are required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan, we will be required to make payments of outstanding principal and interest in 30 equal monthly installments. The stated interest rate on the loan is 12.87 percent. See Note 4, Long-term Debt, for further information on the loan.

We have sustained operating losses since inception and expect such losses to continue over the next several years. Management plans to continue financing our operations with equity issuances, debt arrangements or a combination thereof. We expect current working capital will *not* be sufficient to fund our operations inclusive of planned research and development activities, inclusive of debt repayment in the event of default, through at least





**Table of Contents**

December 31, 2011. If adequate funds are not available, we will be required to delay, reduce the scope of or eliminate one or more of our research or development programs or implement another reduction in workforce.

***Business Combinations***

Our consolidated financial statements include an acquired business's operations after the completion of the acquisition. We account for acquired businesses using the acquisition method of accounting. The acquisition method of accounting requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and that the fair value of acquired in-process research and development, or IPR&D, be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the purchase price over the assigned values of the net assets acquired is recorded as goodwill. In connection with the Avigen transaction we recorded, at fair value, IPR&D and goodwill. See Notes to Consolidated Financial Statements Note 2. Avigen Transaction for a more detailed discussion on IPR&D and goodwill.

***Fair Value***

Financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities, are carried at cost, which we believe approximates fair value given their short-term nature. The carrying amount of our ARS Loan also approximates its fair value due to the loan's short-term nature. We are required to measure certain assets and liabilities at fair value, either upon initial measurement or for subsequent accounting or reporting. We use fair value in the initial measurement of net assets acquired in a business combination and when accounting for and reporting on investment securities and certain financial instruments or assets. We estimate fair value using an exit price approach, which requires, among other things, that we determine the price that would be received to sell an asset or paid to transfer a liability in an orderly market of market participants, considering the highest and best use of assets and, for liabilities, assuming the risk of non-performance will be the same before and after the transfer. Many, but not all, of our financial instruments are carried at fair value. In addition, as required under accounting rules for business combinations, most of the assets acquired and liabilities assumed from Avigen on December 18, 2009 have been recorded at their estimated fair values as of the acquisition date. For additional information on the valuation approach to determine fair value, including a description of the inputs used, see Long Lived Assets below and Notes to Consolidated Financial Statements Note 2. Avigen Transaction. Also, for information on fair value for our financial instruments, see Notes to Consolidated Financial Statements Note 3. Fair Value Measurements Other Than Intangibles and Goodwill.

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

	<b>As of December 31, 2010</b>			
	<b>Total</b>	<b>Fair Value Measurements Using</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Cash and cash equivalents	\$ 28,252	\$ 28,252	\$	\$

As of December 31, 2010, we no longer held any investment securities as they were either been redeemed or liquidated during the year. In addition, as of December 31, 2010, we no longer held the ARS Loan as it was repaid during the year.



**Table of Contents**

	<b>As of December 31, 2009</b>			
	<b>Total</b>	<b>Fair Value Measurements Using</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Cash and cash equivalents	\$ 19,242	\$ 19,242	\$	\$
Current assets:				
Investment securities (ARS)	\$ 24,255	\$	\$	\$ 24,255
ARS Put	2,557			2,557
<b>Total current assets</b>	<b>\$ 26,812</b>	<b>\$</b>	<b>\$</b>	<b>\$ 26,812</b>
Long-term investments:				
Investment securities (ARS)	\$ 2,085	\$	\$	\$ 2,085
<b>Total long-term investments</b>	<b>\$ 2,085</b>	<b>\$</b>	<b>\$</b>	<b>\$ 2,085</b>

The carrying amount of our ARS Loan as of December 31, 2009 approximates its fair value due to its short term nature.

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

	<b>As of December 31, 2010</b>			
	<b>Total</b>	<b>Fair Value Measurements Using</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Current liabilities:				
Current portion of long-term debt(3)	\$ 4,952	\$	\$	\$ 4,952
Convertible notes(1, 2)	\$ 28,626	\$	\$	\$ 28,626
<b>Total current liability</b>	<b>\$ 33,578</b>	<b>\$</b>	<b>\$</b>	<b>\$ 33,578</b>
Non-current liability:				
Long-term debt, less current portion(3)	\$ 9,484	\$	\$	\$ 9,484
<b>Total non-current liability</b>	<b>\$ 9,484</b>	<b>\$</b>	<b>\$</b>	<b>\$ 9,484</b>

- (1) The fair value of the convertible notes and the related conversion feature was based on a binomial option pricing model, or BOPM. Assumptions used in the BOPM included the maturity date of the convertible notes, the time between nodes, volatility, face value of the convertible notes at the merger closing date and the risk-free rate. See Notes to Consolidated Financial Statements Note 2, Avigen Transaction for further information on the BOPM.
- (2) Although we recorded the convertible notes as a liability upon merger closing on December 18, 2009, following ASC 805, the fair value of the conversion feature was accounted for within equity and will not be re-measured during interim periods and subsequent settlements (conversions to our stock) will be accounted for in equity. See Note 2, Avigen Transaction, above for information on the activity impacting the convertible notes liability during the year ended December 31, 2010.
- (3) The carrying value of the long-term debt- current portion and non-current portion- approximates fair value. See Notes to Consolidated Financial Statements Note 4, Long-term Debt, below for further information regarding the valuation of the long-term debt.



**Table of Contents**

	<b>As of December 31, 2009</b>			
	<b>Total</b>	<b>Fair Value Measurements Using</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Current liabilities:</b>				
Escrow holdback(1)	\$ 1,094	\$	\$	\$ 1,094
<b>Total current liability</b>	<b>\$ 1,094</b>	<b>\$</b>	<b>\$</b>	<b>\$ 1,094</b>
<b>Non-current liability:</b>				
Convertible notes(1)	\$ 29,258	\$	\$	\$ 29,258
<b>Total non-current liability</b>	<b>\$ 29,258</b>	<b>\$</b>	<b>\$</b>	<b>\$ 29,258</b>

- (1) The fair value of the convertible notes and escrow holdback and their related conversion feature was based on a BOPM. Assumptions used in the BOPM included the maturity date of the convertible notes and the escrow holdback, the time between nodes, volatility, face value of the convertible notes and the escrow holdback at the merger closing date and the risk-free rate. The maturity date utilized was 1.5 years based on the maturity of the notes in June 2011. As our projected period was 1.5 years we used the average of the one and two year U.S. Treasury bonds as of the closing date and we based volatility on the historical volatility of publicly-traded comparable companies to Avigen and our stock price volatility. See Notes to Consolidated Financial Statements Note 2, Avigen Transaction for further information on the BOPM.

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

***Property and Equipment***

Property and equipment, net, which consists of leasehold improvements, furniture and equipment and software, is stated at cost. Leasehold improvements, furniture and equipment, and software are depreciated using the straight-line method over the estimated useful lives of the related assets. The useful life for furniture, equipment (other than computers) and software is five years, computers is three years and leasehold improvements are amortized over the lesser of the useful life or the term of the lease. Our current lease expires in August 2011. We also lease office space in Tokyo, Japan under a lease that expires in May 2011. Furthermore, pursuant to our acquisition of Avigen we acquired a month-to-month lease for 4,000 square feet of office space in Alameda, California. We vacated the Alameda premises on March 8, 2010 and we were released from our month-to-month lease by the landlord.

***Long-Lived Assets and Impairment of Long-Lived Assets***

We review long-lived assets, including property and equipment, and other intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable and we perform impairment testing for goodwill and IPR&D at least annually. When it is determined that impairment has occurred, a charge to operations will be recorded. Impairment on property and equipment or other intangible assets, if any, is assessed using discounted cash flows. Impairment on goodwill is assessed on our overall market capitalization, as we operate as one reporting segment. Impairment on IPR&D is assessed on a fair value cost approach.

## Edgar Filing: MEDICINOVA INC - Form 10-K

The fair value of intangible assets is determined on a level 3 basis in which significant unobservable inputs were utilized primarily using the income approach, which starts with a forecast of all the expected future net cash flows, some of which are more certain than others. Some of the more significant estimates and assumptions inherent in the intangible asset impairment estimation process include: the amount and timing of projected future cash flows; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical,

## **Table of Contents**

legal, regulatory or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

### ***Revenue Recognition***

We recognized no revenues for each of the years in the three-year period ended December 31, 2010.

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

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

### ***Income Taxes***

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

Effective January 1, 2007, we adopted the authoritative guidance on accounting for uncertainty in income taxes, which prescribes a comprehensive model for how we should recognize, measure, present and disclose in our financial statements for uncertain tax positions that we have taken or expect to take on a tax return. The cumulative effect of adopting the guidance on accounting for uncertainty in income taxes resulted in no adjustment to retained earnings as of January 1, 2007.

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrued interest or penalties since implementation of guidance on accounting for uncertainty in income taxes.

We are subject to taxation in the United States, California and foreign jurisdictions, of which currently no years are under examination. Our tax years for 2000 and forward are subject to examination by the U.S. and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits. At December 31, 2010, income taxes relate to service income earned by our Japanese subsidiary, MediciNova Japan, Inc.

*Stock-Based Compensation*

We grant stock options to our employees, directors and consultants under the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan (the 2004 Plan ), the successor to the MediciNova, Inc. 2000 General Stock Incentive Plan (the 2000 Plan ). No additional stock options have been or will be issued under the 2000 Plan subsequent to our IPO. Stock options issued to non-employees were recorded at their fair value as determined in accordance with the authoritative guidance for equity under ASC 505.



**Table of Contents**

The exercise price of stock options granted during the years ended December 31, 2010, 2009 and 2008 were equal to market value on the date of grant. During the years ended December 31, 2010, 2009 and 2008, options to purchase 525,000, 521,373 and 615,540 shares of common stock, respectively, were granted and stock-based compensation expense for such stock options is reflected in operating results during fiscal years 2010, 2009 and 2008. 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,	
	2010	2009
Risk-free interest rate	1.37%	1.79%
Expected volatility of common stock	76.50%	70.00%
Dividend yield	0.00%	0.00%
Expected option term (in years)	4.40	4.13

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our employee stock options. The expected volatility is based on the historical volatility of our stock since listing on the Nasdaq Global Market in December 2006. We have not paid any dividends on our common stock since our inception, and we do not anticipate paying dividends on our common stock in the foreseeable future. The expected term of employee stock options is based on the simplified method for plain vanilla options as provided by the authoritative guidance on stock compensation, as we concluded that our historical stock option exercise experience does not provide a reasonable basis for us to estimate the expected term.

As stock-based compensation expense recognized in the accompanying consolidated statement of operations for the years ended December 31, 2010, 2009 and 2008 was based on stock option awards ultimately expected to vest, such expense should be reduced for estimated forfeitures. The authoritative guidance for compensation under ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have very few employees and our stock options vest monthly; therefore, we did not estimate any forfeitures during the year ended December 31, 2010, and we will adjust our stock-based compensation expense should any forfeitures occur. Our determination of fair value is affected by our stock price, as well as a number of assumptions that require judgment. The weighted-average fair value of each stock option granted during the years ended December 31, 2010, 2009 and 2008, estimated as of the grant date using the Black-Scholes option valuation model, was \$4.02 per option, \$1.53 per option and \$2.37 per option, respectively.

For the years ended December 31, 2010, 2009 and 2008, stock-based compensation expense related to stock options was \$2.0 million, \$2.4 million and \$3.2 million, respectively, and was recorded as a component of general and administrative expense (\$1.6 million, \$1.9 million and \$1.8 million, respectively) and research and development expense (\$0.4 million, \$0.5 million and \$1.4 million, respectively). During the years ended December 31, 2010 and 2009, there were 44,948 and 100,483 stock options exercised, respectively, from which proceeds of \$0.2 million and \$0.4 million, respectively, were received. No stock options were exercised during the year ended December 31, 2008.

As of December 31, 2010, 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 1.1 years, on a straight-line basis.

**Table of Contents****Comprehensive Income (Loss)**

The authoritative guidance for comprehensive income under ASC 220 requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity (net assets) during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). Our comprehensive loss includes unrealized losses on marketable securities and currency translation. The table below sets forth the components of our accumulated other comprehensive loss at:

	<b>December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Beginning Balance	\$ (64,914)	\$ (29,744)	\$ (131,466)
Currency translation	9,212	(35,170)	101,722
Unrealized loss on marketable securities			
Ending Balance	\$ (55,702)	\$ (64,914)	\$ (29,744)

As of December 31, 2010, 2009 and 2008, our comprehensive loss was \$20,178,096, \$20,404,060 and \$21,823,107, respectively.

**Net Loss Per Share**

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the years ended December 31, 2010 and 2009, there were 182,400 and 4,547,300 potentially dilutive securities, respectively, excluded from determining diluted earnings per share because of their anti-dilutive effect, of which 4,330,300 potentially dilutive securities in 2009 were based on the assumption that all of the convertible notes issued pursuant to the Avigen merger were converted at the closing date. There were no potentially dilutive securities for the year ended December 31, 2008.

**New Accounting Standards Adopted**

In October 2009, the Financial Accounting Standards Board, or FASB, ratified Accounting Standards Update, or ASU, No. 2010-13, which eliminates the residual method of allocation and the requirement to use the relative selling price method when allocating revenue in a multiple deliverable arrangement. When applying the relative selling price method, the selling price for each deliverable shall be determined using vendor specific objective evidence of selling price, if it exists, otherwise third-party evidence of selling price. If neither vendor specific objective evidence nor third-party evidence of selling price exists for a deliverable, companies shall use its best estimate of the selling price for that deliverable when applying the relative selling price method. ASU 2010-13 shall be effective in fiscal years beginning on or after June 15, 2010, with earlier application permitted. Companies may elect to adopt this guidance prospectively for all revenue arrangements entered into or materially modified after the date of adoption, or retrospectively for all periods presented. The adoption of this accounting standard did not have a material effect on our consolidated results of operations or financial condition.

## Edgar Filing: MEDICINOVA INC - Form 10-K

In March 2010, the FASB issued ASU No. 2010-11, Derivatives and Hedging (Topic 815): Scope Exception Related to Embedded Credit Derivatives. The FASB believes this ASU clarifies the type of embedded credit derivative that is exempt from embedded derivative bifurcation requirements. Specifically, only

---

**Table of Contents**

one form of embedded credit derivative qualifies for the exemption one that is related only to the subordination of one financial instrument to another. As a result, entities that have contracts containing an embedded credit derivative feature in a form other than such subordination may need to separately account for the embedded credit derivative feature. The amendments in the ASU are effective for each reporting entity at the beginning of its first fiscal quarter beginning after June 15, 2010. The adoption of this accounting standard did not have a material effect on our consolidated results of operations or financial condition.

In April 2010, the FASB issued ASU No. 2010-12, which indicates that the Securities and Exchange Commission, or SEC, staff would not object to incorporating the effects of the Health Care and Education Reconciliation Act of 2010 (which was enacted on March 30, 2010) when accounting for the Patient Protection and Affordable Care Act (which was enacted on March 23, 2010). This view is based partly on the SEC's understanding that the two aforementioned acts, when taken together, represent the current health care reforms as passed by Congress and signed by the President. We have performed an initial review of the two acts and do not believe that either will have a material impact on our consolidated results of operations or financial condition. Our belief is based on the fact that: (i) we are a development stage biopharmaceutical whose lead drug candidates are in Phase II of development and we have no other revenue generating products; therefore the pharmaceutical industry fee should not be applicable to us, nor would we be impacted by the drug subsidy changes; (ii) we have less than 25 employees so the fee for health plans will have minimal impact to our operating expenses; (iii) we do not have high-cost coverage health plans, nor do we offer retiree medical benefits; thus, the fees and the changes related to these would not impact our operating expenses; and (iv) with regard to the limit on tax-deductible employee compensation this should not impact our tax position as we are currently a net loss company and will continue to be a net loss company in the foreseeable future. The health care reforms also provide for a new investment tax credit for qualified therapeutic discovery, for which we submitted an application on July 16, 2010. In October 2010, we were notified that our application for a grant payment under the investment tax credit for qualified therapeutic discovery was not approved by the Department of Health and Human Services.

In April 2010, the FASB issued ASU No. 2010-17, which codifies the consensus reached in EITF No. 08-9, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and nonsubstantive milestones, and each milestone should be evaluated individually to determine if it is substantive. The amendments in this ASU are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this standard will not have a material effect on our consolidated results of operations or financial condition.

***Recently Issued Accounting Standards***

In December 2010, the FASB issued ASU No. 2010-027, Fees Paid to the Federal Government by Pharmaceutical Manufacturers which provides guidance concerning the recognition and classification of the new annual fee payable by branded prescription drug manufacturers and importers on branded prescription drugs which was mandated under the health care reform legislation enacted in the U.S. in March 2010. Under this new accounting standard, the annual fee would be presented as a component of operating expenses and recognized over the calendar year such fees are payable using a straight-line method of allocation unless another method better allocates the fee over the calendar year. This ASU is effective for calendar years beginning on or after December 31, 2010, when the fee initially becomes effective. The adoption of this accounting standard will not have an impact on our financial position or results of operations.

**Table of Contents*****Internal Controls Material Weakness Remediation***

As of December 31, 2010, management believes that the material weakness in our internal control over financial reporting that was included in Item 4 of our Form 10-Q for the quarter ended September 30, 2010 has been effectively remediated. Prior to December 31, 2010, the remediation measures as described below were implemented.

We have taken appropriate actions to remediate the material weakness related to the identified control overrides and policy deviations by one of our senior executive officers, which, collectively, represented a material weakness in our internal control over financial reporting. Our remediation plan included disclosing the granting of a waiver under our code of conduct to a senior executive and another employee due to the appearance of a possible conflict of interest, re-aligning certain reporting structures, updating our contract review and approval policy to require one signatory to be our Chief Financial Officer, strengthening certain human resource policies by amending our compensation committee charter and creating a strategic and oversight committee comprised of certain board members and the senior management team.

**2. Avigen Transaction**

On December 18, 2009 we acquired 100% of the outstanding shares of Avigen, a biopharmaceutical company that had focused on identifying and developing differentiated products to treat patients with serious disorders, whose potential product candidate is AV411, a glial attenuator and ibudilast small molecule therapeutic, for CNS disorders such as neuropathic pain, opioid withdrawal or methamphetamine addiction. The primary reasons for the Avigen acquisition were to combine the ibudilast development programs each company was respectively pursuing, to utilize the preclinical and clinical data for AV411 as support for the development pathway of MN-166 resulting in cost savings for us, and to capture a potential financing opportunity given Avigen's cash balance prior to the Merger.

The aggregate Merger consideration consisted of a First Payment Consideration of \$35.4 million of which \$3.0 million was funded in cash by us and \$32.4 million was funded in cash by Avigen, and a reduced Second Payment Consideration of \$1.1 million, subject to a reconciliation of expenses on or about June 30, 2010, of which \$0.6 million was funded in cash by Avigen and \$0.5 million is to be funded upon the expiry and release of the restricted letter of credit, which is recorded as such in our consolidated balance sheet, by the letter of credit's beneficiary. The cash payments were deposited in a separate trust account and are considered restricted cash by us. Of the 29,852,115 shares of Avigen common stock outstanding at the closing date, approximately 17 percent of Avigen shareholders elected to receive cash. Thereby, the First Payment Consideration was reduced by the number of shareholders who elected to receive cash, or \$6.0 million, resulting in \$29.4 million of Convertible Notes at face value to be issued by us. The \$1.1 million Second Payment Consideration (which is subject to a reconciliation of expenses) acts as an escrow holdback and is paid out in cash to the 17 percent of Avigen shareholders who elected cash and issued as additional Convertible Notes principal by us after the respective holdback period lapses on June 30, 2010 and November 30, 2010 for the restricted letter of credit. The Convertible Notes can be converted into shares of our common stock at a conversion price of \$6.80 per share. At the date of closing, our closing stock price was \$7.99, resulting in a beneficial conversion feature on the Convertible Notes issued pursuant to the First Payment Consideration and the Convertible Notes to be issued pursuant to the Second Payment Consideration. In addition to the First and Second Payment Considerations, the Merger agreement includes a Contingent Payment Rights Agreement, or CPR Agreement, between us, Avigen and American Stock Transfer & Trust Company, LLC, as rights agent. The CPR Agreement sets forth the rights that former Avigen stockholders have with respect to each CPR held after the closing of the Merger. The CPR Agreement provides for the payment of the following amounts on a pro rata basis:

if the first milestone payment under Avigen's agreement with Genzyme, or the Genzyme Agreement, is received before August 18, 2011, \$6,000,000 or such lesser cash amount paid by Genzyme;



**Table of Contents**

if the first milestone payment has not occurred and the Parkinson's Product, as defined in the Genzyme Agreement, is sold or otherwise disposed of by us before August 18, 2011, 50 percent of the net proceeds of such sale or disposition received before August 18, 2011; and

if the trust established pursuant to the Avigen MTP, is terminated, the amount remaining in such trust upon termination (less any payments required to be made under Avigen's Management Transition Plan Trust Agreement), such amount currently estimated at \$624,000. As of December 31, 2010, the Avigen MTP had not been terminated.

With respect to the first two contingent payment rights described above, we have not ascribed any value to them as we have deemed them not probable and we cannot determine when, or if, the related milestones will be achieved or the events triggering the commencement of payment obligations will occur. With respect to the contingent payment rights related to the Avigen MTP, as none of the assets will revert to us, we have recorded a restricted investment and a corresponding liability in our consolidated balance sheet.

We have included Avigen's business operations in our consolidated financial statements since the acquisition date and we have accounted for the Merger under the acquisition method of accounting. Included in our consolidated statement of operations is approximately \$4,000 of operating expenses since the acquisition date of December 18, 2009. Acquisition method of accounting requires that assets acquired and liabilities assumed are recognized at their fair values as of the acquisition date, that the fair value of acquired in-process research and development, or IPR&D is recorded on the balance sheet, all transaction costs are expensed as incurred and any excess of the purchase price over the assigned values of net assets acquired is recorded as goodwill. In addition, Avigen's historical stockholder's equity accounts were eliminated.

For the year ended December 31, 2009, we expensed \$1.8 million of transaction costs as they were incurred. The estimated fair value of the aggregate Merger consideration, or the Purchase Price, was as follows (table in thousands):

First Payment Consideration (Convertible Notes issued by us)	\$ 29,258
Second Payment Consideration (Escrow Holdback)	1,094
Cash paid by us	3,000
Conversion Feature related to First Payment Convertible Notes	9,227
Conversion Feature related to Second Payment Convertible Notes	286
 Total Purchase Price	 \$ 42,865

The fair value of the First Payment Consideration and Second Payment Consideration and the related fair value of their respective beneficial conversion feature, was based on a BOPM. Assumptions used in the BOPM included the maturity date of the Convertible Notes, time between nodes, volatility, face value of the Convertible Notes at the closing date and the risk-free rate. The maturity date utilized was 1.5 years based on the maturity of the notes in June 2011. As our projected period was 1.5 years, we used the average of the one and two year U.S. Treasury bonds as of the closing date and we based volatility on the historical volatility of publicly-traded comparable companies to Avigen and our stock price volatility. To calculate the fair value of the Convertible Notes and their respective beneficial conversion feature under the BOPM we first had to generate a price tree, which is produced by working forward from the date of closing to the Convertible Notes maturity date. At each step it is assumed that the Convertible Notes will move up or down by a specific factor of volatility. In the second step of the BOPM we had to determine the option value at each final node, which is the intrinsic or exercise value. The intrinsic value is calculated by subtracting the conversion price, or \$6.80 per share, from the expected stock price as determined in the aforementioned step. The third step of the BOPM was to calculate option value at each node, starting at the end node, working back to the first node of the price tree, where the result would be the value of the option, discounted by the risk-free rate. In the last step of the BOPM we determined the fair value of the Convertible Notes without the conversion feature. To calculate the value of the Convertible Notes without the conversion feature, we multiplied the expected payments from the Convertible Notes by a





**Table of Contents**

discount factor, that discount factor being one divided by one plus the discount rate raised to the power of time. We then applied to the result a lack of marketability discount for the conversion feature using a protective put model to account for the lower degree of liquidity which would detract from the face value of the Convertible Notes.

The First Payment Consideration was recorded on our consolidated balance sheet as Convertible Notes at its fair value of \$29.3 million. The \$0.2 million difference between fair value and face value will be accreted to interest expense through the Convertible Note period. At acquisition-date, following ASC 805, the fair value of the conversion feature was accounted for within equity and will not be re-measured during interim periods and subsequent settlements (conversions to our stock) will be accounted for in equity.

The Second Payment Consideration was recorded on our consolidated balance sheet as an Escrow Holdback at its fair value of \$1.1 million. At acquisition-date, although this contingent consideration was recorded as a liability following ASC 805, the fair value of the conversion feature was accounted for within equity and will not be re-measured during interim periods and subsequent settlements for those who elected Convertible Notes (conversions to our stock) will be accounted for in equity.

Based on a third-party valuation, as of the date of closing, amounts of estimated fair value of assets acquired and liabilities assumed at the acquisition date were as follows (table in thousands):

Cash and cash equivalents	\$ 628
Restricted cash	30,046
Restricted investment	676
Restricted letter of credit	500
Identifiable intangible assets	4,800
Accrued interest	2
Prepaid expenses	35
Deferred tax liability	(1,956)
Avigen MTP liability	(676)
Accounts payable	(236)
Accrued compensation	(96)
Identifiable net assets acquired and liabilities assumed	33,723
Goodwill	9,142
Total purchase price	\$ 42,865

With the reconciliation of expenses performed in June 2010 and the expiry of the restricted letter of credit in November 2010, goodwill was adjusted by approximately \$458,000 to \$9,600,241 to reflect the shortfall in the escrow holdback. We deemed the overall change in goodwill amount inconsequential to the overall financial statements and we accounted for this change prospectively.

The carrying value of all assets acquired, except for identifiable intangible assets discussed below, and all liabilities assumed approximates fair value.

*Identifiable intangible assets.* Identifiable intangible assets acquired have been attributed as follows: (table in thousands):

Edgar Filing: MEDICINOVA INC - Form 10-K

IPR&D	\$ 4,800
Genzyme Agreement	
Total	\$ 4,800

---

**Table of Contents**

*IPR&D.* The fair value attributed to IPR&D represents an estimate of fair value of in-process technology related to Avigen's AV411 program, which at the Merger closing date, had not received U.S. Food and Drug Administration, or FDA, approval for any indication. As such, pursuant to ASC 805, amortization of the IPR&D will not occur until it reaches market feasibility. Although we plan to integrate the two ibudilast-based development programs (our MN-166 and the acquired AV411) and pursue discussions with potential partners to secure a strategic collaboration to advance clinical development of the combined development programs, the fair value for the AV411 IPR&D was determined using the income approach, although the cost and market approaches were also reviewed. Under the income approach we used a multi-period excess earning method in which the forecast of all expected future cash flows was predicated on a collaboration partner structure in which revenue streams were generated in the short-term by milestone payments and royalty payments in the long-term. As several significant milestones need to be achieved prior to expected commercialization, a probability adjustment was applied to the forecasted revenue to account for the risk associated with being able to successfully commercialize. We also applied a discount rate on the overall valuation based on the industry composite weighted average cost of capital to account for the perceived risk of the technology with respect to successful commercialization, market acceptance and growth and profitability. To validate the reasonableness of the IPR&D fair value under the income approach, we also valued the technology under the cost and market approaches. Under the cost approach we estimated the cost to recreate the technology's preclinical and clinical data package, which this cost was considered a savings benefit by us and was part of our rationale for doing the Merger. Under the market approach we considered the formal and informal bids that Avigen received while it marketed its AV411 program for sale. After reviewing the results derived from all three approaches, we concluded that the income approach was a reasonable basis to fair value IPR&D.

*Genzyme Agreement.* In the event the first milestone is not reached and we can dispose of the respective Parkinson's product or FDA approval is received on the respective Parkinson's product, then, the Genzyme Agreement could potentially have value. At the date of closing, however, we are unable to estimate the likelihood that we will be able to sell or dispose of our rights under the Genzyme Agreement and we are unable to estimate the likelihood of the respective Parkinson's product receiving FDA approval. Because we cannot determine the probability of selling or disposing of the Parkinson's product and we are unable to determine the probability that the Parkinson's product will receive FDA approval, we have not ascribed any value to this contingent asset at the acquisition date as its fair value cannot be reasonably estimated.

*Goodwill.* The authoritative guidance for business combinations requires that contingent consideration be recognized at acquisition-date fair value as part of the consideration transferred. As such, as stated above, we included in the purchase price the fair value of the aggregate Merger consideration, which included both the Convertible Notes associated with the First and Second Payment Considerations, the cash paid by us and the beneficial conversion feature on the Convertible Notes. The goodwill is primarily a direct result of the fair value of the beneficial conversion feature of the Convertible Notes. We were willing to set the conversion price of the Convertible Notes issued and to be issued at \$6.80 per share, which at acquisition-date was less than our closing stock price, as we viewed the Merger as a financing opportunity given the cash balance held by Avigen prior to the Merger. We also believe that the cost for a development stage company to raise \$30 million in today's economic environment exceeds the goodwill recorded on our books. Through December 31, 2010, we have raised approximately \$1.8 million as a result of conversions into shares of our common stock.

We tested goodwill for impairment at December 31, 2010, utilizing a market based approach in which our total market capitalization was significantly higher than the corresponding value of net assets, including goodwill; thus, noting no impairment. We also tested IPR&D for impairment at December 31, 2010, utilizing a cost approach in which the total cost to recreate the technology's preclinical and clinical data package was significantly higher than our IPR&D carrying value; thus, noting no impairment.

**Table of Contents**

The accompanying consolidated statement of operations for the year ended December 31, 2009, includes the operations of Avigen from the date of acquisition. Assuming the acquisition of Avigen had occurred January 1, 2009 and 2008, the pro forma unaudited condensed results of operations would have been as follows (in thousands, except per share amounts):

	<b>Year Ending December 31,</b>	
	<b>2009</b>	<b>2008</b>
Revenues	\$ 144	\$ 7,100
Operating Expenses	\$ (31,917)	\$ (50,191)
Net Loss	\$ (29,978)	\$ (47,024)
Basic and diluted net loss per common share	\$ (1.82)	\$ (2.86)

The above proforma unaudited results of operations do not include proforma adjustments relating to costs of integration or post-integration cost reductions that may be incurred or realized by us in excess of actual amounts incurred or realized through December 31, 2009.

The following table reconciles the December 31, 2009 acquisition related balances with their respective balances at December 31, 2010:

	<b>Carrying Value at 12/31/09</b>	<b>Value of Notes Converted and Fractional Share Payout 1/1/10- 12/31/10(9)</b>	<b>Interest Earned 1/1/10-12/31/10(10)</b>	<b>Other Expense (Accretion) 1/1/10-12/31/10(11)</b>	<b>Other Activity 1/1/10-12/31/10</b>	<b>Carrying Value at 12/31/10</b>
Restricted cash(1)					\$ 433,000(15);	
					\$ (73,449)(15)	
					\$ 226,000(6)	
	\$ 30,045,965	\$ (1,805,487)	\$ 2,982	\$	\$ (140,119)(13)	\$ 28,688,892
Restricted investment(2)	\$ 676,499	\$	\$ 51	\$	\$ (52,799)(12)	\$ 623,751
					\$ (433,000)(3)	
Restricted letter of credit(3)	\$ 500,042	\$	\$ 495	\$	\$ (67,490)(3)	\$ 47
IPR&D(4)	\$ 4,800,000	\$	\$	\$	\$	\$ 4,800,000
Goodwill(5)					\$ 232,036(15)	
	\$ 9,142,205	\$	\$	\$	\$ 226,000 (6)	\$ 9,600,241
					\$ 200,964(15)	
					\$ 67,490(3)	
Escrow holdback(6)	\$ (1,094,045)	\$	\$ (488)	\$	\$ 140,119(13)	\$ (47)
					\$ 685,913(14)	
Management transition plan liability(2)	\$ (676,499)	\$	\$ (51)	\$	\$ 52,799(12)	\$ (623,751)
Deferred tax liability(7)	\$ (1,956,000)	\$	\$	\$	\$	\$ (1,956,000)

## Edgar Filing: MEDICINOVA INC - Form 10-K

Convertible notes(8)					\$ (359,551)(15)	
	\$ (29,258,137)	\$ 1,805,342	\$ (2,804)	\$ (125,229)	(685,917)(14)	\$ (28,626,296)

- (1) Restricted cash consists of cash held in a separate trust account, managed by a third-party, in connection with the \$32.4 million of cash funded by Avigen and the \$3.0 million of cash paid by us, or the First Payment Consideration, less the \$6.0 million paid out to Avigen shareholders who elected a cash payout at the merger closing date and the Second Payment Consideration described in (6) below.
- (2) Restricted investment consists of cash held in an irrevocable grantor trust, or rabbi trust, which is intended to fund benefit obligations under the Avigen MTP. These funds represent reserves for benefits eligible to terminated employees as defined by the Avigen MTP. Accordingly, we booked the associated Avigen MTP

**Table of Contents**

- liability. Upon termination of the trust, these funds are to be paid to the former Avigen stockholders on a pro rata basis.
- (3) Restricted letter of credit consists of cash provided as a credit guarantee and security for an irrevocable letter of credit related to Avigen's original lease of office space which expired November 30, 2010. The \$67,490 reduction related to the beneficiary's draw on the letter of credit in satisfaction of certain property damage. The \$433,000 reduction relates to the remaining funds reverting to the restricted cash account described in (1) above. The \$47 remaining in the account related to December interest which posted after the bulk of the funds were transferred to the escrow holdback account. These funds were transferred to the restricted cash account in January 2011.
  - (4) In-process research and development, or IPR&D, represents an estimate of fair value of in-process technology related to Avigen's AV411 program, which at the merger closing date, had not received FDA approval for any indication. As such, pursuant to ASC 805, amortization of the IPR&D will not occur until it reaches market feasibility. The annual test date for IPR&D impairment is December 31. During year ended December 31, 2010 and through the date of this report, there were no triggering events, market conditions or other factors that would indicate possible or actual impairment of IPR&D.
  - (5) We included in the purchase price of Avigen the fair value of the aggregate merger consideration, which included both the convertible notes associated with the First Payment Consideration described in (1) above and the Second Payment Consideration described in (6) below, the \$3.0 million cash paid by us and the conversion feature on the convertible notes. As such, we originally recorded \$9.1 million of goodwill related to the excess purchase price over the assigned values of the net assets acquired. See Second Payment Consideration reconciliation discussion, described in (6) below, for the \$226,000 increase in goodwill and see (15) below for the additional \$232,036 increase in goodwill. The goodwill was primarily a direct result of the fair value of the conversion feature of the convertible notes. The annual test date for goodwill impairment is December 31. During the year ended December 31, 2010 and through the date of this report, there were no triggering events, market conditions or other factors that would indicate possible or actual impairment of goodwill.
  - (6) At the closing of the merger, we and Avigen funded \$1,500,000 in a combination of cash and a letter of credit in a separate escrow account, or Second Payment Consideration, pursuant to an escrow agreement. The Second Payment Consideration is considered the escrow holdback. We and Avigen identified certain additional liabilities of approximately \$400,000 prior to closing of the Merger. As such, in accordance with the procedures set forth in the escrow agreement, \$400,000 was released from the escrow account in satisfaction of these additional liabilities. At acquisition date, we recorded the escrow holdback in our consolidated balance sheet at fair value. Upon reconciliation of the escrow holdback in June 2010, we recorded increased goodwill by \$226,000. We deemed this amount inconsequential to the overall financial statements and we accounted for this change prospectively. In addition, the \$226,000 was deposited into restricted cash.
  - (7) The deferred tax liability represents the book to tax basis difference related to IPR&D acquired through the acquisition of Avigen.
  - (8) At the closing of the merger, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into an indenture governing the terms of the convertible notes. Under the terms of a separate trust agreement, \$29.4 million, which represents the initial principal amount of the convertible notes, or 83% of the First Payment Consideration, was deposited with a trust agent for the benefit of the holders and us (the amount of such deposit together with interest accrued and capitalized thereon, the Property). See (11) below which discusses the discount on the convertible notes. At the election of the respective convertible note holders, the convertible notes can be converted into our common stock at the conversion price of \$6.80 per share. Upon maturity of the convertible notes on June 18, 2011, the 18-month anniversary of the closing of the merger, we plan to use the Property to pay the principal amount of, and accrued interest on, the remaining convertible notes. For the year ended December 31, 2010, \$2,804 was the amount of interest capitalized on the convertible notes.
  - (9) During the year ended December 31, 2010, 265,409 shares of our common stock were issued in connection with the conversion of convertible notes to our common stock at a conversion price of \$6.80, with any fractional shares being paid out of restricted cash. The approximately \$1.8 million of proceeds received during the year ended December 31, 2010, as a result of the convertible notes conversions into our common

**Table of Contents**

- stock, were deposited into a money market account and recorded as cash and cash equivalents in our consolidated balance sheet at December 31, 2010.
- (10) Interest earned on the restricted cash, investment and letter of credit balances is added to the principal of the respective liability accounts.
  - (11) At December 31, 2009, the fair value of the convertible notes was less than their face value. As a result, over the term of the convertible notes (18 months) we will accrete the discount on the convertible notes with the offset being charged to other expense.
  - (12) The reduction in restricted investments and Avigen MTP liability relate to the payout of eligible benefits to terminated employees and fees associated with managing the trust account.
  - (13) Pursuant to the first payment release out of the escrow holdback account after the reconciliation of expenses in July 2010, we paid \$140,119 which represents the cash paid to Avigen shareholders who elected a cash payment.
  - (14) Pursuant to the first payment release out of the escrow holdback account after the reconciliation of expenses in July 2010, we issued \$685,913 in principal of additional convertible notes to Avigen shareholders who elected for convertible notes in lieu of a cash payment.
  - (15) Pursuant to release of \$433,000 in December 2010, upon expiry of the restricted letter of credit (as discussed in (3) above), we paid \$73,449 which represents the cash paid to Avigen shareholders who elected a cash payment and we issued \$359,551 in principal of additional convertible notes to Avigen shareholders who elected for convertible notes in lieu of a cash payment. In addition, upon release of the funds, the remaining liability in the escrow holdback of \$200,964 was debited to clear the escrow holdback liability account to the remaining \$47, and the offset was an increase in goodwill of \$232,036 due to a shortfall in the escrow holdback liability. We also deemed this change in goodwill amount inconsequential to the overall financial statements and we accounted for this change prospectively.

**3. Fair Value Measurements Other Than Intangibles and Goodwill**

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

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

At December 31, 2010, cash and cash equivalents (instruments with maturities of three months or less at the date of purchase) were \$28.3 million and primarily invested in money market accounts. At December 31, 2010, restricted cash and restricted investments were \$29.3 million and primarily invested in money market funds. We measure our cash equivalents, restricted cash and restricted investments on a recurring basis. The fair value of our cash equivalents, which are current assets, is based on Level 1 criteria in which their carrying amount is a reasonable estimate of their fair value based on daily quoted market prices.

Our investment securities had consisted of ARS, all of which had AAA ratings at the time of original purchase. ARS are generally long-term debt instruments that historically have provided liquidity through a Dutch auction process that resets the applicable interest rate at predetermined calendar intervals, typically seven, 28, 35 or 49 days. All of our ARS principally represent insurance notes and portfolios of securities (primarily commercial paper).

**Table of Contents**

In August 2008, UBS, the brokerage firm through which we had purchased the majority of our investment securities, all of which were auction rate securities, or ARS, entered into a settlement with the SEC, the New York Attorney General and other state agencies. Under the settlement, we had received the right to sell to UBS the ARS held in accounts with UBS at par value at any time during the period beginning June 30, 2010 and ending July 2, 2012. The right to sell the ARS back to UBS was considered an ARS Put. As part of the settlement, UBS also offered to us a no net cost loan program, or ARS Loan, whereby we would be able to borrow up to 75 percent of the market value, as determined by UBS at its sole discretion, of our ARS that have been pledged as collateral at an interest cost that would not exceed the interest being paid on the underlying ARS investments. We had measured the UBS ARS on a Level 3 basis, as defined by ASC 820, using a discounted cash flow valuation model, employing liquidity discounts and assumptions made regarding interest rate and maturity.

We had elected to measure the ARS Put under the fair value option of ASC 825, authoritative guidance on financial instruments (formerly SFAS No. 159), to mitigate the volatility in reported earnings due to the linkage of certain of our ARS and the ARS Put. Under ASC 825, any subsequent increase or decrease in the fair value of the ARS Put would be recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations. The fair value of the ARS Put was also determined by a discounted cash flow valuation model with assumptions being made related to interest rate, maturity and liquidity.

At December 31, 2008, we had designated our investment securities portfolio as trading investment securities; therefore, any additional increase or decrease in the fair value of our investment securities is recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations.

We exercised our ARS Put on June 30, 2010. Upon settlement of the ARS Put in July 2010, the UBS ARS were redeemed at par value by UBS and the associated ARS Loan was repaid, which resulted in a net gain of approximately \$138,000 being recorded in our consolidated statement of operations related to the redemption of the UBS ARS and ARS Put. Therefore, at December 31, 2010, we no longer held any investment securities originally purchased by UBS and we no longer held the ARS Put.

In the third quarter of 2010, we reclassified our long-term investment securities to current investment securities because we no longer had the intent to hold these securities for more than a year. In addition, the fair market value of these investment securities were no longer determined on a Level 3 basis based on a discounted cash flow model employing liquidity discounts, but rather on a Level 2 basis, as defined by ASC 820, based on indicative liquidation quotes in an inactive market. During the twelve months ended December 31, 2010, we recorded impairment charges of \$923,000 on these investment securities to write them down to fair market value based on the indicative quotes received from third party brokers. All impairment charges were recorded in our consolidated statement of operations in the current year.



**Table of Contents**

At December 31, 2010, we no longer held any investment securities and the table below summarizes the ARS trading investment securities and the ARS Put activities from December 31, 2009 to December 31, 2010:

	Fair Value at 12/31/09	Transfers (out) of Level 3 and long-term asset/in to Level 2 and current asset 1/1/10-12/31/10	Sales/ Redemptions 1/1/10- 12/31/10	Impairment Charge 1/1/10-12/31/10	Gain 1/1/10-12/31/10	Fair Value at 12/31/10
Investment securities-current asset(1)	\$ 24,254,987	\$ 840,000	\$ (27,817,749)	\$ (542,256)	\$ 3,265,018	\$
Investment securities-long-term asset(2)	\$ 2,085,425	\$ (840,000)	\$ (294,192)	\$ (956,110)	\$ 4,877	\$
ARS Put-current asset(3)	\$ 2,557,007	\$	\$	\$ (2,785,978)	\$ 228,971	\$

- (1) Aggregated fair value of the investment securities- current asset was previously determined on a Level 3 basis based on a discounted cash flow model, which employed liquidity discounts and included assumptions regarding future cash flows and the likelihood of the redemption or refinancing of such ARS. At December 31, 2010, we no longer held investment securities- current asset associated with the UBS ARS Rights Offer. We initiated the redemption of these ARS on June 30, 2010, with settlement occurring on July 1, 2010. At September 30, 2010, we reclassified the long-term private placement investment securities to current assets, which these securities were subsequently sold in October 2010. See (2) below for discussion on their fair market valuation.
- (2) Aggregated fair value of the long-term private placement investment securities was previously determined on a Level 3 basis based on a discounted cash flow model, which employed liquidity discounts and included assumptions regarding future cash flows and the likelihood of the redemption or refinancing of such ARS. At September 30, 2010, we had determined that we no longer had the intent to hold these investment securities for more than a year. At September 30, 2010, fair value of these securities was determined on a Level 2 basis, based on quotes received from investment brokers assuming liquidation of these assets in a short time frame (within a month). We believed the liquidation value of these investment securities fairly approximated their fair value as we recorded a gain of approximately \$28,000 upon sale of these investment securities in October 2010. At December 31, we no longer held any investment securities.
- (3) We had elected to measure the ARS Put under the fair value option of ASC 825, authoritative guidance on financial instruments, to mitigate the volatility in reported earnings due to the linkage of our UBS ARS and the ARS Put. Fair value of the ARS Put, was previously determined on a Level 3 basis based on a discounted cash flow model, which employed a liquidity discount taking into consideration UBS's cost of capital. At December 31, 2010, we no longer held the ARS Put as it was redeemed by UBS on July 1, 2010.

**4. Long-term Debt**

On May 10, 2010, we entered the Loan Agreement with Oxford, under which we borrowed \$15.0 million.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We also have agreed not to pledge or otherwise encumber our intellectual property assets. Our obligations under the Loan Agreement are guaranteed on a senior secured basis by Avigen.

In addition, the Loan Agreement contains covenants that restrict our ability to:

incur additional indebtedness;

**Table of Contents**

create liens;

enter into certain merger and licensing transactions;

dispose of certain of our assets;

enter into certain fundamental corporate changes;

make certain types of investments; and

make certain payments and distributions.

The Loan Agreement requires that on or before March 31, 2011 we must have either (i) entered into a collaboration, joint venture or partnership with a non-affiliate providing for up-front cash proceeds to us (with such proceeds received on or before March 31, 2011) of not less than \$15.0 million from either or a combination of an upfront payment(s) or proceeds from the sale or conversion of our securities issued in connection therewith or (ii) received positive Phase IIb data on MN-221, as defined in a completed partnership or joint venture agreement relating to MN-221, or had a positive end-of-Phase II meeting with the FDA and obtained the approval of the board of directors to proceed to Phase III with MN-221. A failure to meet the Loan Agreement requirements by March 31, 2011, would result in an immediate requirement for Loan repayment (as well as an increase in interest rate). As of December 31, 2010, we were in compliance with the Loan Agreement covenants. See Notes to Consolidated Financial Statements Note 12, Subsequent Events, for further information on the Oxford loan.

We are required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan on August 1, 2013, we will be required to make payments of outstanding principal and interest in 30 equal monthly installments. The stated interest rate on the loan is 12.87 percent. The effective interest rate on the debt financing is calculated to be 18.14 percent and for the year ended December 31, 2010, we recorded total interest expense on this loan of approximately \$1.7 million.

We paid the Lender a facility fee of \$150,000 and we have paid outside third parties approximately \$180,000 in connection with procuring the loan. We will also pay Oxford a deferred interest payment equal to \$450,000, payable on September 30, 2011, provided that a pro rata portion of such deferred interest payment shall be paid upon any prepayment of the loan. In addition, if we prepay all or a portion of the loan prior to maturity, we will pay Oxford a prepayment penalty of three percent of the total amount prepaid if the prepayment occurs prior to May 10, 2011, two percent of the total amount prepaid if the prepayment occurs between May 11, 2011 and May 10, 2012 and one percent of the total amount prepaid if the prepayment occurs on or after May 10, 2012.

In connection with the Loan Agreement, we issued to Oxford a warrant to purchase up to 198,020 shares of our common stock. This warrant is exercisable, in whole or in part, immediately, has a per share exercise price of \$6.06 and may be exercised on a cashless basis. The warrant will terminate on the earlier of May 10, 2017 or the closing date of a merger or consolidation transaction in which we are not the surviving entity. In addition, the warrant and debt instrument are immediately separable and were issued separately; thus, we accounted for the warrant as a component of stockholders' equity as the agreement requires settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

**Table of Contents**

We accounted for the interest on the long-term debt using the effective interest method wherein we treated the debt issuance costs paid directly to the lender (financing fees) and the relative fair value of the warrants issued to the lender as a discount on the debt (or a contra liability) and we treated the debt issuance costs paid to third parties (primarily legal fees) as an other asset in our consolidated balance sheet. The amortization of the debt discount is recorded as interest expense and the amortization of the debt issuance costs paid to third parties is recorded as other expense in our consolidated statement of operations. The table below summarizes the long-term debt activity recorded during the year ended December 31, 2010:

	<b>Gross Amount 5/10/10</b>	<b>Amortization (Interest Expense) 5/10/10-12/31/10</b>	<b>Amortization (Other Expense) 5/10/10-12/31/10</b>	<b>Carrying Value 12/31/2010</b>
<b>Other Assets:</b>				
Debt issuance costs paid to third parties	\$ 180,000	\$	\$ (55,278)	\$ 124,722
<b>Liability:</b>				
Loan	\$ (15,000,000)	\$	\$	\$ (15,000,000)
Deferred interest charge		(134,491)		(134,491)
	\$ (15,000,000)	\$ (134,491)	\$	\$ (15,134,491)
<b>Contra Liability:</b>				
Relative fair value of warrants issued to lender(1)	\$ 859,209	\$ (263,867)	\$	\$ 595,342
Debt issuance costs paid to lender	150,000	(46,066)		103,934
	\$ 1,009,209	\$ (309,933)	\$	\$ 699,276

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

**5. Balance Sheet Details****Property and Equipment**

Property and equipment, net, consist of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Leasehold improvements	\$ 498,581	\$ 498,581
Furniture and equipment	794,498	867,083

Edgar Filing: MEDICINOVA INC - Form 10-K

Software	219,652	367,146
	1,512,731	1,732,810
Less accumulated depreciation and amortization	(1,447,522)	(1,579,263)
	\$ 65,209	\$ 153,547
Depreciation and amortization expense	\$ 108,257	\$ 219,202

**Table of Contents*****Accrued Expenses***

A substantial portion of our ongoing research and development activities are performed under agreements we enter into with external service providers, including clinical research organizations, which conduct many of our research and development activities. A portion of our ongoing general and administrative activities relate to legal, accounting and consulting services. We accrue for costs incurred as the services are being provided by monitoring the status of clinical trials or specific projects or services provided, contractual factors such as milestones or retainer fees and the invoices received from our external service providers. Accrued expenses consist of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Research and development costs	\$ 766,886	\$ 864,471
Professional services fees	226,362	187,367
Other	140,025	224,198
	\$ 1,133,273	\$ 1,276,036

**6. Related Party Transactions**

We and Danerius, LLC, or Danerius, an affiliate of Alan W. Dunton, M.D., one of our directors, entered into a consulting agreement dated June 12, 2009 under which Danerius, will provide consulting services to us related to our product development programs at a rate of \$27,500 per month. For the years ended December 31, 2010 and 2009, we paid Danerius approximately \$302,000 and \$193,000, respectively. We terminated the contract with Danerius in November 2010 and Dr. Dunton resigned as a director in January 2011.

There were no related party transactions for the year ended December 31, 2008.

**7. Commitments and Contingencies*****Facility Lease***

In January 2004, we leased 16,609 square feet of space for our corporate headquarters under a non-cancelable operating lease that was set to expire in February 2008. In January 2008, we entered into a fourth amendment to lease for our corporate headquarters at the same location in which we reduced the amount of space under lease to 12,699 square feet of office space through August 2011. In June 2005, we leased 1,726 square feet of office space in Tokyo, Japan under a non-cancelable operating lease that expires in May 2011. Furthermore, pursuant to our acquisition of Avigen we acquired a month-to-month lease for 4,000 square feet of office space in Alameda, California. We vacated the Alameda premises on March 8, 2010 and, accordingly, we were released from our month-to-month lease by the landlord. We currently do not intend to renew our corporate headquarters facility lease. We are considering month-to-month options, reducing our office space requirements and/or utilizing virtual offices. Rent expense for the years ended December 31, 2010 and 2009 was \$612,291 and \$578,493, respectively, and rent expense, net of sub-lease income for the period from September 26, 2000 (inception) to December 31, 2010 was \$4,208,733.

Future minimum payments are as follows:

<b>Years ending December 31:</b>	
2011	\$ 390,509
Thereafter	\$
<b>Total minimum payments</b>	<b>\$ 390,509</b>

---

## **Table of Contents**

### ***License Agreements***

We have entered into numerous license agreements to acquire the rights to develop and commercialize a variety of product candidates. Pursuant to these agreements, we have obtained exclusive licenses to the patent rights and know-how for all indications under the agreements within our licensed territories. We generally make an upfront payment and are required to make additional payments upon the achievement of specific development and regulatory approval milestones. We are also obligated to pay royalties under the agreements until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis.

The amounts expended under these agreements and charged to research and development expense during the years ended December 31, 2010, 2009, 2008, and the period from September 26, 2000 (inception) to December 31, 2010 were \$0, \$0, \$100,000 and \$9,850,000, respectively. As of December 31, 2010, future potential milestone payments totaled approximately \$94.1 million, and there are no minimum royalties required under any of the license agreements. We are unable at this time to estimate with certainty the timing on when these milestone payments will occur as these payments are dependent upon the progress of our product development programs. From June 19, 2002 (the date of our first license agreement) through December 31, 2010, we have entered into nine license agreements with Japanese and British pharmaceutical companies and a non-profit research institute.

### ***Legal Proceedings***

On August 24, 2009, The Pennsylvania Avenue Funds, an Avigen stockholder, filed a complaint in Alameda County Superior Court alleging that Avigen's directors breached their fiduciary duties in connection with the proposed transaction with us. On October 15, 2009, The Pennsylvania Avenue Funds filed an amended complaint adding us as a defendant. In the amended complaint, The Pennsylvania Avenue funds alleged, among other things, that we aided and abetted the alleged breach of fiduciary duties by the Avigen directors. Avigen and The Pennsylvania Avenue Funds have signed a stipulation of settlement agreement and moved the court for preliminary approval. The Court heard oral arguments on the Motion for Preliminary Approval of Settlement and held a case management conference on March 8, 2010, during which it raised a few issues regarding the settlement provisions. On April 6, 2010, the Superior Court for the State of California for the County of Alameda approved the preliminary settlement and set a final settlement hearing for June 24, 2010. Under the terms of the Stipulation of Settlement, Avigen agreed not to oppose a fee motion by counsel to The Pennsylvania Avenue Funds for fees and expenses in the amount not to exceed \$140,000 and a petition by The Pennsylvania Avenue Funds for an incentive award of up to \$2,500. On June 24, 2010, the final order and judgment approving final settlement of \$140,000 for fees and expenses was received. The petition for the \$2,500 incentive award was denied. Avigen's insurance carrier paid the \$140,000 balance due to The Pennsylvania Avenue Funds on July 2, 2010.

On March 3, 2011, we received a legal letter from a former employee who had been terminated in January 2011 pursuant to our planned reduction-in-force to save costs. The legal letter did not assert a claim outright; however, there were allegations made in the legal letter that could threaten litigation against us. We have engaged legal counsel in connection with the possibility of a lawsuit given this legal letter and the fact that this former employee's separation agreement has expired. No accrual has been made for this threatened lawsuit in our financial statement as of December 31, 2010. In the event of a lawsuit, we intend to defend ourselves.

We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any of these matters may occur which could harm our business. We are currently not a party to any legal proceedings.



## **Table of Contents**

### **8. Redeemable Convertible Preferred Stock, Convertible Notes and Stockholders' Equity**

#### ***Initial Public Offering in Japan***

On February 4, 2005, we completed an IPO of 3,000,000 shares of common stock in Japan and received aggregate proceeds of \$104,486,895, net of underwriting discounts and commissions and offering expenses. In addition, on March 8, 2005, we closed the sale of an additional 157,300 shares of our common stock pursuant to the partial exercise by our underwriters of an over-allotment option which resulted in aggregate proceeds to us of \$5,557,773, net of underwriting discounts and commissions. In connection with our IPO, redeemable convertible and convertible preferred stock outstanding as of February 4, 2005 was automatically converted into 6,678,285 shares of common stock.

#### ***Public Offering in the United States***

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

#### ***Redeemable Convertible Preferred Stock***

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

#### ***Warrants***

In May 2010, we issued to Oxford a warrant to purchase up to 198,020 shares of our common stock. This warrant is exercisable, in whole or in part, immediately, has a per share exercise price of \$6.06 and may be exercised on a cashless basis. The warrant will terminate on the earlier of May 10, 2017 or the closing date of a merger or consolidation transaction in which we are not the surviving entity. In addition, the warrant and debt instrument are immediately separable and were issued separately; thus, we accounted for the warrant as a component of stockholders' equity as the agreement requires settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

#### ***Stock Options***

## Edgar Filing: MEDICINOVA INC - Form 10-K

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

### *2000 General Stock Incentive Plan*

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

## **Table of Contents**

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

At December 31, 2010, stock options to purchase a total of 28,500 shares of common stock were outstanding under the 2000 Plan at a weighted average exercise price of \$10.00 per share. No additional stock options have been or will be issued under the 2000 Plan subsequent to our IPO. However, stock options previously granted under the 2000 Plan will remain outstanding until the earlier of expiration or exercise.

### *2004 Stock Incentive Plan*

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

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

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

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

Fully vested automatic grants of nonstatutory stock options will be made to non-employee directors in an initial amount of 1,000 shares upon first becoming a member of our board of directors. Immediately after each of our regularly scheduled annual meetings of stockholders, each non-employee director will be automatically granted a nonstatutory option to purchase 1,000 shares of our common stock, at 100% of the fair market value at the time of grant, provided that the director has served on our board for at least six months. Each annual option will be fully vested and exercisable on the date which is six months after the date of grant.

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

A summary of our stock option activity and related information as of December 31, 2010 is as follows:

	<b>Number of Option Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding at January 1, 2010	2,055,576	\$ 8.63
Granted	525,000	\$ 6.81
Exercised	(44,948)	\$ 3.71
Cancelled	(254,697)	\$ 8.04
<b>Outstanding at December 31, 2010</b>	<b>2,280,931</b>	<b>\$ 8.38</b>
Exercisable at December 31, 2010	1,638,782	\$ 9.54

**Table of Contents**

The weighted average contractual life of options outstanding at December 31, 2010 was 6.9 years and the weighted average contractual life of exercisable options at December 31, 2010 was 6.2 years. The intrinsic value of stock options exercised, outstanding and exercisable during the year ended December 31, 2010 was \$65,000, \$0.7 million and \$0.4 million, respectively, based on the Nasdaq Global Market on such date.

***Common Stock Reserved for Future Issuance***

The following table summarizes common stock reserved for future issuance at December 31, 2010:

Common Stock under the employee stock purchase program	259,127
Common stock reserved for issuance upon conversion of convertible notes	4,209,749
Common stock reserved for issuance upon exercise of warrant	198,020
Common stock options outstanding (under the 2000 Plan and 2004 Plan)	2,280,931
Common stock options authorized for future grant (under the 2004 Plan)	1,798,638
	8,746,465

***Convertible Notes***

At the closing of the Merger, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into the indenture. Under the terms of a separate trust agreement (the "Trust Agreement"), \$29.4 million, which represents the initial principal amount of the Convertible Notes, was deposited with a trust agent for the benefit of the holders and us (the amount of such deposit together with interest accrued and capitalized thereon, the "Property"). Provided no event of default has occurred and is continuing, we are able to direct the investment and reinvestment of the Property in certain approved investment options, including certain money market funds. At the maturity of the Convertible Notes on June 18, 2011, the 18-month anniversary of the closing of the Merger, we plan to use the Property to pay the principal amount of, and accrued interest on, the Convertible Notes.

The Convertible Notes are our secured obligation, and the indenture does not limit our other indebtedness, secured or unsecured. The indenture contains limited covenants, including a requirement that we deliver to holders of the Convertible Notes quarterly statements setting forth the principal amount of the Convertible Notes at the close of the fiscal quarter as well as information regarding the amount of interest capitalized to such Convertible Notes during the fiscal quarter. The amounts of interest capitalized on the Convertible Notes during the years ended December 31, 2010 and 2009, and the period from September 26, 2000 (inception) to December 31, 2010 were \$2,804, \$137, \$ and \$2,941, respectively. The interest rate on the Convertible Notes is equal to the interest earned on the money market funds in the trust account, which was less than half of a percentage point. The \$0.2 million in discount is being accreted to interest expense over the conversion period of the Convertible Notes.

Holders of the Convertible Notes may submit conversion notices, which are irrevocable, instructing the trustee to convert such Convertible Notes into shares of our common stock at an initial conversion price of \$6.80 per share. Following each conversion date, which date generally is the final business day of each calendar month, we will issue the number of whole shares of common stock issuable upon conversion as promptly as practicable (and in any event within 10 business days). The trustee will in turn release to us the respective amount of restricted cash to cover the stock issuance. We will then invest the unrestricted cash into either a money market fund or a money market account. Any fractional shares (after aggregating all Convertible Notes being converted by a holder on such date) will be rounded down and we will deliver cash for the current market value of the fractional share. The indenture includes customary anti-dilution adjustments and events of default.

As of December 31, 2010, \$1.8 million of the Convertible Notes were converted into 265,409 shares our common stock.

**Table of Contents****9. Income Taxes**

The significant components of our deferred income taxes at December 31, 2010 and 2009 are as follows:

	December 31,	
	2010	2009
<b>Deferred Tax Assets:</b>		
Net operating loss carry forwards	72,100,000	64,627,000
Capitalized licenses	2,313,000	2,559,000
Research tax credits	6,723,000	6,037,000
Stock Options	846,000	420,000
Unrealized loss on marketable securities		387,000
Other, net	1,224,000	305,000
<b>Total Deferred Tax Assets</b>	<b>83,206,000</b>	<b>74,335,000</b>
<b>Deferred Tax Liabilities</b>		
IPR&D	(1,956,000)	(1,956,000)
<b>Total Deferred Tax Liabilities</b>	<b>(1,956,000)</b>	<b>(1,956,000)</b>
Net deferred tax assets	81,250,000	72,379,000
Valuation Allowance	(83,206,000)	(74,335,000)
<b>Net Deferred Tax Liability</b>	<b>(1,956,000)</b>	<b>(1,956,000)</b>

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

At December 31, 2010, we had federal and California net operating loss carryforwards of approximately \$177 million and \$176.5 million, respectively. Included in these amounts are federal and California tax expense of approximately \$22,000 attributable to stock option deductions which will be debited to equity when realized. The federal net operating loss carryforwards begin to expire in 2020, and the California net operating loss carryforwards begin to expire in 2013. At December 31, 2010, we also had federal and California research tax credit carryforwards of approximately \$5.9 million and \$1.2 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.

Additionally, utilization of the net operating losses, or NOL, and tax credit carryforwards will be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred. These ownership changes will limit the amount of NOL and tax credit 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. An analysis was performed which indicated that multiple ownership changes have occurred in previous years which created annual limitations on our ability to utilize NOL and tax credit carryovers. Such limitations will result in approximately \$7.3 million and \$1 million of tax benefits related to federal and state NOL and tax credit carryforwards, respectively, that will expire unused. Accordingly, the related NOL and R&D credit carryforwards have been removed from deferred tax assets accompanied by a corresponding reduction of the valuation allowance. Due to the existence of the

valuation allowance, limitations created by future ownership changes, if any, related to our operations in the U.S. will not impact our effective tax rate.



**Table of Contents**

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

	Year Ended December 31,		
	2010	2009	2008
Federal statutory income tax rate	35.0%	35.0%	35.0%
State income taxes, net of federal benefit	6.4	8.8	5.3
Tax credits	2.8	2.7	2.6
Change in valuation allowance	(44.0)	(60.9)	(38.2)
Permanent differences	(0.2)	14.5	(5.9)
Other		(0.1)	1.2
Provision for income taxes	0.0%	0.0%	0.0%

We file income tax returns in the United States, California and foreign jurisdictions. Due to our losses incurred, we are essentially subject to income tax examination by tax authorities from our inception to date. Our policy is to recognize interest expense and penalties related to income tax matters as tax expense. At December 31, 2010, we do not have any significant accruals for interest related to unrecognized tax benefits or tax penalties.

**10. Employee Savings Plan and Employee Stock Purchase Plan**

We have an employee savings plan available to substantially all employees. Under the plan, an employee may elect salary reductions which are contributed to the plan. The plan provides for discretionary contributions by us, which totaled \$139,621, \$149,994, and \$151,488 and \$1,001,747 for the years ended December 31, 2010, 2009, 2008 and the period from September 26, 2000 (inception) to December 31, 2010, respectively.

Under the MediciNova, Inc. 2007 Employee Stock Purchase Plan, or ESPP, 300,000 shares of our common stock have been reserved for issuance. In addition, the shares reserved will automatically increase by a number equal to the lesser of: (i) 15,000 shares, (ii) 1% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year or (iii) such lesser amount as determined by the Board. The ESPP permits full-time employees to purchase our common stock through payroll deductions (which cannot exceed 15% of each employee's compensation) at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month offering period. For the year ended December 31, 2010, 6,558 shares were issued under the ESPP, leaving 259,127 shares available for future issuance.

**Table of Contents****11. Quarterly Financial Data (Unaudited)**

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for fiscal 2009 and 2008 are as follows (in thousands, except per share data):

	Year Ended December 31, 2010			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
<b>Selected quarterly financial data:</b>				
Revenue	\$	\$	\$	\$
Total operating expenses	5,236	4,152	4,148	4,347
Net loss	(5,161)	(4,334)	(5,701)	(4,991)
Net loss applicable to common stockholders	(5,161)	(4,334)	(5,701)	(4,991)
Basic and diluted net loss per common share(1)	(0.42)	(0.35)	(0.46)	(0.40)
	Year Ended December 31, 2009			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
<b>Selected quarterly financial data:</b>				
Revenue	\$	\$	\$	\$
Total operating expenses	5,265	4,945	4,943	6,086
Net loss	(4,993)	(4,665)	(4,795)	(5,916)
Net loss applicable to common stockholders	(4,993)	(4,665)	(4,795)	(5,916)
Basic and diluted net loss per common share(1)	(0.41)	(0.39)	(0.40)	(0.49)

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

**12. Subsequent Events**

We have evaluated subsequent events after the balance sheet date of December 31, 2010 and up to the date we filed this report.

*Joint Venture Letter of Intent*

On March 3, 2011, we executed a joint venture letter of intent with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd., which provides for the establishment of a joint venture company to develop and commercialize MN-221 in China. The agreement provides that the business scope of the joint venture company will be to in-license authorized drug candidates from us, manage and operate a facility to manufacture such drug candidates for the Chinese market and promote, distribute and sell such drug candidates in the Chinese market. The joint venture company will also be responsible for conducting all clinical trials necessary to gain regulatory approval in China. The joint venture company will initially conduct the activities described above with respect to MN-221; however other drug candidates may be brought within the scope if the parties to the agreement unanimously agree. We will contribute 4,290,000 RMB in cash for a 30% interest in the joint venture. Our responsibilities relate to granting rights to MN-221 in China to the joint venture, while the other parties are responsible for providing funding for the joint venture's activities. We will receive a license fee payment equal to our capital contribution for the license to

MN-221. Any amendment requires the written agreement of all three parties thereto.

**Table of Contents**

*Avigen Management Transition Plan*

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

*Firm Commitment Underwritten Public Offering*

On March 23, 2011, we announced a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of \$3.00 per unit for gross proceeds of \$8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of \$3.56 per share. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallocation. On March 29, 2011, we received net proceeds of approximately \$7.9 million, after underwriter discount and underwriter expenses and no warrants exercised.

*Oxford Loan Update*

In anticipation of not achieving either of the affirmative covenants required under our loan agreement with Oxford by March 31, 2011, we negotiated with Oxford the repayment of the loan in full on April 1, 2011, wherein Oxford agreed to waive the early payment penalty of approximately \$437,000.

## **Table of Contents**

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

None

### **Item 9A. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as defined in the Rules 13(a)-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission's rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2010, our disclosure controls and procedures were effective.

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

#### **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for 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 Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ( "COSO" ) in Internal Control - Integrated Framework. Our management has concluded that, as of December 31, 2010, our internal control over financial reporting was effective based on these criteria.

#### **Remediation of Prior Material Weakness**

As of December 31, 2010, management believes that the material weakness in our internal control over financial reporting that was included in Item 4 of our Form 10-Q for the quarter ended September 30, 2010, has been effectively remediated. Prior to the quarter ended December 31, 2010, the remediation measures as described below were implemented.

## Edgar Filing: MEDICINOVA INC - Form 10-K

We have taken appropriate actions to remediate the material weakness related to the identified control overrides and policy deviations by one of our senior executive officers, which, collectively, represented a material weakness in our internal control over financial reporting. Our remediation plan included disclosing the granting of a waiver under our code of conduct to a senior executive and another employee due to the appearance of a possible conflict of interest, re-aligning certain reporting structures, updating our contract review and approval policy to require one signatory to be our CFO, strengthening certain human resource policies by amending our compensation committee charter and creating a strategic and oversight committee comprised of certain board members and the senior management team to review key issues.

KPMG LLP, an independent registered public accounting firm, has audited our financial statements included herein and has issued an audit report on the effectiveness of our internal control over financial reporting, which report is included below.

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

MediciNova, Inc.:

We have audited MediciNova, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission. 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 MediciNova, Inc.'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, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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 U.S. 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 U.S. 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, 2010, based on criteria established in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission.

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. and subsidiaries as of December 31, 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the two-year period ended December 31, 2010 and for the period from September 26, 2000 (inception) through December 31, 2010, and our report dated March 31, 2011 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

San Diego, California

March 31, 2011



**Table of Contents**

**Item 9B. Other Information**

Not applicable.

**Table of Contents****PART III****Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2010, or the Proxy Statement, 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, 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](http://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 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 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, 2010 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights</b>	<b>Weighted Average Exercise Price of Outstanding Options and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans</b>
Equity Compensation Plans Approved by Stockholders(1)	2,252,431	\$ 8.36	1,798,638

Edgar Filing: MEDICINOVA INC - Form 10-K

Equity Compensation Plans Approved by Stockholders(2)	695	\$	4.45(2)	259,127
Equity Compensation Plans Not Approved by Stockholders(3)	28,500	\$	10.00	
Total	2,281,626	\$	8.38	2,057,765

- (1) Consists of the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan, or 2004 Plan. Awards under the 2004 Plan shall not exceed 3,330,000 shares, plus an annual increase on the first day of each fiscal year, with the first increase occurring on January 1, 2006, in an amount equal to the lesser of (i) 100,000 shares, (ii) 3% of the outstanding shares on the last day of the immediately preceding year, or (iii) an amount determined by the Board. Stock options under the 2004 Plan have an exercise price equal to the fair market value of the underlying common stock at the date of grant, generally vest over a period of four years and have a ten-year life.

**Table of Contents**

- (2) Consists of the MediciNova, Inc. 2007 Employee Stock Purchase Plan, or ESPP. Under the ESPP, 300,000 shares of our common stock have been reserved for issuance. In addition, the shares reserved will automatically increase by a number equal to the lesser of: (i) 15,000 shares, (ii) 1% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year or (iii) such lesser amount as determined by the Board. The ESPP permits full-time employees to purchase our common stock through payroll deductions (which cannot exceed 15% of each employee's compensation) at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month offering period.
- (3) 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 4, 2005. The material terms of the 2000 Plan are described in Note 8 to our consolidated financial statements contained in this Annual Report on Form 10-K.

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

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

**Item 14. Principal Accounting Fees and Services**

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

**Table of Contents****PART IV****Item 15. Exhibits, Financial Statement Schedules**

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

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

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	80
<u>Consolidated Balance Sheets</u>	82
<u>Consolidated Statements of Operations</u>	83
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	84
<u>Consolidated Statements of Cash Flows</u>	88
<u>Notes to Consolidated Financial Statements</u>	89

2. *Financial Statement Schedules.* None.

3. *Exhibits.*

**Exhibit**

<b>Number</b>	<b>Description</b>
2.1(22)	Agreement and Plan of Merger dated as of August 20, 2009 by and among Registrant, Absolute Merger, Inc. and Avigen, Inc. (attached as Annex A to the joint proxy statement/prospectus).
3.1(19)	Restated Certificate of Incorporation of the Registrant, as amended.
3.2(1)	Amended and Restated Bylaws of the Registrant.
4.1(11)	Specimen of Common Stock Certificate.
4.2(1)	Amended and Restated Registration Rights Agreement by and among the Registrant, its founders and the investors named therein, dated September 2, 2004.
4.3(12)	Rights Agreement between the Registrant and American Stock Transfer & Trust Company, which includes the form of Rights Certificate as <i>Exhibit B</i> and the Summary of Rights as <i>Exhibit C</i> , dated November 24, 2006.
4.4(22)	Form of Indenture by and between Registrant and American Stock Transfer and Trust Company, LLC (attached as Annex C to the joint proxy statement/prospectus).
4.5(22)	Form of Convertible Note (included in Exhibit 4.4).
4.6(29)	Warrant dated May 10, 2010 issued to Oxford Finance Corporation.
10.1(1)*	2000 General Stock Incentive Plan of the Registrant.

## Edgar Filing: MEDICINOVA INC - Form 10-K

- 10.2(2)\* 2004 Stock Incentive Plan of the Registrant.
- 10.3(5)\* Form of Indemnification Agreement between the Registrant and its officers and directors.
- 10.4(2) License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated March 14, 2002.
- 10.5(2) License Agreement between the Registrant and Angiogene Pharmaceuticals, Ltd., dated June 19, 2002.

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description</b>
10.6(2)	Exclusive License Agreement between the Registrant and Kissei Pharmaceutical Co., Ltd., dated February 25, 2004.
10.7(2)	License Agreement between the Registrant and Mitsubishi Tanabe Pharma Corporation, dated April 27, 2004.
10.8(3)	License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated October 22, 2004.
10.9(2)	Office Lease Agreement between the Registrant and CA-LA Jolla II Limited Partnership, dated January 28, 2004 and the First Amendment thereto, dated August 10, 2004.
10.10(3)	License Agreement between the Registrant and Mitsubishi Tanabe Pharma Corporation, dated December 8, 2004.
10.11(4)	Second Amendment to Office Lease Agreement between the Registrant and CA-La Jolla II Limited Partnership, dated March 21, 2005.
10.13(11)*	Executive Employment Agreement between the Registrant and Masatsune Okajima, dated September 1, 2006.
10.14(7)	License Agreement, dated October 31, 2006 by and between the Registrant and Meiji Seika Kaisha, Ltd.
10.15(7)	License Agreement, dated October 31, 2006 by and between the Registrant and Meiji Seika Kaisha, Ltd.
10.16(8)*	Executive Employment Agreement between the Registrant and Yuichi Iwaki, M.D., Ph.D., dated April 1, 2007.
10.17(13)*	2007 Employee Stock Purchase Plan of the Registrant.
10.18(9)*	Form of Severance Protection Agreement between the Registrant and certain of its executive officers, dated September 12, 2007.
10.19(10)	Third Amendment to Office Lease Agreement between the Registrant and 4350 La Jolla Village LLC, dated January 31, 2008.
10.22(15)*	Amendment to the Amended and Restated 2004 Stock Incentive Plan of the Registrant, dated June 6, 2008.
10.23(16)	Fourth Amendment to Lease Agreement between the Registrant and 4350 La Jolla Village LLC, dated October 3, 2008.
10.24(17)	Credit Line Account Application and Agreement for Organizations and Businesses, executed by the Registrant on January 8, 2009, by and between the Registrant and UBS Bank USA.
10.25(17)	Addendum to Credit Line Account Application and Agreement, executed by the Registrant on January 8, 2009, by and between the Registrant, UBS Bank USA and UBS Financial Services Inc.
10.26(17)	Addendum to Credit Line Agreement, executed by the Registrant on January 8, 2009, by and between the Registrant and UBS Bank USA.
10.27(17)	Important Notice on Interest Rates and Payments, executed by the Registrant on January 8, 2009, by and between the Registrant and UBS Bank USA.
10.28(18)	Development and Supply Agreement between the Registrant and Hospira Worldwide, Inc., dated as of March 26, 2009.

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description</b>
10.31(22)	Form of Contingent Payment Rights Agreement by and among Registrant, Avigen, Inc. and American Stock Transfer and Trust Company, LLC (attached as Annex B to the joint proxy statement/prospectus).
10.32(22)	Form of Trust Agreement by and between Registrant and American Stock Transfer and Trust Company, LLC (attached as Annex D to the joint proxy statement/prospectus).
10.33(22)	Form of Escrow Agreement by and between Registrant and American Stock Transfer and Trust Company, LLC (attached as Annex E to the joint proxy statement/prospectus).
10.34(23)	Assignment Agreement, dated December 19, 2005, by and between Genzyme Corporation and Avigen, Inc.
10.35(25)	Asset Purchase Agreement, dated December 17, 2008, by and between Baxter Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. and Avigen, Inc.
10.36(28)*	Executive Employment Agreement between Registrant and Kirk Johnson, dated February 1, 2010.
10.37(29)	Loan and Security Agreement dated May 10, 2010 by and among Registrant, Avigen, Inc. and Oxford Finance Corporation.
10.38(24)*	Executive Employment Agreement between Registrant and Michael Coffee, dated June 14, 2010.
10.39(26)*	Form of Amendment to Employment Agreement between Registrant and certain of its executive officers, dated December 31, 2010.
10.40(26)*	Form of Severance Protection Agreement between Registrant and certain of its executive officers, dated December 31, 2010.
14.1(11)	Code of Ethics of the Registrant.
21.1(27)	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Registered Public Accounting Firm.
24.1	Powers of Attorney (included in Signature page).
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Act of 1933.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Act of 1933.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Filed with the Registrant's Registration Statement on Form S-1 filed October 1, 2004 and incorporated herein by reference.
- (2) Filed with the Registrant's Amendment to Registration Statement on Form S-1/A filed November 24, 2004 and incorporated herein by reference.
- (3) Filed with the Registrant's Amendment to Registration Statement on Form S-1/A filed January 6, 2005 and incorporated herein by reference.
- (4) Filed with the Registrant's Quarterly Report on Form 10-Q filed May 12, 2005 and incorporated herein by reference.



**Table of Contents**

- (5) Filed with the Registrant s Registration Statement on Form S-1 filed on September 1, 2005 and incorporated herein by reference.
- (6) Filed with the Registrant s Registration Statement on Form S-3 filed November 14, 2006 and incorporated herein by reference.
- (7) Filed with the Registrant s Current Report on Form 8-K filed November 2, 2006 and incorporated herein by reference.
- (8) Filed with the Registrant s Current Report on Form 8-K filed April 4, 2007 and incorporated herein by reference.
- (9) Filed with the Registrant s Current Report on Form 8-K filed September 14, 2007 and incorporated herein by reference.
- (10) Filed with the Registrant s Current Report on Form 8-K filed February 4, 2008 and incorporated herein by reference.
- (11) Filed with the Registrant s Annual Report on Form 10-K filed February 15, 2007 and incorporated herein by reference.
- (12) Filed with the Registrant s Registration Statement on Form 8-A filed November 29, 2006 and incorporated herein by reference.
- (13) Filed with the Registrant s Definitive Proxy Statement on Schedule 14A filed March 13, 2007 and incorporated herein by reference.
- (14) Filed with the Registrant s Current Report on Form 8-K filed May 1, 2008 and incorporated herein by reference.
- (15) Filed with the Registrant s Current Report on Form 8-K filed June 10, 2008 and incorporated herein by reference.
- (16) Filed with the Registrant s Current Report on Form 8-K filed October 8, 2008 and incorporated herein by reference.
- (17) Filed with the Registrant s Current Report on Form 8-K filed January 21, 2009 and incorporated herein by reference.
- (18) Filed with the Registrant s Current Report on Form 8-K filed March 30, 2009 and incorporated herein by reference.
- (19) Filed with the Registrant s Current Report on Form 8-K filed May 29, 2009 and incorporated herein by reference.
- (20) Filed with the Registrant s Current Report on Form 8-K filed July 2, 2009 and incorporated herein by reference.
- (21) Filed with the Registrant s Current Report on Form 8-K filed July 16, 2009 and incorporated herein by reference.
- (22) Filed with the Registrant s Registration Statement on Form S-4 initially filed September 17, 2009 and incorporated herein by reference.
- (23) Filed with Avigen, Inc. s Annual Report on Form 10-K filed March 16, 2006 and incorporated herein by reference.
- (24) Filed with the Registrant s Current Report on Form 8-K filed June 16, 2010 and incorporated herein by reference.
- (25) Filed with Avigen, Inc. s Annual Report on Form 10-K filed with the SEC on March 16, 2009.
- (26) Filed with the Registrant s Current Report on Form 8-K filed January 4, 2011 and incorporated herein by reference.
- (27) Filed with the Registrant s Annual Report on Form 10-K filed March 24, 2010 and incorporated herein by reference.
- (28) Filed with the Registrant s Current Report on Form 8-K filed February 1, 2010 and incorporated herein by reference.
- (29) Filed with the Registrant s Current Report on Form 8-K filed May 14, 2010 and incorporated herein by reference.

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

\* Indicates management contract or compensatory plan.

**Table of Contents**

**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 31, 2011

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 and Michael Coffee and each of them, his true and lawful attorneys-in-fact, each 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 each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Yuichi Iwaki Yuichi Iwaki, M.D., Ph.D.	Director, President & Chief Executive Officer (Principal Executive Officer)	March 31, 2011
/s/ Michael Coffee Michael Coffee	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2011
/s/ Jeff Himawan Jeff Himawan, Ph.D.	Director	March 31, 2011
/s/ Arlene Morris Arlene Morris	Director	March 31, 2011
/s/ John K.A. Prendergast John K.A. Prendergast, Ph.D.	Director	March 31, 2011

/s/ Hiroaki Shigeta

Director

March 31, 2011

Hiroaki Shigeta